UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)		
☑ QUARTERLY REPORT PURSUANT TO 1934	SECTION 13 OR 15(d) OF THE SECUR	ITIES EXCHANGE ACT OF
For the qua	rterly period ended September 30, 2019	
	or	
☐ TRANSITION REPORT PURSUANT TO 1934	SECTION 13 OR 15(d) OF THE SECUR	RITIES EXCHANGE ACT OF
For the tr	ansition period from to	
Com	mission File Number: 001-12400	
· -	ΓΕ CORPORATION e of registrant as specified in its charter)	
Delaware	94-3	136539
(State or other jurisdiction of	•	Employer
incorporation or organization)	Identific	cation No.)
1801 Augustine Cut-Off		
Wilmington, DE 19803		9803
(Address of principal executive offices)		Code)
, · •	(302) 498-6700 s telephone number, including area code)	
Securities regi	stered pursuant to Section 12(b) of the Act:	
<u>Title of each class</u> Common Stock, \$.001 par value per share	Trading Symbol(s) INCY Nan	ne of exchange on which registered The Nasdaq Stock Market LLC
Indicate by check mark whether the registrant (1) has filed a during the preceding 12 months (or for such shorter period the requirements for the past 90 days. \boxtimes Yes \square No		
Indicate by check mark whether the registrant has submitte Regulation S-T (§ 232.405 of this chapter) during the precedifiles). \boxtimes Yes \square No	* *	*
Indicate by check mark whether the registrant is a large accemerging growth company. See the definitions of "large acceleratin Rule 12b-2 of the Exchange Act.		
Large accelerated filer \boxtimes	Accelera	ated filer \square
Non-accelerated filer \square	Smaller repor	ting company
	Emerging gro	owth company
If an emerging growth company, indicate by check mark if the or revised financial accounting standards provided pursuant to Section 1.	ě	cion period for complying with any new

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). \square Yes \boxtimes No $The number of outstanding shares of the \ registrant's \ Common \ Stock, \$.001 \ par \ value, \ was \ 215,397,290 \ as \ of \ October \ 22, \ 2019.$

INCYTE CORPORATION

INDEX

PART I:	FINANCIAL INFORMATION	3
Item 1.	Financial Statements	3
	Condensed Consolidated Balance Sheets	3
	Condensed Consolidated Statements of Operations	4
	Condensed Consolidated Statements of Comprehensive Income	5
	Condensed Consolidated Statements of Stockholders' Equity	6
	Condensed Consolidated Statements of Cash Flows	8
	Notes to Condensed Consolidated Financial Statements	9
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	40
Item 3.	Quantitative and Qualitative Disclosures about Market Risk	65
Item 4.	Controls and Procedures	65
PART II:	OTHER INFORMATION	
Item 1A.	Risk Factors	66
Item 5.	Other Information	88
Item 6.	<u>Exhibits</u>	89
	<u>Signatures</u>	91

PART I: FINANCIAL INFORMATION Item 1. Financial Statements

INCYTE CORPORATION CONDENSED CONSOLIDATED BALANCE SHEETS (in thousands, except number of shares and par value)

ASSETS Current assets: \$1,702,023 \$1,163,98 Marketable securities—available-for-sale 284,195 274,34 Accounts receivable 276,116 307,55 Inventory 7,365 6,96 Prepaid expenses and other current assets 49,896 79,36 Total current assets 2,319,595 1,832,25 Restricted cash and investments 995 1,00 Long term investments 117,902 99,15
Cash and cash equivalents \$ 1,702,023 \$ 1,163,98 Marketable securities—available-for-sale 284,195 274,34 Accounts receivable 276,116 307,55 Inventory 7,365 6,96 Prepaid expenses and other current assets 49,896 79,36 Total current assets 2,319,595 1,832,25 Restricted cash and investments 995 1,00 Long term investments 117,902 99,19
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Inventory 7,365 6,96 Prepaid expenses and other current assets 49,896 79,36 Total current assets 2,319,595 1,832,25 Restricted cash and investments 995 1,00 Long term investments 117,902 99,19
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Total current assets 2,319,595 1,832,25 Restricted cash and investments 995 1,00 Long term investments 117,902 99,15
Restricted cash and investments 995 1,00 Long term investments 117,902 99,19
Long term investments 117,902 99,19
Long term investments 117,902 99,19
Inventors 5 052 2 40
Inventory 5,953 3,43 Property and equipment, net 347,250 319,75
Finance lease right-of-use assets, net 29,690 -
Other intangible assets, net 199,212 215,36
Goodwill 155,593 155,59
Other assets, net 38,628 19,15
Total assets \$ 3,214,818 \$ 2,645,76
10tal assets 5 3,214,616 5 2,043,70
LIABILITIES AND STOCKHOLDERS' EQUITY
Current liabilities:
Accounts payable \$ 95,376 \$ 103,82
Accrued compensation 80,638 60,17
Interest payable 89 2
Accrued and other current liabilities 249,721 229,40
Finance lease liabilities 763
Acquisition-related contingent consideration 35,096 31,84
Total current liabilities 461,683 425,27
101,000 120,2
Convertible senior notes 18,080 17,43
Acquisition-related contingent consideration 246,904 255,15
Finance lease liabilities 31,732 -
Other liabilities 33,892 21,92
Total liabilities 792,291 719,79
Stockholders' equity:
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; none issued or
outstanding as of September 30, 2019 and December 31, 2018 — — —
Common stock, \$0.001 par value; 400,000,000 shares authorized; 215,373,548 and
213,274,660 shares issued and outstanding as of September 30, 2019 and
December 31, 2018, respectively 215 21
Additional paid-in capital 3,972,689 3,813,67
Accumulated other comprehensive loss (8,614) (10,16
Accumulated deficit (1,541,763) (1,877,75
Total stockholders' equity $2,422,527$ $1,925,96$
Total liabilities and stockholders' equity $\frac{$3,214,818}{}$ $\frac{$2,645,76}{}$

^{*} The condensed consolidated balance sheet at December 31, 2018 has been derived from the audited financial statements at that date. See accompanying notes.

INCYTE CORPORATION CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited, in thousands, except per share amounts)

		nths Ended aber 30,		ths Ended aber 30, 2018	
Revenues:	2019	2018	2019	2018	
Product revenues, net	\$ 453,998	\$ 367,715	\$ 1,284,144	\$ 1,067,744	
Product royalty revenues	80,083	61,923	217,726	165,592	
Milestone and contract revenues	17,500	20,000	77,500	120,000	
Other revenues		45		145	
Total revenues	551,581	449,683	1,579,370	1,353,481	
Costs and expenses:					
Cost of product revenues (including definite-lived intangible					
amortization)	30,040	24,795	82,034	67,757	
Research and development	281,336	292,527	841,244	893,719	
Selling, general and administrative	102,608	96,522	332,534	326,049	
Change in fair value of acquisition-related contingent					
consideration	3,281	4,720	16,560	18,708	
Total costs and expenses	417,265	418,564	1,272,372	1,306,233	
Income from operations	134,316	31,119	306,998	47,248	
Other income (expense), net	11,961	10,211	36,334	20,481	
Interest expense	(597)	(405)	(1,248)	(1,188)	
Unrealized gain (loss) on long term investments	2,339	(9,949)	18,703	(21,911)	
Income before provision for income taxes	148,019	30,976	360,787	44,630	
Provision for income taxes	19,748	1,800	24,886	4,200	
Net income	\$ 128,271	\$ 29,176	\$ 335,901	\$ 40,430	
Net income per share:					
Basic	\$ 0.60	\$ 0.14	\$ 1.57	\$ 0.19	
Diluted	\$ 0.59	\$ 0.14	\$ 1.55	\$ 0.19	
Shares used in computing net income per share:					
Basic	215,199	212,627	214,628	212,172	
Diluted	217,791	215,964	217,393	215,516	

See accompanying notes.

INCYTE CORPORATION CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (unaudited, in thousands)

	Three Mon Septem		Nine Mon Septem	
	2019	2018	2019	2018
Net income	\$ 128,271	\$ 29,176	\$ 335,901	\$ 40,430
Other comprehensive income:				
Foreign currency translation	187	(38)	29	97
Unrealized gain (loss) on marketable securities, net of tax	36	214	1,175	(189)
Defined benefit pension obligations, net of tax	128	111	347	333
Other comprehensive income	351	287	1,551	241
Comprehensive income	\$ 128,622	\$ 29,463	\$ 337,452	\$ 40,671

See accompanying notes.

INCYTE CORPORATION CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (unaudited, in thousands, except number of shares)

Balances at January 1, 2019 2 3 3 3,813,678 3 (10,165) 4 (10,165) 5 (10,175) <th></th> <th colspan="8">For the Nine Months Ended September 30, 2019</th>		For the Nine Months Ended September 30, 2019							
Issuance of 1,044,745 shares of Common Stock upon exercise of stock options and settlement of employee restricted stock units 1 15,480 — — 15,481 Issuance of 1,200 shares of Common Stock for services rendered — 104 — — 104 Stock compensation — 40,690 — — 40,690 Other comprehensive income — — 918 — 918 Net income — — — 918 — 918 Net income — — — 92 918 — 918 Net income — — — 918 — 918 Net income — — — 918 — 918 Net income — — — 924 918 — 918 Net income — — — 924 924 924 928 928 928 928 928 928 928 928 928 928 928					Additional	Ac	cumulated Other	Accumulated	Stockholders'
exercise of stock options and settlement of employee restricted stock units 1 15,480 — — 15,481 Issuance of 1,200 shares of Common Stock for services rendered — 104 — — 104 Stock compensation — 40,690 — — 40,690 Adoption of ASU No. 2016-02 (Note 2) — — — 918 — 918 Other comprehensive income — — — 918 — 918 Net income — — — — 102,312 <	3 /	\$	213	\$	3,813,678	\$	(10,165)	\$ (1,877,759)	\$ 1,925,967
Testricted stock units 1 15,480	, ,								
Sisuance of 1,200 shares of Common Stock for services rendered	1								
Tendered Stock compensation Stock compensatio			1		15,480		_	_	15,481
Stock compensation — 40,690 — — 40,690 Adoption of ASU No. 2016-02 (Note 2) — — — 95 95 Other comprehensive income — — — 918 — 918 Net income — — — — 102,312 102,312 Balances at March 31, 2019 — — — — 102,312 102,312 Issuance of 400,292 shares of Common Stock upon exercise of stock options and settlement of employee restricted stock units and 143,379 shares of Common Stock for services rendered — — — — — — 15,191 Issuance of 1,444 shares of Common Stock for services rendered — — — — — — — 15,191 Stock compensation —									
Adoption of ASU No. 2016-02 (Note 2) — — — 95 95 Other comprehensive income — — — 918 — 918 Net income — — — — 102,312 102,312 Balances at March 31, 2019 \$ 214 \$ 3,869,952 \$ (9,247) \$ (1,775,352) \$ 2,085,667 Issuance of 400,292 shares of Common Stock upon exercise of stock options and settlement of employee restricted stock units and 143,379 shares of Common Stock for services rendered — — — — — — 15,191 Issuance of 1,444 shares of Common Stock for services rendered — — — — — — — — 123 — <td></td> <td></td> <td>_</td> <td></td> <td></td> <td></td> <td>_</td> <td>_</td> <td></td>			_				_	_	
Other comprehensive income — — 918 — 918 Net income — — — 102,312 102,312 Balances at March 31, 2019 \$ 214 \$ 3,869,952 \$ (9,247) \$ (1,775,352) \$ 2,085,567 Issuance of 400,292 shares of Common Stock upon exercise of stock options and settlement of employee restricted stock units and 143,379 shares of Common Stock for services rendered — 1 15,190 — — 15,191 Issuance of 1,444 shares of Common Stock for services rendered — 123 — — 123 Stock compensation — 40,710 — — 40,710 Other comprehensive income — — — 282 — 282 Net income — — — 105,318 105,318 105,318 Balances at June 30, 2019 \$ 215 \$ 3,925,975 \$ (8,965) \$ (1,670,034) \$ 2,247,191 Issuance of 506,199 shares of Common Stock upon exercise of stock options and settlement of employee restricted stock units — 3,111 — — 3,111 <td< td=""><td>1</td><td></td><td>_</td><td></td><td>40,690</td><td></td><td>_</td><td>_</td><td></td></td<>	1		_		40,690		_	_	
Net income — — — — 102,312 102,312 102,312 Balances at March 31, 2019 \$ 214 \$ 3,869,952 \$ (9,247) \$ (1,775,352) \$ 2,085,567 Issuance of 400,292 shares of Common Stock upon exercise of stock options and settlement of employee restricted stock units and 143,379 shares of Common Stock for services rendered 1 15,190 — — 15,191 Issuance of 1,444 shares of Common Stock for services rendered — 123 — — 123 Stock compensation — 40,710 — — 40,710 Other comprehensive income — — — 105,318 105,318 Balances at June 30, 2019 \$ 215 \$ 3,925,975 \$ (8,965) \$ (1,670,034) \$ 2,247,191 Issuance of 506,199 shares of Common Stock upon exercise of stock options and settlement of employee restricted stock units — 3,111 — — 3,111 Issuance of 1,629 shares of Common Stock for services rendered — 129 — — 3,111 Issuance of 1,629 shares of Common Stock for services rendered — 129	1		_		_		_	95	
Balances at March 31, 2019 \$ 214 \$ 3,869,952 \$ (9,247) \$ (1,775,352) \$ 2,085,567 Issuance of 400,292 shares of Common Stock upon exercise of stock options and settlement of employee restricted stock units and 143,379 shares of Common Stock under the ESPP 1 15,190 — — 15,191 Issuance of 1,444 shares of Common Stock for services rendered — 123 — — 123 Stock compensation — 40,710 — — 40,710 Other comprehensive income — — — 282 — 282 Net income — — — — 105,318 105,318 105,318 Balances at June 30, 2019 \$ 215 \$ 3,925,975 \$ (8,965) \$ (1,670,034) \$ 2,247,191 Issuance of 506,199 shares of Common Stock upon exercise of stock options and settlement of employee restricted stock units — 3,111 — — 3,111 Issuance of 1,629 shares of Common Stock for services rendered — — 3,111 — — 3,111 Issuance of 1,629 shares of Common Stock for servi			_				918	_	
Issuance of 400,292 shares of Common Stock upon exercise of stock options and settlement of employee restricted stock units and 143,379 shares of Common Stock under the ESPP	Net income							102,312	102,312
exercise of stock options and settlement of employee restricted stock units and 143,379 shares of Common Stock under the ESPP 1 15,190 — — 15,191 Issuance of 1,444 shares of Common Stock for services rendered — 123 — — 123 Stock compensation — 40,710 — — 40,710 — — 40,710 Other comprehensive income — — — 282 — 282 Net income — — — — 105,318 105,318 Issuance of 506,199 shares of Common Stock upon exercise of stock options and settlement of employee restricted stock units — 3,111 — — 3,111 Issuance of 1,629 shares of Common Stock for services rendered — 129 — — 129 Stock compensation — 43,474 — — 43,474 Other comprehensive income — — — 351 — 351 Net income — — — — — — 128,271 128,271	Balances at March 31, 2019	\$	214	\$	3,869,952	\$	(9,247)	\$ (1,775,352)	\$ 2,085,567
restricted stock units and 143,379 shares of Common Stock under the ESPP 1 15,190 — — 15,191 Issuance of 1,444 shares of Common Stock for services rendered — 123 — — 123 — — 123 Stock compensation — 40,710 — — 40,710 — — 40,710 Other comprehensive income — — — — 282 — — 282 Net income — — — — 105,318 105,318 Balances at June 30, 2019 \$ 215 \$ 3,925,975 \$ (8,965) \$ (1,670,034) \$ 2,247,191 Issuance of 506,199 shares of Common Stock upon exercise of stock options and settlement of employee restricted stock units — 3,111 — — 3,111 Issuance of 1,629 shares of Common Stock for services rendered — 129 — — 129 Stock compensation — 43,474 — — 43,474 Other comprehensive income — — — 351 — 351 Net income — — — — — — 128,271 128,271	Issuance of 400,292 shares of Common Stock upon								
Stock under the ESPP 1 15,190 — — 15,191 Issuance of 1,444 shares of Common Stock for services rendered — 123 — — 123 Stock compensation — 40,710 — — 40,710 Other comprehensive income — — — 282 — 282 Net income — — — 105,318 105,318 105,318 Balances at June 30, 2019 \$ 215 \$3,925,975 \$ (8,965) \$(1,670,034) \$2,247,191 Issuance of 506,199 shares of Common Stock upon exercise of stock options and settlement of employee restricted stock units — 3,111 — — 3,111 Issuance of 1,629 shares of Common Stock for services rendered — 129 — — 129 Stock compensation — 43,474 — — 43,474 Other comprehensive income — — — 351 — 351 Net income — — — — 128,2	1								
Issuance of 1,444 shares of Common Stock for services rendered — 123 — — 123 Stock compensation — 40,710 — — 40,710 Other comprehensive income — — 282 — 282 Net income — — — 105,318 105,318 Balances at June 30, 2019 \$ 215 \$ 3,925,975 \$ (8,965) \$ (1,670,034) \$ 2,247,191 Issuance of 506,199 shares of Common Stock upon exercise of stock options and settlement of employee restricted stock units — 3,111 — — 3,111 Issuance of 1,629 shares of Common Stock for services rendered — 129 — — 129 Stock compensation — 43,474 — — 43,474 Other comprehensive income — — — 351 — 351 Net income — — — — — 128,271 128,271	restricted stock units and 143,379 shares of Common								
rendered — 123 — — 123 Stock compensation — 40,710 — — 40,710 Other comprehensive income — — — 282 — 282 Net income — — — 105,318 105,318 Balances at June 30, 2019 \$ 215 \$ 3,925,975 \$ (8,965) \$ (1,670,034) \$ 2,247,191 Issuance of 506,199 shares of Common Stock upon exercise of stock options and settlement of employee restricted stock units — 3,111 — — 3,111 Issuance of 1,629 shares of Common Stock for services rendered — 129 — — 129 Stock compensation — 43,474 — — 43,474 Other comprehensive income — — — 351 — 351 Net income — — — — 128,271 128,271 128,271	Stock under the ESPP		1		15,190		_	_	15,191
Stock compensation — 40,710 — — 40,710 Other comprehensive income — — — 282 — 282 Net income — — — 105,318 105,318 Balances at June 30, 2019 \$ 215 \$ 3,925,975 \$ (8,965) \$ (1,670,034) \$ 2,247,191 Issuance of 506,199 shares of Common Stock upon exercise of stock options and settlement of employee restricted stock units — 3,111 — — 3,111 Issuance of 1,629 shares of Common Stock for services rendered — 129 — — 129 Stock compensation — 43,474 — — 43,474 Other comprehensive income — — 351 — 351 Net income — — — — 128,271 128,271	Issuance of 1,444 shares of Common Stock for services								
Other comprehensive income — — — 282 — 282 Net income — — — 105,318 105,318 105,318 Balances at June 30, 2019 \$ 215 \$ 3,925,975 \$ (8,965) \$ (1,670,034) \$ 2,247,191 Issuance of 506,199 shares of Common Stock upon exercise of stock options and settlement of employee restricted stock units — 3,111 — — 3,111 Issuance of 1,629 shares of Common Stock for services rendered — 129 — — 129 Stock compensation — 43,474 — — 43,474 Other comprehensive income — — 351 — 351 Net income — — — — 128,271 128,271	rendered		_		123		_	_	123
Net income — — — 105,318 105,318 Balances at June 30, 2019 \$ 215 \$ 3,925,975 \$ (8,965) \$ (1,670,034) \$ 2,247,191 Issuance of 506,199 shares of Common Stock upon exercise of stock options and settlement of employee restricted stock units — 3,111 — — 3,111 Issuance of 1,629 shares of Common Stock for services rendered — 129 — — 129 Stock compensation — 43,474 — — 43,474 Other comprehensive income — — 351 — 351 Net income — — — 128,271 128,271 128,271	Stock compensation		_		40,710		_	_	40,710
Balances at June 30, 2019 \$ 215 \$ 3,925,975 \$ (8,965) \$ (1,670,034) \$ 2,247,191 Issuance of 506,199 shares of Common Stock upon exercise of stock options and settlement of employee restricted stock units — 3,111 — — 3,111 Issuance of 1,629 shares of Common Stock for services rendered — 129 — — — 129 Stock compensation — 43,474 — — — 43,474 Other comprehensive income — — — — 351 — 351 Net income — — — — — — 128,271 128,271	Other comprehensive income		_		_		282	_	282
Issuance of 506,199 shares of Common Stock upon exercise of stock options and settlement of employee restricted stock units — 3,111 — — 3,111 Issuance of 1,629 shares of Common Stock for services rendered — 129 — — 129 Stock compensation — 43,474 — — 43,474 Other comprehensive income — — 351 — 351 Net income — — — 128,271 128,271	Net income				<u> </u>		<u> </u>	105,318	105,318
exercise of stock options and settlement of employee restricted stock units — 3,111 — — 3,111 Issuance of 1,629 shares of Common Stock for services rendered — 129 — — 129 Stock compensation — 43,474 — — 43,474 Other comprehensive income — — — 351 — 351 Net income — — — — 128,271 128,271	Balances at June 30, 2019	\$	215	\$	3,925,975	\$	(8,965)	\$ (1,670,034)	\$ 2,247,191
restricted stock units — 3,111 — — 3,111 Issuance of 1,629 shares of Common Stock for services rendered — 129 — — 129 Stock compensation — 43,474 — — 43,474 Other comprehensive income — — — 351 — 351 Net income — — — — 128,271 128,271	Issuance of 506,199 shares of Common Stock upon								
Issuance of 1,629 shares of Common Stock for services rendered — 129 — — 129 Stock compensation — 43,474 — — 43,474 Other comprehensive income — — — 351 — 351 Net income — — — — 128,271 128,271	exercise of stock options and settlement of employee								
rendered — 129 — — 129 Stock compensation — 43,474 — — 43,474 Other comprehensive income — — — 351 — 351 Net income — — — — 128,271 128,271	restricted stock units		_		3,111		_	_	3,111
Stock compensation — 43,474 — — 43,474 Other comprehensive income — — — 351 — 351 Net income — — — — 128,271 128,271	Issuance of 1,629 shares of Common Stock for services								
Other comprehensive income — — 351 — 351 Net income — — — — 128,271 128,271	rendered		_		129		_	_	129
Net income	Stock compensation		_		43,474		_	_	43,474
7, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1,	Other comprehensive income		_		_		351	_	351
Balances at September 30, 2019 \$ 215 \$ 3,972,689 \$ (8,614) \$ (1,541,763) \$ 2,422,527	Net income		_		_		_	128,271	128,271
	Balances at September 30, 2019	\$	215	\$	3,972,689	\$	(8,614)	\$ (1,541,763)	\$ 2,422,527

INCYTE CORPORATION CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (CONTINUED) (unaudited, in thousands, except number of shares)

	For the Nine Months Ended September 30, 2018							
	Common Stock		Pa	Additional aid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity	
Balances at January 1, 2018	\$	211	\$			\$ (1,990,005)		
Issuance of 623,709 shares of Common Stock upon								
exercise of stock options and settlement of employee								
restricted stock units		1		2,575	_	_	2,576	
Issuance of 1,032 shares of Common Stock for services								
rendered		_		87	_	_	87	
Issuance of 539 shares of Common Stock upon conversion								
of Convertible Senior Notes due 2018		_		27	_	_	27	
Stock compensation		_		36,224	_	_	36,224	
Adoption of ASU No. 2016-01		_		_	(2,753)	2,753	_	
Other comprehensive loss		_		_	(359)	_	(359)	
Net loss		_		_	_	(41,140)	(41,140)	
Balances at March 31, 2018	\$	212	\$	3,666,346	\$ (10,122)	\$ (2,028,392)	\$ 1,628,044	
Issuance of 369,109 shares of Common Stock upon								
exercise of stock options and settlement of employee								
restricted stock units and 150,538 shares of Common Stock	ζ							
under the ESPP		_		15,480	_	_	15,480	
Issuance of 1,281 shares of Common Stock for services								
rendered		_		85	_	_	85	
Issuance of 38 shares of Common Stock upon conversion								
of Convertible Senior Notes due 2018		_		2	_	_	2	
Stock compensation		_		36,605	_	_	36,605	
Other comprehensive income		_		_	313	_	313	
Net income		_		_	_	52,394	52,394	
Balances at June 30, 2018	\$	212	\$	3,718,518	\$ (9,809)	\$ (1,975,998)	\$ 1,732,923	
Issuance of 343,592 shares of Common Stock upon						- =====		
exercise of stock options and settlement of employee								
restricted stock units		1		2,423	_	_	2,424	
Issuance of 1,242 shares of Common Stock for services								
rendered		_		86	_	_	86	
Issuance of 38 shares of Common Stock upon conversion								
of Convertible Senior Notes due 2018		_		2	_	_	2	
Stock compensation		_		38,001	_	_	38,001	
Other comprehensive income		_		_	287	_	287	
Net income		_		_		29,176	29,176	
Balances at September 30, 2018	\$	213	\$	3,759,030	\$ (9,522)	\$ (1,946,822)	\$ 1,802,899	
•			_					

See accompanying notes.

INCYTE CORPORATION CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (unaudited, in thousands)

	Nine Mont Septemb			30,
	_	2019	_	2018
Cash flows from operating activities:	¢.	225 001	Φ	40.420
Net income	\$	335,901	\$	40,430
Adjustments to reconcile net income to net cash provided by operating activities: Depreciation and amortization		41,188		40,743
Stock-based compensation		124,566		110,830
Other, net		356		258
Unrealized (gain) loss on long term investments		(18,703)		21,911
Change in fair value of acquisition-related contingent consideration		16,560		18,708
Changes in operating assets and liabilities:		10,500		10,700
Accounts receivable		31,482		18,563
Prepaid expenses and other assets		9,999		(21,330)
Inventory		(2,913)		3,030
Accounts payable		(8,451)		27,807
Accrued and other liabilities		49,053		(8,561)
Net cash provided by operating activities		579,038	_	252,389
Cash flows from investing activities:	_	017,000	_	202,000
Purchase of long term investments		_		(8,936)
Capital expenditures		(48,749)		(48,202)
Purchases of marketable securities		(222,157)		(104,228)
Sale and maturities of marketable securities		213,480		111,040
Net cash used in investing activities		(57,426)		(50,326)
Cash flows from financing activities:				
Proceeds from issuance of common stock under stock plans		33,783		20,480
Payment of finance lease liabilities		(626)		
Payment of contingent consideration		(16,766)		(9,886)
Net cash provided by financing activities		16,391		10,594
Effect of exchange rates on cash, cash equivalents, restricted cash and investments		29		97
Net increase in cash, cash equivalents, restricted cash and investments		538,032		212,754
Cash, cash equivalents, restricted cash and investments at beginning of period		1,164,986		900,434
Cash, cash equivalents, restricted cash and investments at end of period	\$ 1	1,703,018	\$	1,113,188
Supplemental Schedule of Cash Flow Information				
Interest paid	\$	119	\$	134
Income taxes paid	\$	12,398	\$	2,932
Reclassification to common stock and additional paid in capital in connection with conversions				
of 0.375% convertible senior notes due 2018	\$	_	\$	31
Leased assets obtained in exchange for new operating lease liabilities	\$	6,686	\$	_
Leased assets obtained in exchange for new finance lease liabilities	\$	29,740	\$	_

See accompanying notes.

INCYTE CORPORATION NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS September 30, 2019

(Unaudited)

1. Organization and business

Incyte Corporation (including its subsidiaries, "Incyte," "we," "us," or "our") is a biopharmaceutical company focused on developing and commercializing proprietary therapeutics. Our portfolio includes compounds in various stages, ranging from preclinical to late stage development, and commercialized products JAKAFI® (ruxolitinib) and ICLUSIG® (ponatinib). Our operations are treated as one operating segment.

2. Summary of significant accounting policies

Basis of presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. The condensed consolidated balance sheet as of September 30, 2019, the condensed consolidated statements of operations, comprehensive income, and stockholders' equity for the three and nine months ended September 30, 2019 and 2018, and the condensed consolidated statements of cash flows for the nine months ended September 30, 2019 and 2018 are unaudited, but include all adjustments, consisting only of normal recurring adjustments, which we consider necessary for a fair presentation of the financial position, operating results and cash flows for the periods presented. The condensed consolidated balance sheet at December 31, 2018 has been derived from audited financial statements.

Although we believe that the disclosures in these financial statements are adequate to make the information presented not misleading, certain information and footnote information normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") have been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission.

Results for any interim period are not necessarily indicative of results for any future interim period or for the entire year. The accompanying financial statements should be read in conjunction with the financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2018.

Principles of Consolidation. The condensed consolidated financial statements include the accounts of Incyte Corporation and our wholly owned subsidiaries. All inter-company accounts, transactions, and profits have been eliminated in consolidation.

Foreign Currency Translation. Operations in non-U.S. entities are recorded in the functional currency of each entity. For financial reporting purposes, the functional currency of an entity is determined by a review of the source of an entity's most predominant cash flows. The results of operations for any non-U.S. dollar functional currency entities are translated from functional currencies into U.S. dollars using the average currency rate during each month. Assets and liabilities are translated using currency rates at the end of the period. Adjustments resulting from translating the financial statements of our foreign entities that use their local currency as the functional currency into U.S. dollars are reflected as a component of other comprehensive income (loss). Transaction gains and losses are recorded in other income (expense), net, in the condensed consolidated statements of operations.

Use of Estimates. The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Concentrations of Credit Risk. Cash, cash equivalents, marketable securities, and trade receivables are financial instruments which potentially subject us to concentrations of credit risk. The estimated fair value of financial instruments approximates the carrying value based on available market information. We primarily invest our excess available funds in

debt securities and, by policy, limit the amount of credit exposure to any one issuer and to any one type of investment, other than securities issued or guaranteed by the U.S. government and money market funds that meet certain guidelines. Our receivables mainly relate to our product sales of JAKAFI, ICLUSIG and collaborative agreements with pharmaceutical companies. We have not experienced any significant credit losses on cash, cash equivalents, marketable securities, or trade receivables to date and do not require collateral on receivables.

Cash and Cash Equivalents. Cash and cash equivalents are held in banks or in custodial accounts with banks. Cash equivalents are defined as all liquid investments and money market funds with maturity from date of purchase of 90 days or less that are readily convertible into cash.

Marketable Securities—Available-for-Sale. Our marketable securities consist of investments in corporate debt securities and U.S. government securities that are classified as available-for-sale. Available-for-sale securities are carried at fair value, based on quoted market prices and observable inputs, with unrealized gains and losses, net of tax, reported as a separate component of stockholders' equity. We classify marketable securities that are available for use in current operations as current assets on the condensed consolidated balance sheets. Realized gains and losses and declines in value judged to be other than temporary for available-for-sale securities are included in other income (expense), net on the condensed consolidated statements of operations. The cost of securities sold is based on the specific identification method.

Accounts Receivable. As of September 30, 2019 and December 31, 2018, we had a de minimis allowance for doubtful accounts. We provide an allowance for doubtful accounts based on experience and specifically identified risks. Accounts receivable are carried at fair value and charged off against the allowance for doubtful accounts when we determine that recovery is unlikely and we cease collection efforts.

Inventory. Inventories are determined at the lower of cost and net realizable value with cost determined under the specific identification method and may consist of raw materials, work in process and finished goods.

JAKAFI and ICLUSIG raw materials and work-in-process inventory is not subject to expiration and the shelf life of finished goods inventory is 36 months from the start of manufacturing of the finished goods. We evaluate for potential excess inventory by analyzing current and future product demand relative to the remaining product shelf life. We build demand forecasts by considering factors such as, but not limited to, overall market potential, market share, market acceptance and patient usage. We classify inventory as current on the condensed consolidated balance sheets when we expect inventory to be consumed for commercial use within the next twelve months.

Variable Interest Entities. We perform an initial and ongoing evaluation of the entities with which we have variable interests, such as equity ownership, in order to identify entities (i) that do not have sufficient equity investment at risk to permit the entity to finance its activities without additional subordinated financial support or (ii) in which the equity investors lack an essential characteristic of a controlling financial interest as variable interest entities ("VIE" or "VIEs"). If an entity is identified as a VIE, we perform an assessment to determine whether we have both (i) the power to direct activities that most significantly impact the VIE's economic performance and (ii) have the obligation to absorb losses from or the right to receive benefits of the VIE that could potentially be significant to the VIE. If both of these criteria are satisfied, we are identified as the primary beneficiary of the VIE. As of September 30, 2019, there were no entities in which we held a variable interest which we determined to be VIEs.

Long Term Investments. Our long term investments consist of equity investments in common stock of publicly-held companies with whom we have entered into collaboration and license agreements. We classify all of our equity investments in common stock of publicly-held companies as long term investments on the condensed consolidated balance sheets. Our equity investments are accounted for at fair value using readily determinable pricing available on a securities exchange on the condensed consolidated balance sheets. All changes in fair value are reported in the condensed consolidated statements of operations as an unrealized gain (loss) on long term investments.

In assessing whether we exercise significant influence over any of the companies in which we hold equity investments, we consider the nature and magnitude of our investment, any voting and protective rights we hold, any participation in the governance of the other company, and other relevant factors such as the presence of a collaboration or

other business relationship. Currently, none of our equity investments in publicly-held companies are considered relationships in which we are able to assert control.

Property and Equipment, net. Property and equipment, net is stated at cost, less accumulated depreciation and amortization. Depreciation is recorded using the straight-line method over the estimated useful lives of the respective assets. Leasehold improvements are amortized over the shorter of the estimated useful life of the assets or lease term.

Lease Accounting. The new accounting standard for leases, Accounting Standard Codification ("ASC") 842, Leases, was adopted for the fiscal year beginning on January 1, 2019. Per the new standard, all leases with a lease term greater than 12 months, regardless of lease type classification, are recorded as an obligation on the balance sheet with a corresponding right-of-use asset. Under the prior leasing standard, only contracts assessed as capital leases were recorded on the balance sheet. Both finance and operating leases are reflected as liabilities on the commencement date of the lease based on the present value of the lease payments to be made over the lease term. Current operating lease liabilities are reflected in accrued and other current liabilities and noncurrent operating lease liabilities are reflected in other liabilities on the condensed consolidated balance sheet. Right-of-use assets are valued at the initial measurement of the lease liability, plus any initial direct costs or rent prepayments, minus lease incentives and deferred lease payments. Operating right-of-use assets are recorded in property and equipment, net on the condensed consolidated balance sheet. For operating leases, the expense recognition is similar to that of operating leases under ASC 840, with a single lease cost recognized on a straight-line basis. For finance leases, the expense recognition is similar to that of capital leases under ASC 840, with separate amortization and interest expense, with higher interest expense in the earlier periods of a lease. Leases with an initial term of 12 months or less are not recorded on the balance sheet and we recognize lease expense for these leases on a straight-line basis over the term of the lease. In determining whether a contract contains a lease, asset and service agreements are assessed at onset and upon modification for criteria of specifically identified assets, control and economic benefit.

Other Intangible Assets, net. Other intangible assets, net consist of licensed intellectual property rights acquired in business combinations, which are reported at acquisition date fair value, less accumulated amortization. Intangible assets with finite lives are amortized over their estimated useful lives using the straight-line method.

Impairment of Long-Lived Assets. Long-lived assets with finite lives are tested for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. If indicators of impairment are present, the asset is tested for recoverability by comparing the carrying value of the asset to the related estimated undiscounted future cash flows expected to be derived from the asset. If the expected cash flows are less than the carrying value of the asset, then the asset is considered to be impaired and its carrying value is written down to fair value, based on the related estimated discounted future cash flows.

Goodwill. Goodwill is calculated as the difference between the acquisition date fair value of the consideration transferred and the values assigned to the assets acquired and liabilities assumed. Goodwill is not amortized but is tested for impairment at the reporting unit level at least annually as of October 1 or when a triggering event occurs that could indicate a potential impairment by assessing qualitative factors or performing a quantitative analysis in determining whether it is more likely than not that the fair value of net assets are below their carrying amounts. A reporting unit is the same as, or one level below, an operating segment. Our operations are currently comprised of a single, entity wide reporting unit. We completed our most recent annual impairment assessment as of October 1, 2018 and determined that the carrying value of our goodwill was not impaired.

Income Taxes. We account for income taxes using the asset and liability approach which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and amounts reportable for income tax purposes. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more-likely-than-not that some portion or all of the deferred tax assets will not be realized.

We recognize the tax benefit from an uncertain tax position only if it is more-likely-than-not that the position will be sustained upon examination by the taxing authorities, including resolutions of any related appeals or litigation processes, based on the technical merits of the position. The tax benefit that is recorded for these positions is measured at the largest

amount of benefit that is greater than 50 percent likely of being realized upon ultimate settlement. We adjust the level of the liability to reflect any subsequent changes in the relevant facts surrounding the uncertain positions. Any interest and penalties on uncertain tax positions are included within the tax provision.

Financing Costs Related to Long-term Debt. Costs associated with obtaining long-term debt are deferred and amortized over the term of the related debt using the effective interest method. Such costs are presented as a direct deduction from the carrying amount of the long-term debt liability, consistent with debt discounts, on the condensed consolidated balance sheets

Grant Accounting. Grant amounts received from government agencies for operations are deferred and are amortized into income over the service period of the grant. Grant amounts received for purchases of capital assets are deferred and amortized into other income (expense), net over the useful life of the related capital assets. Such amounts are recorded in other liabilities on the condensed consolidated balance sheets.

Net Income (Loss) Per Share. Our basic and diluted net income (loss) per share is calculated by dividing the net income (loss) by the weighted average number of shares of common stock outstanding during all periods presented. Options to purchase stock, restricted stock units, performance stock units and shares issuable upon the conversion of convertible debt are included in diluted earnings per share calculations, unless the effects are anti-dilutive.

Accumulated Other Comprehensive Income (Loss). Accumulated other comprehensive income (loss) consists of unrealized gains or losses on marketable securities that are classified as available-for-sale, foreign currency translation gains or losses and defined benefit pension obligations.

Revenue Recognition. Revenue-generating contracts are assessed under ASC 606, Revenue from contracts with customers, to identify distinct performance obligations, determine the transaction price of the contract and allocate the transaction price to each of the distinct performance obligations. Revenue is recognized when we have satisfied a performance obligation through transferring control of the promised good or service to a customer. Control, in this instance, may mean the ability to prevent other entities from directing the use of, and receiving benefit from, a good or service. We determine at contract inception whether we will transfer control of a promised good or service over time or satisfy the performance obligation at a point in time through analysis of the following criteria: (i) the entity has a present right to payment, (ii) the customer has legal title, (iii) the customer has physical possession, (iv) the customer has the significant risks and rewards of ownership and (v) the customer has accepted the asset. We assess collectability based primarily on the customer's payment history and on the creditworthiness of the customer.

Product Revenues

Our product revenues consist of U.S. sales of JAKAFI and European sales of ICLUSIG. Product revenues are recognized once we satisfy the performance obligation at a point in time under the revenue recognition criteria as described above. In November 2011, we began shipping JAKAFI to our customers in the U.S., which include specialty pharmacies and wholesalers. In June 2016, we acquired the right to and began shipping ICLUSIG to our customers in the European Union and certain other jurisdictions, which include retail pharmacies, hospital pharmacies and distributors.

We recognize revenues for product received by our customers net of allowances for customer credits, including estimated rebates, chargebacks, discounts, returns, distribution service fees, patient assistance programs, and government rebates, such as Medicare Part D coverage gap reimbursements in the U.S. At September 30, 2019 and December 31, 2018, \$59.3 million and \$44.8 million, respectively, of accrued sales allowances were included in accrued and other current liabilities on the condensed consolidated balance sheets. Product shipping and handling costs are included in cost of product revenues.

Customer Credits: Our customers are offered various forms of consideration, including allowances, service fees and prompt payment discounts. We expect our customers will earn prompt payment discounts and, therefore, we deduct the full amount of these discounts from total product sales when revenues are recognized. Service fees are also deducted from total product sales as they are earned.

Rebates and Discounts: Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program in the U.S. and mandated discounts in Europe in markets where government-sponsored healthcare systems are the primary payers for healthcare. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements or legal requirements with public sector benefit providers. The accrual for rebates is based on statutory discount rates and expected utilization as well as historical data we have accumulated since product launches. Our estimates for expected utilization of rebates are based on data received from our customers. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarters' unpaid rebates. If actual future rebates vary from estimates, we may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

Chargebacks: Chargebacks are discounts that occur when certain contracted customers, which currently consist primarily of group purchasing organizations, Public Health Service institutions, non-profit clinics, and Federal government entities purchasing via the Federal Supply Schedule, purchase directly from our wholesalers. Contracted customers generally purchase the product at a discounted price. The wholesalers, in turn, charges back to us the difference between the price initially paid by the wholesalers and the discounted price paid by the contracted customers. In addition to actual chargebacks received we maintain an accrual for chargebacks based on the estimated contractual discounts on the inventory levels on hand in our distribution channel. If actual future chargebacks vary from these estimates, we may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

Medicare Part D Coverage Gap: Medicare Part D prescription drug benefit mandates manufacturers to fund 70% of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients. Our estimates for the expected Medicare Part D coverage gap are based on historical invoices received and in part from data received from our customers. Funding of the coverage gap is generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarters. If actual future funding varies from estimates, we may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

Co-payment Assistance: Patients who have commercial insurance and meet certain eligibility requirements may receive co-payment assistance. We accrue a liability for co-payment assistance based on actual program participation and estimates of program redemption using data provided by third-party administrators.

Product Royalty Revenues

Royalty revenues on commercial sales for ruxolitinib (marketed as JAKAVI® outside the United States) by Novartis Pharmaceutical International Ltd. ("Novartis") are based on net sales of licensed products in licensed territories as provided by Novartis. Royalty revenues on commercial sales for baricitinib (marketed as OLUMIANT) by Eli Lilly and Company ("Lilly") are based on net sales of licensed products in licensed territories as provided by Lilly. We recognize royalty revenues in the period the sales occur.

Cost of Product Revenues

Cost of product revenues includes all JAKAFI related product costs as well as ICLUSIG related product costs. The acquired ICLUSIG inventories were recorded at fair value less costs to sell in connection with our June 2016 acquisition of ARIAD Pharmaceuticals (Luxembourg) S.à.r.l. ("ARIAD"), since renamed Incyte Biosciences Luxembourg S.à.r.l. (the "Acquisition"). Cost of product revenues also includes employee personnel costs, including stock compensation, for those employees dedicated to the production of our commercial products. In addition, cost of product revenues include low single-digit royalties under our collaboration and license agreement to Novartis on all future sales of JAKAFI in the United States. Subsequent to the Acquisition on June 1, 2016, cost of product revenues also includes the amortization of our licensed intellectual property for ICLUSIG using the straight-line method over the estimated useful life of 12.5 years.

Milestone and Contract Revenues

Our license agreements, which fall within the scope of ASC 606, *Revenue from Contracts with Customers*, include distinct drug compound out-licensing, collection of upfront payments, milestones or royalty revenues from a counterparty, and provision of commercially available products to suppliers. Our agreements often include contractual milestones, which typically relate to the achievement of pre-specified development, regulatory and commercialization events outside of our control, such as regulatory approval of a compound, first patient dosing or achievement of sales-based thresholds. For such cases, we believe that revenue related to these events should not be recognized until the milestone has been achieved.

Some contracts form collaborative arrangements of various types with third-parties. We assess whether the nature of the arrangement is within the scope of ASC 808, *Collaborative Arrangements*, in conjunction with the new revenue guidance to determine the nature of the performance obligations and associated transaction prices. A collaborative relationship may exist when we participate in an activity or process with another party, such as performance of research and development services or the exchange of intellectual property for use in clinical trials, when both parties share in the risks and rewards that result from the activity or participate and govern contract activities through a joint steering committee.

The regulatory review and approval process, which includes preclinical testing and clinical trials of each drug candidate, is lengthy, expensive and uncertain. Securing approval by the U.S. Food and Drug Administration (the "FDA") requires the submission of extensive preclinical and clinical data and supporting information to the FDA for each indication to establish a drug candidate's safety and efficacy. The approval process takes many years, requires the expenditure of substantial resources, involves post-marketing surveillance and may involve ongoing requirements for post-marketing studies. Before commencing clinical investigations of a drug candidate in humans, we must submit an Investigational New Drug application ("IND"), which must be reviewed by the FDA.

The steps generally required before a drug may be marketed in the United States include preclinical laboratory tests, animal studies and formulation studies, submission to the FDA of an IND for human clinical testing, performance of adequate and well-controlled clinical trials in three phases, as described below, to establish the safety and efficacy of the drug for each indication, submission of a new drug application ("NDA") or biologics license application ("BLA") to the FDA for review and FDA approval of the NDA or BLA.

Similar requirements exist within foreign regulatory agencies as well. The time required satisfying the FDA requirements or similar requirements of foreign regulatory agencies may vary substantially based on the type, complexity and novelty of the product or the targeted disease.

Preclinical testing includes laboratory evaluation of product pharmacology, drug metabolism, and toxicity, which includes animal studies, to assess potential safety and efficacy as well as product chemistry, stability, formulation, development, and testing. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND. The FDA may raise safety concerns or questions about the conduct of the clinical trials included in the IND, and any of these concerns or questions must be resolved before clinical trials can proceed. We cannot be sure that submission of an IND will result in the FDA allowing clinical trials to commence. Clinical trials involve the administration of the investigational drug or the marketed drug to human subjects under the supervision of qualified investigators and in accordance with good clinical practices regulations covering the protection of human subjects. Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Phase I usually involves the initial introduction of the investigational drug into healthy volunteers to evaluate its safety, dosage tolerance, absorption, metabolism, distribution and excretion. Phase II usually involves clinical trials in a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse effects and safety risks, and evaluate and gain preliminary evidence of the efficacy of the drug for specific indications. Phase III clinical trials usually further evaluate clinical efficacy and safety by testing the drug in its final form in an expanded patient population, providing statistical evidence of efficacy and safety, and providing an adequate basis for labeling. We cannot guarantee that Phase I, Phase II or Phase III testing will be completed successfully within any specified period of time, if at all. Furthermore, we, the institutional review board for a trial, or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Generally, the milestone events contained in our collaboration agreements coincide with the progression of our drugs from development, to regulatory approval and then to commercialization. The process of successfully discovering a new development candidate, having it approved and successfully commercialized is highly uncertain. As such, the milestone payments we may earn from our partners involve a significant degree of risk to achieve. Therefore, as a drug candidate progresses through the stages of its life-cycle, the value of the drug candidate generally increases.

Research and Development Costs. Our policy is to expense research and development costs as incurred. We often contract with clinical research organizations ("CROs") to facilitate, coordinate and perform agreed upon research and development of a new drug. To ensure that research and development costs are expensed as incurred, we record monthly accruals for clinical trials and preclinical testing costs based on the work performed under the contract.

These CRO contracts typically call for the payment of fees for services at the initiation of the contract and/or upon the achievement of certain clinical trial milestones. In the event that we prepay CRO fees, we record the prepayment as a prepaid asset and amortize the asset into research and development expense over the period of time the contracted research and development services are performed. Most professional fees, including project and clinical management, data management, monitoring, and medical writing fees are incurred throughout the contract period. These professional fees are expensed based on their percentage of completion at a particular date. Our CRO contracts generally include pass through fees. Pass through fees include, but are not limited to, regulatory expenses, investigator fees, travel costs, and other miscellaneous costs, including shipping and printing fees. We expense the costs of pass through fees under our CRO contracts as they are incurred, based on the best information available to us at the time. The estimates of the pass through fees incurred are based on the amount of work completed for the clinical trial and are monitored through correspondence with the CROs, internal reviews and a review of contractual terms. The factors utilized to derive the estimates include the number of patients enrolled, duration of the clinical trial, estimated patient attrition, screening rate and length of the dosing regimen. CRO fees incurred to set up the clinical trial are expensed during the setup period. Under our clinical trial collaboration agreements we may be reimbursed for certain development costs incurred. Such costs are recorded as a reduction of research and development expense in the period in which the related expense is incurred.

Stock Compensation. Share-based payment transactions with employees, which include stock options, restricted stock units ("RSUs") and performance shares ("PSUs"), are recognized as compensation expense over the requisite service period based on their estimated fair values as well as expected forfeiture rates. The stock compensation process requires significant judgment and the use of estimates, particularly surrounding Black-Scholes assumptions such as stock price volatility over the option term and expected option lives, as well as expected forfeiture rates and the probability of PSUs vesting. The fair value of stock options, which are subject to graded vesting, are recognized as compensation expense over the requisite service period using the accelerated attribution method. The fair value of RSUs that are subject to cliff vesting are recognized as compensation expense over the requisite service period using the straight-line attribution method, and the fair value of RSUs that are subject to graded vesting are recognized as compensation expense over the requisite service period using the accelerated attribution method. The fair value of PSUs are recognized as compensation expense beginning at the time in which the performance conditions are deemed probable of achievement, which we assess as of the end of each reporting period. Once a performance condition is considered probable, we record compensation expense based on the portion of the service period elapsed to date with respect to that award, with a cumulative catch-up, net of estimated forfeitures, and recognize any remaining compensation expense, if any, over the remaining requisite service period using the straight-line attribution method for PSUs that are subject to cliff vesting and using the accelerated attribution method for PSUs that are subject to graded vesting.

Long term Incentive Plans. We have long term incentive plans which provide eligible employees with the opportunity to receive performance and service-based incentive compensation, which may be comprised of cash, stock options, restricted stock units and/or performance shares. The payment of cash and the grant or vesting of equity may be contingent upon the achievement of pre-determined regulatory, sales and internal performance milestones.

Acquisition-Related Contingent Consideration. Acquisition-related contingent consideration, which consists of our future royalty and certain potential milestone obligations to Takeda Pharmaceutical Company Limited, which acquired ARIAD ("Takeda"), is recorded on the acquisition date at the estimated fair value of the obligation, in accordance with the acquisition method of accounting. The fair value measurement is based on significant inputs that are unobservable in the market and thus represents a Level 3 measurement. The fair value of the acquisition-related contingent consideration is

remeasured each reporting period, with changes in fair value recorded in the condensed consolidated statements of operations.

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASC 842, Leases, that requires lesses to recognize assets and liabilities on the balance sheet for most leases including operating leases. Additionally, the FASB issued clarifying guidance to the topic in ASUs No. 2018-10, No. 2018-11, No. 2018-20 and No. 2019-01 which clarified certain aspects of the new leases standard and provided an optional transition method. The guidance requires that the lessess classify leases as either a finance or operating lease and lessors classify all leases as sales-type, direct financing or operating leases. The statement of operations presentation and expense recognition for lessees for finance leases is similar to that of capital leases under ASC 840, with separate interest and amortization expense with higher interest expense in the earlier periods of a lease. For operating leases, the statement of operations presentation and expense recognition is similar to that of operating leases under ASC 840, with a single lease cost recognized on a straight-line basis. We implemented a third-party information technology application to facilitate activities for the new accounting and disclosure requirements and implemented new internal control procedures to support the new accounting and reporting processes associated with adopting the guidance. We elected the package of practical expedients and adopted utilizing the optional transition method as defined within ASU No. 2018-11. Accordingly, prior periods will not be restated to reflect the adopted standard. We did not elect the hindsight expedient.

As a result of adoption on January 1, 2019, we recorded \$23.6 million of lease right-of-use assets, \$23.7 million of lease liabilities and an adjustment to retained earnings of \$0.1 million. In addition, our capital lease assets and liabilities are now classified as finance lease right-of-use assets and liabilities. The capital asset and financing liability of \$18.7 million recorded in 2018 related to the Morges office building and construction, described more fully in Note 7, was derecognized upon adoption. The adoption of the standard did not materially impact our consolidated net income and had no impact on our consolidated cash flows.

In June 2016, the FASB issued ASU No. 2016-13, "Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments." This guidance applies to all entities and impacts how entities account for credit losses for most financial assets and other instruments. ASU 2016-13 requires financial assets measured at amortized cost to be presented at the net amount expected to be collected. The measurement of expected credit losses is based on relevant information about past events, including historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amounts. An entity must use judgment in determining the relevant information and estimation methods that are appropriate in its circumstances. For trade receivables, loans and held-to-maturity debt securities, entities will be required to estimate expected credit losses over the lifetime of the asset. For available-for-sale debt securities, entities will be required to recognize an allowance for credit losses rather than an other-than-temporary impairment that reduces the cost basis of the investment. Further, an entity will recognize any improvements in estimated credit losses on its available-for-sale debt securities immediately in earnings.

The FASB also released clarifying guidance in April 2019 within ASU No. 2019-04, "Codification Improvements to Topic 326, Financial Instruments – Credit Losses," and in May 2019 within ASU No. 2019-05, "Financial Instruments – Credit Losses (Topic 326): Targeted Transition Relief." The updates provide guidance on estimating credit losses, including transition relief by allowing for election of the fair value methodology on an instrument-by-instrument basis for eligible financial instruments within the scope of ASC 825-10. This guidance is effective for fiscal years beginning after December 15, 2019 and interim periods therein. Elections under ASU 2019-05 require a modified retrospective application through a cumulative-effect adjustment in the opening balance of retained earnings upon adoption. We are currently analyzing the impact of the ASUs on our condensed consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, "Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting." This guidance expanded the scope of ASC 718 to include share-based payments granted to nonemployees in exchange for goods or services and supersedes the guidance in ASC 505-50. Under this new standard, nonemployee awards are measured on the grant date by estimating the fair value of the equity instruments to be issued rather than the fair value of the goods or services received. Entities may use the expected term when estimating the fair value of a nonemployee option or elect to use the contractual term as the expected

term, on an award-by-award basis. The cumulative effect of the transition adjustment is to be recorded as an adjustment to retained earnings as of the beginning of the annual period of adoption. We adopted this standard for the period beginning January 1, 2019 and concluded there to be no change in our previous accounting for nonemployee awards and no impact on our condensed consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-14, "Compensation – Retirement Benefits – Defined Benefit Plans – General," an update to Subtopic ASC 715-20. The guidance amended year-end disclosure requirements related to defined benefit pension plans, and does not affect interim disclosures. The guidance is effective for fiscal years ending after December 15, 2020, and is permitted for early adoption. The standard is to be applied on a retrospective basis. Incyte sponsors defined benefit plans for employees located in Europe. We are currently analyzing the impact of ASU No. 2018-14 on our consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-15, "Intangibles – Goodwill and Other – Internal-Use Software," an update to Subtopic ASC 350-40. The guidance directs accounting for service contracts for cloud computing arrangements to follow guidance within ASC 350-40 to determine capitalization of implementation costs. The guidance is effective for fiscal years beginning after December 15, 2019, and is permitted for early adoption. The standard may be applied on either a retrospective or prospective basis. We are currently analyzing the impact of ASU No. 2018-15 on our condensed consolidated financial statements.

In August 2018, the SEC issued a final rule Release No. 33-10532, "Disclosure Update and Simplification," to amend certain disclosure requirements now seen as redundant, duplicative, overlapping, outdated or superseded in the wake of recent accounting pronouncements. The amended rules became effective November 5, 2018. We analyzed the release in preparation of our Form 10-Q during the first interim period in 2019, which resulted in the additional disclosure of changes to stockholders' equity during interim periods, as presented within the condensed consolidated statements of stockholders' equity. We note that many of the amended requirements under this Release are not applicable to the Company, as we do not make dividend payments to stockholders, currently report our activities under a single business segment, and already provided all other significant disclosure requirements.

In November 2018, the FASB issued ASU No. 2018-18, "Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606." The guidance clarifies the interactions between Topic 808 and Topic 606, including clarifications on revenue recognition, unit of account, and reporting disclosure requirements. The guidance is effective for fiscal years beginning after December 15, 2019, and is permitted for early adoption. The standard is to be applied on a retrospective basis to the date of the initial application of Topic 606. We utilize collaborative arrangements as described in our license agreements footnote and are currently analyzing the impact of ASU No. 2018-18 on our condensed consolidated financial statements.

3. Revenues

The following table presents our disaggregated revenue for the periods presented (in thousands):

	 Three Mon Septem			nded 0,			
	 2019		2018		2019		2018
JAKAFI revenues, net	\$ 433,387	\$	347,567	\$	1,218,504	\$	1,006,911
ICLUSIG revenues, net	20,611		20,148		65,640		60,833
Total product revenues, net	 453,998		367,715		1,284,144		1,067,744
JAKAVI product royalty revenues	58,440		50,923		160,906		139,361
OLUMIANT product royalty revenues	21,643		11,000		56,820		26,231
Total product royalty revenues	 80,083		61,923		217,726		165,592
Milestone and contract revenues	17,500		20,000		77,500		120,000
Other revenues	_		45		_		145
Total revenues	\$ 551,581	\$	449,683	\$	1,579,370	\$	1,353,481

For further information on our revenue-generating contracts, refer to our license agreements footnote.

4. Fair value of financial instruments

FASB accounting guidance defines fair value as the price that would be received to sell an asset or paid to transfer a liability ("the exit price") in an orderly transaction between market participants at the measurement date. The guidance outlines a valuation framework and creates a fair value hierarchy in order to increase the consistency and comparability of fair value measurements and the related disclosures. In determining fair value we use quoted prices and observable inputs. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of us. The fair value hierarchy is broken down into three levels based on the source of inputs as follows:

Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2—Valuations based on observable inputs and quoted prices in active markets for similar assets and liabilities.

Level 3—Valuations based on inputs that are unobservable and models that are significant to the overall fair value measurement.

Recurring Fair Value Measurements

Our marketable securities consist of investments in corporate debt securities and U.S. government securities that are classified as available-for-sale.

At September 30, 2019 and December 31, 2018, our Level 2 corporate debt and U.S. government securities were valued using readily available pricing sources which utilize market observable inputs, including the current interest rate and other characteristics for similar types of investments. Our long term investments classified as Level 1 were valued using their respective closing stock prices on The Nasdaq Stock Market.

Our policy is to recognize transfers into and transfers out of fair value hierarchy levels as of the end of the reporting period. There were no transfers out of or into hierarchy levels during the nine months ended September 30, 2019.

The following fair value hierarchy table presents information about each major category of our financial assets measured at fair value on a recurring basis (in thousands):

		Fair Value Meas								
	Quoted Prices in Significant Other Significant Active Markets for Observable Unobservable									
		Active Markets for Identical Assets		Inputs		Inputs	В	Balance as of		
		(Level 1)				(Level 2)		Level 3)		ember 30, 2019
Cash and cash equivalents	\$	1,702,023	\$	_	\$		\$	1,702,023		
Debt securities (corporate and government)		_		284,195		_		284,195		
Long term investments (Note 9)		117,902		_		_		117,902		
Total assets	\$	1,819,925	\$	284,195	\$		\$	2,104,120		
	_		_							
		Fair Value Meas	uren	ent at Reportin	g Dat	e Using:				
		uoted Prices in	Sig	nificant Other	Si	gnificant				
	Act	uoted Prices in ive Markets for	Sig	nificant Other Observable	Si	gnificant observable)-l		
	Act	uoted Prices in	Sig	nificant Other	Si Un	gnificant		Balance as of ember 31, 2018		
Cash and cash equivalents	Act	uoted Prices in ive Markets for lentical Assets	Sig	nificant Other Observable Inputs	Si Un	gnificant observable Inputs				
Cash and cash equivalents Debt securities (corporate and government)	Act	uoted Prices in ive Markets for lentical Assets (Level 1)	Sig	nificant Other Observable Inputs	Si Un	gnificant observable Inputs		ember 31, 2018		
*	Act	uoted Prices in ive Markets for lentical Assets (Level 1)	Sig	nificant Other Observable Inputs (Level 2)	Si Un	gnificant observable Inputs		1,163,980		

The following fair value hierarchy table presents information about each major category of our financial liabilities measured at fair value on a recurring basis as (in thousands):

	Fair Value Meast Quoted Prices in Active Markets for Identical Liabilities (Level 1)	rement at Reporting Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of September 30, 2019					
Acquisition-related contingent consideration	\$ —	\$ —	\$ 282,000	\$ 282,000					
Total liabilities	\$ —	\$ —	\$ 282,000	\$ 282,000					
	Fair Value Measurement at Reporting Date Using: Ouoted Prices in Significant Other Significant								
	Active Markets for Identical Liabilities	Observable Inputs	Unobservable Inputs	Balance as of					
	(Level 1)	(Level 2)	(Level 3)	December 31, 2018					
Acquisition-related contingent consideration	\$	\$ —	\$ 287,001	\$ 287,001					
Total liabilities	\$	\$ —	\$ 287,001	\$ 287,001					

The following is a rollforward of our Level 3 liabilities (in thousands):

Balance at January 1, 2019	\$ 287,001
Contingent consideration earned during the period but not yet paid	(14,889)
Payments made during the period	(6,672)
Change in fair value of contingent consideration	16,560
Balance at September 30, 2019	\$ 282,000

The fair value of the contingent consideration was determined using an income approach based on projected ICLUSIG revenues in the European Union and other countries for the approved third-line treatment and discount rates. The fair value of the contingent consideration is remeasured each reporting period, with changes in fair value recorded in the condensed consolidated statements of operations. The change in fair value of the contingent consideration during the nine months ended September 30, 2019 was due primarily to the passage of time as there were no other significant changes in the key assumptions during the period.

We make payments to Takeda quarterly based on the royalties or any additional milestone payments earned in the previous quarter. At September 30, 2019 and December 31, 2018, contingent consideration earned but not yet paid was \$14.9 million and \$13.2 million, respectively. Royalties earned in the second quarter of 2019 of \$7.6 million and royalties earned in the third quarter of 2019 of \$7.3 million were included in accrued and other current liabilities at September 30, 2019. Royalties earned in the third quarter of 2018 of \$6.7 million were included in accounts payable and the royalties earned in the fourth quarter of 2018 of \$6.5 million were included in accrued and other current liabilities at December 31, 2018.

The following is a summary of our marketable security portfolio (in thousands):

	Amortized Cost	Net Unrealized Gains	Net Unrealized Losses	Estimated Fair Value
September 30, 2019				
Debt securities (corporate and government)	\$ 284,082	\$ 113	\$ —	\$ 284,195
December 31, 2018				
Debt securities (corporate and government)	\$ 275,405	\$ —	\$ (1,062)	\$ 274,343

Our debt securities generally have contractual maturity dates of between 12 to 18 months.

5. Concentration of credit risk

In December 2009, we entered into a license, development and commercialization agreement with Lilly. In November 2009, we entered into a collaboration and license agreement with Novartis. In December 2018, we entered into a research collaboration and licensing agreement with Innovent Biologics, Inc. ("Innovent"). In July 2019, we entered into a collaboration and license agreement with Zai Lab (Shanghai) Co., Ltd., a subsidiary of Zai Lab Limited (collectively, "Zai Lab"). The concentration of credit risk related to our collaborative partners is as follows:

	Percentage of Milestone and Contract Three Month September	t Revenues for the as Ended	Percentage o Milestone and Contract Nine Months September	Revenues for the Ended
	2019	2018	2019	2018
Collaboration Partner A	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Collaboration Partner B	— %	100 %	— %	100 %
Collaboration Partner C	— %	— %	77 %	— %
Collaboration Partner D	100 %	— %	23 %	— %

Collaboration Partners A, B, C and D comprised, in aggregate, 33% and 42% of the accounts receivable balance as of September 30, 2019 and December 31, 2018, respectively.

In November 2011, we began commercialization and distribution of JAKAFI to a number of customers. Our product revenues are concentrated in a number of these customers. The concentration of credit risk related to our JAKAFI product revenues is as follows:

	Product Reve Three Mon	Percentage of Total Net Product Revenues for the Three Months Ended September 30.		of Total Net enues for the hs Ended ber 30.
	2019	2018	2019	2018
Customer A	20 %	19 %	19 %	20 %
Customer B	14 %	12 %	14 %	13 %
Customer C	16 %	16 %	16 %	15 %
Customer D	11 %	12 %	12 %	11 %

We are exposed to risks associated with extending credit to customers related to the sale of products. Customers A, B, C and D comprised, in aggregate, 38% and 30% of the accounts receivable balance as of September 30, 2019 and December 31, 2018, respectively.

The concentration of credit risk relating to ICLUSIG product revenues or accounts receivable is not significant.

6. Inventory

Our inventory balance consists of the following (in thousands):

	Sep	September 30, 2019		2018
Raw materials	\$	674	\$	481
Work-in-process		6,511		3,488
Finished goods		6,133		6,436
		13,318		10,405
Inventories-current		7,365		6,967
Inventories-noncurrent	\$	5,953	\$	3,438

Inventories, stated at the lower of cost and net realizable value, consist of raw materials, work in process and finished goods. At September 30, 2019, \$7.4 million of inventory was classified as current on the condensed consolidated balance sheet as we expect this inventory to be consumed for commercial use within the next twelve months. At September 30, 2019, \$6.0 million of inventory was classified as noncurrent on the condensed consolidated balance sheets as we did not expect this inventory to be consumed for commercial use within the next twelve months. We obtain some inventory components from a limited number of suppliers due to technology, availability, price, quality or other considerations. The loss of a supplier, the deterioration of our relationship with a supplier, or any unilateral violation of the contractual terms under which we are supplied components by a supplier could adversely affect our total revenues and gross margins.

7. Property and equipment, net

Property and equipment, net consists of the following (in thousands):

	Se	ptember 30, 2019	D	ecember 31, 2018
Office equipment	\$	15,224	\$	16,955
Laboratory equipment		66,700		61,697
Computer equipment		56,743		55,436
Land		10,069		10,122
Building and leasehold improvements		211,342		213,196
Operating lease right-of-use assets		30,479		_
Construction in progress		83,209		65,576
	,	473,766		422,982
Less accumulated depreciation and amortization		(126,516)		(103,231)
Property and equipment, net	\$	347,250	\$	319,751

In February 2018, we signed an agreement to rent a building in Morges, Switzerland for an initial term of 15 years, with multiple options to extend for an additional 20 years. The building will serve as our new European headquarters and will consist of approximately 100,000 square feet of office space. This building will allow for consolidation of our European operations that are currently located in Geneva and Lausanne, Switzerland. Building permits were granted by the local government authorities in September 2018, and construction activity began immediately thereafter. In June 2019, we obtained control of the Morges building to begin our construction activity. At that time, we determined the lease to be a finance lease and recorded a lease liability of \$31.1 million and a lease right-of-use asset of \$29.1 million, net of a lease incentive from our landlord of \$2.0 million. As of September 30, 2019, we have capitalized approximately \$7.8 million in on site preparation, design and construction costs.

In July 2018, we signed an agreement to purchase land located within Y-PARC, Switzerland's largest technology park in Yverdon. The land was purchased, in cash, for approximately \$4.8 million. Upon this parcel, we are constructing a large molecule production facility. Construction activity commenced in July 2018, and as of September 30, 2019, we have capitalized approximately \$59.9 million in costs for construction, ground preparation and architectural and engineering studies. We currently anticipate the facility to be completed in the second half of 2020.

As stated in Note 2, in January 2019, we adopted ASC 842, Leases, which changed the accounting and reporting of our lease activity. Although we do not have significant lease activity, we are the lessee of several contracts, including those to secure fleet vehicles, buildings and equipment. Our lease agreements do not contain any material residual value guarantees or restrictive covenants. Some of our building leases include options to renew and the exercise of these options is at our discretion. Our current operating lease liabilities are reflected in accrued and other current liabilities and our noncurrent operating lease liabilities are reflected in other liabilities on the condensed consolidated balance sheets.

As of September 30, 2019 our lease liabilities are as follows (in thousands):

Current	
Operating lease liabilities	\$ 10,372
Finance lease liabilities	763
Noncurrent	
Operating lease liabilities	13,326
Finance lease liabilities	31,732
Total lease liabilities	\$ 56,193

The cash paid for amounts included in the measurement of our operating lease liabilities for the nine months ended September 30, 2019 was \$8.6 million in operating cash flows. The cash paid for amounts included in the measurement of our finance lease liabilities for the nine months ended September 30, 2019 was \$0.6 million in financing cash flows.

The maturity of our lease liabilities are as follows (in thousands):

	 Operating		Finance
Remainder of 2019	\$ 3,469	\$	212
2020	9,907		697
2021	5,894		2,454
2022	2,901		2,706
2023	1,575		2,713
After 2023	1,331		35,263
Total lease cash payments	\$ 25,077	\$	44,045
Less: discount	1,379		11,550
Present value of lease liabilities	\$ 23,698	\$	32,495

As of September 30, 2019, our finance and operating leases had a weighted average lease term of approximately 15.9 and 3.9 years, respectively. The discount rate of our leases is an approximation of an estimated incremental borrowing rate and is dependent upon the term and economics of each agreement. The weighted average discount rate of our finance and operating leases is approximately 3.7% and 4.7%, respectively. For the three and nine months ended September 30, 2019, we incurred approximately \$3.6 million and \$10.9 million, respectively, of expense related to our operating leases, approximately \$0.7 million and \$1.1 million, respectively, of amortization on our finance lease right-of-use assets and approximately \$0.3 million of interest expense on our finance lease liabilities. Rent expense for the three and nine months ended September 30, 2018 was \$3.6 million and \$10.6 million, respectively. For the three and nine months ended September 30, 2019, the cost of our short term leases with a term less than 12 months was de minimis.

8. Intangible assets and goodwill

Intangible Assets, Net

The components of intangible assets were as follows (in thousands, except for useful life):

		Balanc	e at September :	30, 2019	Balanc	ce at December 3	1, 2018
	Weighted- Average Useful Lives (Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Finite-lived intangible assets:							
Licensed IP	12.5	\$ 271,000	\$ 71,788	\$ 199,212	\$ 271,000	\$ 55,636	\$ 215,364

Estimated aggregate amortization expense based on the current carrying value of amortizable intangible assets is as follows (in thousands):

	Re	mainder of					
		2019	2020	2021	2022	2023	Thereafter
Amortization expense	\$	5.387	\$ 21.536	\$ 21.536	\$ 21.536	\$ 21.536	\$ 107.681

Goodwill

There were no changes to the carrying amount of goodwill for the nine months ended September 30, 2019.

9. License agreements

Novartis

In November 2009, we entered into a Collaboration and License Agreement with Novartis. Under the terms of the agreement, Novartis received exclusive development and commercialization rights outside of the United States to our JAK inhibitor ruxolitinib and certain back-up compounds for hematologic and oncology indications, including all hematological malignancies, solid tumors and myeloproliferative diseases. We retained exclusive development and commercialization rights to JAKAFI (ruxolitinib) in the United States and in certain other indications. Novartis also received worldwide exclusive development and commercialization rights to our MET inhibitor compound capmatinib and certain back-up compounds in all indications. We retained options to co-develop and to co-promote capmatinib in the United States.

Under this agreement, we received an upfront payment and immediate milestone payment totaling \$210.0 million and were initially eligible to receive up to \$1.2 billion in milestone payments across multiple indications upon the achievement of pre-specified events, including up to \$174.0 million for the achievement of development milestones, up to \$495.0 million for the achievement of regulatory milestones and up to \$500.0 million for the achievement of commercialization milestones. In April 2016, we amended this agreement to provide that Novartis has exclusive research, development and commercialization rights outside of the United States to ruxolitinib (excluding topical formulations) in the graft-versus-host-disease ("GVHD") field. We became eligible to receive up to \$75.0 million of additional potential development and regulatory milestones relating to GVHD. Exclusive of the upfront payment of \$150.0 million received in 2009 and the immediate milestone of \$60.0 million earned in 2010, we have recognized and received, in the aggregate, \$132.0 million for the achievement of development milestones, \$215.0 million for the achievement of regulatory milestones and \$120.0 million for the achievement of sales milestones through September 30, 2019.

In 2018, under this agreement, we recognized a \$60.0 million sales milestone for Novartis achieving annual net sales of a JAK licensed product of \$900.0 million. In 2017, we recognized a \$40.0 million sales milestone for Novartis achieving annual net sales of a JAK licensed product of \$600.0 million and a \$25.0 million development milestone based on the formal initiation by Novartis of a Phase III clinical trial evaluating ruxolitinib in GVHD. In 2016, we recognized a \$5.0 million payment in exchange for the development and commercialization rights to ruxolitinib in GVHD outside of

the United States and a \$40.0 million regulatory milestone for the reimbursement of JAKAVI in Europe for the treatment of patients with polycythemia vera. In 2015, we recognized a \$5.0 million development milestone based on the formal initiation by Novartis of a Phase II clinical trial evaluating capmatinib for a third indication, a \$25.0 million regulatory milestone triggered by the Committee for Medicinal Products for Human Use of the European Medicines Agency adopting a positive opinion for JAKAVI (ruxolitinib) for the treatment of adult patients with polycythemia vera who are resistant to or intolerant of hydroxyurea, a \$15.0 million regulatory milestone for the approval of JAKAVI in Japan for the treatment of patients with polycythemia vera, and a \$20.0 million sales milestone for Novartis achieving annual net sales of a JAK licensed product of \$300.0 million. In 2014, we recognized a \$60.0 million regulatory milestone related to reimbursement of JAKAVI in Europe. a \$25.0 million regulatory milestone for the approval of JAKAVI in Japan for the treatment of patients with myelofibrosis and a \$7.0 million development milestone based on the formal initiation by Novartis of a Phase II clinical trial evaluating capmatinib in non-small cell lung cancer. In 2013, we recognized a \$25.0 million development milestone based on the formal initiation by Novartis of a Phase II clinical trial evaluating capmatinib. In 2012, we recognized a \$40.0 million regulatory milestone for the achievement of a predefined milestone for the European Union regulatory approval of JAKAVI. In 2011, we recognized a \$15.0 million development milestone for the achievement of a predefined milestone in the Phase I dose-escalation trial for capmatinib in patients with solid tumors and a \$10.0 million regulatory milestone for the approval of JAKAFI in the United States. In 2010, we recognized \$50.0 million in development milestones for the initiation of the global Phase III trial, RESPONSE, in patients with polycythemia vera. We determined that each of these milestones were substantive as their achievement required substantive efforts by us and was at risk until the milestones were ultimately achieved.

We also are eligible to receive tiered, double-digit royalties ranging from the upper-teens to the mid-twenties on future JAKAVI net sales outside of the United States, and tiered, worldwide royalties on future capmatinib net sales that range from 12% to 14%. Since the achievement of the \$60.0 million regulatory milestone related to reimbursement of JAKAVI in Europe in September 2014, we are obligated to pay to Novartis tiered royalties in the low single-digits on future JAKAFI net sales within the United States. During the three and nine months ended September 30, 2019, such royalties payable to Novartis on net sales within the United States totaled \$21.2 million and \$54.7 million, respectively, and are reflected in cost of product revenues on the condensed consolidated statements of operations. During the three and nine months ended September 30, 2018, such royalties payable to Novartis on net sales within the United States totaled \$17.0 million and \$44.3 million, respectively, and are reflected in cost of product revenues on the condensed consolidated statements of operations. At September 30, 2019 and December 31, 2018, \$38.0 million and \$18.6 million, respectively, of accrued royalties payable to Novartis were included in accrued and other current liabilities on the condensed consolidated balance sheets. Each company is responsible for costs relating to the development and commercialization of ruxolitinib in its respective territories, with costs of collaborative studies shared equally. Novartis is also responsible for all costs relating to the development and commercialization of capmatinib.

The Novartis agreement will continue on a program-by-program basis until Novartis has no royalty payment obligations with respect to such program or, if earlier, the termination of the agreement or any program in accordance with the terms of the agreement. Royalties are payable by Novartis on a product-by-product and country-by-country basis until the latest to occur of (i) the expiration of the last valid claim of the licensed patent rights covering the licensed product in the relevant country, (ii) the expiration of regulatory exclusivity for the licensed product in such country and (iii) a specified period from first commercial sale in such country of the licensed product by Novartis or its affiliates or sublicensees. The agreement may be terminated in its entirety or on a program-by-program basis by Novartis for convenience. The agreement may also be terminated by either party under certain other circumstances, including material breach.

We determined that there were two deliverables under the agreement: (i) the ex-U.S. license for ruxolitinib and (ii) our obligations in connection with our participation on the joint development committee for myelofibrosis and polycythemia vera/essential thrombocythemia. We concluded that these deliverables should be accounted for as a single unit of accounting and the \$150.0 million upfront payment received in December 2009 and the immediate \$60.0 million milestone payment received in January 2010 should be recognized on a straight-line basis through December 2013, when we estimated we would complete our obligations in connection with our participation on the joint development committee for myelofibrosis and polycythemia vera, our estimated performance period under the agreement. We completed this substantive performance obligation related to this arrangement in December 2013.

At December 31, 2009, we recorded \$10.9 million of reimbursable costs incurred prior to the effective date of the agreement as deferred revenue on the consolidated balance sheet. These costs were recognized on a straight-line basis through December 2013 consistent with the aforementioned upfront and milestone payments. Future reimbursable costs incurred after the effective date of the agreement with Novartis are recorded net against the related research and development expenses. At September 30, 2019 and December 31, 2018, \$0.6 million and \$0.7 million, respectively, of reimbursable costs were included in accounts receivable on the condensed consolidated balance sheets. Research and development expenses for the three and nine months ended September 30, 2019 were net of \$0.0 million and \$1.0 million, respectively, of costs reimbursed by Novartis. Research and development expenses for the three and nine months ended September 30, 2018 were net of \$1.2 million and \$2.4 million, respectively, of costs reimbursed by Novartis.

Milestone and contract revenue under the Novartis agreement for the three and nine months ended September 30, 2019 and 2018 was \$0.0 million. Product royalty revenue related to Novartis net sales of JAKAVI outside of the United States for the three and nine months ended September 30, 2019 was \$58.4 million and \$160.9 million, respectively. Product royalty revenue related to Novartis net sales of JAKAVI outside of the United States for the three and nine months ended September 30, 2018 was \$50.9 million and \$139.4 million, respectively. At September 30, 2019 and December 31, 2018, \$58.4 million and \$55.4 million, respectively, of product royalties were included in accounts receivable on the condensed consolidated balance sheets.

Lilly - Baricitinib

In December 2009, we entered into a License, Development and Commercialization Agreement with Lilly. Under the terms of the agreement, Lilly received exclusive worldwide development and commercialization rights to our JAK inhibitor baricitinib, and certain back-up compounds for inflammatory and autoimmune diseases. We received an upfront payment of \$90.0 million, and were initially eligible to receive up to \$665.0 million in substantive milestone payments across multiple indications upon the achievement of pre-specified events, including up to \$150.0 million for the achievement of development milestones, up to \$365.0 million for the achievement of regulatory milestones and up to \$150.0 million for the achievement of commercialization milestones. Exclusive of the upfront payment of \$90.0 million received in 2009, we have recognized and received, in aggregate, \$149.0 million for the achievement of development milestones and \$235.0 million for the achievement of regulatory milestones through September 30, 2019.

In January 2016, Lilly submitted an NDA to the FDA and a Marketing Authorization Application (MAA) to the European Medicines Agency for baricitinib as treatment for rheumatoid arthritis. In February 2017, we and Lilly announced that the European Commission approved baricitinib as OLUMIANT for the treatment of moderate-to-severe rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to, one or more disease-modifying antirheumatic drugs. In July 2017, Japan's Ministry of Health, Labor and Welfare granted marketing approval for OLUMIANT for the treatment of rheumatoid arthritis in patients with inadequate response to standard-of-care therapies. In June 2018, the FDA approved the 2mg dose of OLUMIANT for the treatment of adults with moderately-to-severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor inhibitor therapies.

In 2018, under this agreement, we recognized a \$20.0 million development milestone for the first patient treated in the systemic lupus erythematosus Phase III program for baricitinib and a \$100.0 million regulatory milestone for the FDA approval of the 2mg dose of OLUMIANT (baricitinib) for the treatment of adults with moderately-to-severely active rheumatoid arthritis. In 2017, we recognized a \$30.0 million development milestone for the first patient treated in the atopic dermatitis Phase III program for baricitinib, \$15.0 million regulatory milestone for the approval of baricitinib for the treatment of rheumatoid arthritis by Japan's Ministry of Health, Labor and Welfare and a \$65.0 million regulatory milestone for the approval of baricitinib for the treatment of moderate-to-severe rheumatoid arthritis in adult patients by the European Commission. In 2016, we recognized a \$35.0 million regulatory milestone for the submission of an NDA to the FDA for the approval of oral once-daily baricitinib for the treatment of moderate-to-severe rheumatoid arthritis and a \$20.0 million regulatory milestone for the submission of a Marketing Authorization Application to the European Medicines Agency for the approval of oral once-daily baricitinib for the treatment of moderate-to-severe rheumatoid arthritis. In 2012, we recognized a \$50.0 million development milestone for the initiation of the rheumatoid arthritis Phase III program for baricitinib. In 2010, we recognized a \$30.0 million development milestone based upon the initial three month data in the Phase III clinical trial initiation of baricitinib for the treatment of rheumatoid arthritis and a \$19.0 million development milestone for the Phase IIb clinical trial initiation of baricitinib for the treatment of rheumatoid arthritis. We determined that each of

these milestones were substantive as their achievement required substantive efforts by us and was at risk until the milestones were ultimately achieved.

We retained options to co-develop our JAK1/JAK2 inhibitors with Lilly on a compound-by-compound and indication-by-indication basis. Lilly is responsible for all costs relating to the development and commercialization of the compounds unless we elect to co-develop any compounds or indications. If we elect to co-develop any compounds and/or indications, we would be responsible for funding 30% of the associated future global development costs from the initiation of a Phase IIb trial through regulatory approval, including post-launch studies required by a regulatory authority. We would receive an incremental royalty rate increase across all tiers resulting in effective royalty rates ranging up to the high twenties on potential future global net sales for compounds and/or indications that we elect to co-develop. For indications that we elect not to co-develop, we would receive tiered, double-digit royalty payments on future global net sales with rates ranging up to 20% if the product is successfully commercialized. If we have started co-development funding for any indication, we can at any time opt out and stop future co-development cost sharing. If we elect to do this we would still be eligible for our base royalties plus an incremental pro-rated royalty commensurate with our contribution to the total co-development cost for those indications for which we co-funded. We previously had retained an option to co-promote products in the United States but, in March 2016, we waived our co-promotion option as part of an amendment to the agreement.

In July 2010, we elected to co-develop baricitinib with Lilly in rheumatoid arthritis and became responsible for funding 30% of the associated future global development costs for this indication from the initiation of the Phase IIb trial through regulatory approval, including post-launch studies required by a regulatory authority. We subsequently elected to co-develop baricitinib with Lilly in psoriatic arthritis, atopic dermatitis, alopecia areata, systemic lupus erythematosus and axial spondyloarthritis and were responsible for funding 30% of future global development costs for those indications through regulatory approval, including post-launch studies required by a regulatory authority. In April 2019, we elected to end additional co-funding of the development of baricitinib effective as of January 1, 2019. We will continue to receive royalties on global net sales of OLUMIANT, pursuant to the terms in the Lilly agreement, as described above.

We recorded no research and development expense under the Lilly agreement for co-funding the development of baricitinib for the three and nine months ended September 30, 2019. Research and development expenses recorded under the Lilly agreement representing 30% of the global development costs for baricitinib for the treatment of rheumatoid arthritis, psoriatic arthritis and atopic dermatitis for the three and nine months ended September 30, 2018 were \$18.9 million and \$45.6 million, respectively. At December 31, 2018, a total of \$23.1 million of such costs were included in accrued and other liabilities on the condensed consolidated balance sheets.

The Lilly agreement will continue until Lilly no longer has any royalty payment obligations or, if earlier, the termination of the agreement in accordance with its terms. Royalties are payable by Lilly on a product-by-product and country-by-country basis until the latest to occur of (i) the expiration of the last valid claim of the licensed patent rights covering the licensed product in the relevant country, (ii) the expiration of regulatory exclusivity for the licensed product in such country and (iii) a specified period from first commercial sale in such country of the licensed product by Lilly or its affiliates or sublicensees. The agreement may be terminated by Lilly for convenience, and may also be terminated under certain other circumstances, including material breach.

We determined that there were two deliverables under the agreement: (i) the worldwide license and (ii) our obligations in connection with a co-development option. We concluded that these deliverables should be accounted for as a single unit of accounting and the \$90.0 million upfront payment should be recognized on a straight-line basis as revenue through December 2016, our estimated performance period under the agreement. We completed our substantive performance obligation related to this arrangement in December 2016.

Milestone and contract revenue under the Lilly agreement for the three and nine months ended September 30, 2019 was \$0.0 million. Milestone revenue under the Lilly agreement for the three and nine months ended September 30, 2018 was \$20.0 million and \$120.0 million, respectively. Product royalty revenue related to Lilly global net sales of OLUMIANT for the three and nine months ended September 30, 2019 was \$21.6 million and \$56.8 million, respectively. Product royalty revenue related to Lilly global net sales of OLUMIANT for the three and nine months ended September 30, 2018 was \$11.0 million and \$26.2 million, respectively. At September 30, 2019 and December 31, 2018, \$21.7 million

and \$14.0 million, respectively, of product royalties were included in accounts receivable on the condensed consolidated balance sheets.

Lilly - Ruxolitinib

In March 2016, we entered into an amendment to the agreement with Lilly that amended the non-compete provision of the agreement to allow us to engage in the development and commercialization of ruxolitinib in the GVHD field. We paid Lilly an upfront payment of \$35.0 million and Lilly is eligible to receive up to \$40.0 million in additional regulatory milestone payments relating to ruxolitinib in the GVHD field. In May 2019, the approval of JAKAFI in steroid-refractory acute GVHD triggered a \$20.0 million milestone payment to Lilly.

Agenus

In January 2015, we entered into a License, Development and Commercialization Agreement with Agenus Inc. and its wholly-owned subsidiary, 4-Antibody AG, (now known as Agenus Switzerland Inc.), which we collectively refer to as Agenus. Under this agreement, the parties have agreed to collaborate on the discovery of novel immuno-therapeutics using Agenus' antibody discovery platforms. The agreement became effective on February 18, 2015, upon the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. Upon closing of the agreement, we paid Agenus total consideration of \$60.0 million.

In February 2017, we and Agenus amended this agreement (the "Amended Agreement"). Under the terms of the Amended Agreement, we received exclusive worldwide development and commercialization rights to four checkpoint modulators directed against GITR, OX40, LAG-3 and TIM-3. In addition to the initial four program targets, we and Agenus have the option to jointly nominate and pursue additional targets within the framework of the collaboration, and in November 2015, three more targets were added. Targets may be designated profit-share programs, where all costs and profits are shared equally by us and Agenus, or royalty-bearing programs, where we are responsible for all costs associated with discovery, preclinical, clinical development and commercialization activities. The programs relating to GITR and OX40 and two of the undisclosed targets were profit-share programs until February 2017, while the other targets currently under collaboration are royalty-bearing programs. The Amended Agreement converted the programs relating to GITR and OX40 to royalty-bearing programs and removed from the collaboration the profit-share programs relating to the two undisclosed targets, with one reverting to us and one reverting to Agenus. Should any of those removed programs be successfully developed by a party, the other party will be eligible to receive the same milestone payments as the royalty-bearing programs and royalties at a 15% rate on global net sales. There are currently no profit-share programs. For each royalty-bearing product other than GITR and OX40, Agenus will be eligible to receive tiered royalties on global net sales ranging from 6% to 12%. For GITR and OX40, Agenus will be eligible to receive tiered royalties on global net sales.

Under the Amended Agreement, we paid Agenus \$20.0 million in accelerated milestones relating to the clinical development of the GITR and OX40 programs, which was recorded in research and development expense. Agenus is eligible to receive up to an additional \$510.0 million in future contingent development, regulatory and commercialization milestones across all programs in the collaboration. The agreement may be terminated by us for convenience upon 12 months' notice and may also be terminated under certain other circumstances, including material breach. In June 2018, we recorded a \$5.0 million development milestone due to Agenus for the LAG-3 program and in September 2018 we recorded a \$5.0 million development milestone due to Agenus for the TIM-3 program.

In connection with the Amended Agreement, we also agreed to purchase 10.0 million shares of Agenus Inc. common stock for an aggregate purchase price of \$60.0 million in cash, or \$6.00 per share. We completed the purchase of the shares on February 14, 2017, when the closing price on The Nasdaq Stock Market for Agenus Inc. shares was \$4.40 per share. The shares we acquired were not registered under the Securities Act of 1933 on the purchase date and were subject to certain security specific restrictions for a period of time, and accordingly, we estimated a discount for lack of marketability on the shares on the issuance date of \$4.5 million, which resulted in a net fair value of the shares on the issuance date of \$39.5 million. Therefore, of the total consideration paid of \$60.0 million, \$39.5 million was allocated to our stock purchase in Agenus Inc. and was recorded within long term investments and \$20.5 million was allocated to research and development expense.

We have concluded Agenus Inc. is not a VIE because it has sufficient equity to finance its activities without additional subordinated financial support and its at-risk equity holders have the characteristics of a controlling financial interest. From the date of our initial stock purchase in February 2015 and up to the date of our second stock purchase in February 2017, we owned between 9% and 11% of the outstanding shares of Agenus Inc. common stock. As a result of our February 2017 stock purchase, we owned approximately 13% of the outstanding shares of Agenus Inc. common stock as of September 30, 2019. We concluded that we have the ability to exercise significant influence, but not control, over Agenus Inc. based primarily on our ownership interest, the fact that we have been the largest Agenus stockholder since the date of our initial stock purchase, the level of intra-entity transactions between us and Agenus related to development expenses, as well as other qualitative factors. We have elected the fair value option to account for our long term investment in Agenus Inc. whereby the investment is marked to market through earnings in each reporting period. We believe the fair value option to be the most appropriate accounting method to account for securities in publicly held collaborators for which we have significant influence. For the three and nine months ended September 30, 2019, we recorded an unrealized loss of \$7.5 million and an unrealized gain of \$3.5 million, respectively, based on the change in fair value of Agenus Inc.'s common stock during these periods. For the three and nine months ended September 30, 2018, we recorded an unrealized loss of \$2.3 million and \$19.9 million, respectively, based on the change in fair value of Agenus Inc.'s common stock during these periods. The fair market value of our long term investment in Agenus Inc. at September 30, 2019 and December 31, 2018 was \$45.8 million and \$42.3 million, respectively.

For the three and six months ended June 30, 2019, Agenus reported within its Form 10-Q total revenues of approximately \$15.7 million and \$95.6 million, respectively, and net loss of approximately \$51.9 million and \$34.4 million, respectively, within their condensed consolidated financial statements.

Research and development expenses for the three and nine months ended September 30, 2019 also included \$0.4 million and \$1.3 million, respectively, of development costs incurred pursuant to the Agenus arrangement. Research and development expenses for the three and nine months ended September 30, 2018 also included \$1.0 million and \$3.8 million, respectively, of development costs incurred pursuant to the Agenus arrangement. At September 30, 2019 and December 31, 2018, a total of \$2.2 million and \$2.3 million, respectively, of such costs were included in accrued and other liabilities on the condensed consolidated balance sheets.

Merus

In December 2016, we entered into a Collaboration and License Agreement with Merus N.V. ("Merus"). Under this agreement, which became effective in January 2017, the parties have agreed to collaborate with respect to the research, discovery and development of bispecific antibodies utilizing Merus' technology platform. The collaboration encompasses up to eleven independent programs.

The most advanced collaboration program is MCLA-145, a bispecific antibody targeting PD-L1 and CD137, for which we received exclusive development and commercialization rights outside of the United States. Merus retained exclusive development and commercialization rights in the United States to MCLA-145. Each party will share equally the costs of mutually agreed global development activities for MCLA-145, and fund itself any independent development activities in its territory. Merus will be responsible for commercializing MCLA-145 in the United States and we will be responsible for commercializing it outside of the United States.

In addition to receiving rights to MCLA-145 outside of the United States, we received worldwide exclusive development and commercialization rights to up to ten additional programs. Of these ten additional programs, Merus retained the option, subject to certain conditions, to co-fund development of up to two such programs. If Merus exercises its co-funding option for a program, Merus would be responsible for funding 35% of the associated future global development costs and, for certain of such programs, would be responsible for reimbursing us for certain development costs incurred prior to the option exercise. Merus will also have the right to participate in a specified proportion of detailing activities in the United States for one of those co-developed programs. All costs related to the co-funded collaboration programs are subject to joint research and development plans and overseen by a joint development committee, but we will have final determination as to such plans in cases of dispute. We will be responsible for all research, development and commercialization costs relating to all other programs.

In February 2017, we paid Merus an upfront non-refundable payment of \$120.0 million. For each program as to which Merus does not have commercialization or development co-funding rights, Merus will be eligible to receive up to \$100.0 million in future contingent development and regulatory milestones, and up to \$250.0 million in commercialization milestones as well as tiered royalties ranging from 6% to 10% of global net sales. For each program as to which Merus exercises its option to co-fund development, Merus will be eligible to receive a 50% share of profits (or sustain 50% of any losses) in the United States and be eligible to receive tiered royalties ranging from 6% to 10% of net sales of products outside of the United States. If Merus opts to cease co-funding a program as to which it exercised its co-development option, then Merus will no longer receive a share of profits in the United States but will be eligible to receive the same milestones from the co-funding termination date and the same tiered royalties described above with respect to programs where Merus does not have a right to co-fund development and, depending on the stage at which Merus chose to cease co-funding development costs, Merus will be eligible to receive additional royalties ranging up to 4% of net sales in the United States. For MCLA-145, we and Merus will each be eligible to receive tiered royalties on net sales in the other party's territory at rates ranging from 6% to 10%.

The Merus agreement will continue on a program-by-program basis until we have no royalty payment obligations with respect to such program or, if earlier, the termination of the agreement or any program in accordance with the terms of the agreement. The agreement may be terminated in its entirety or on a program-by-program basis by us for convenience. The agreement may also be terminated by either party under certain other circumstances, including material breach, as set forth in the agreement. If the agreement is terminated with respect to one or more programs, all rights in the terminated programs revert to Merus, subject to payment to us of a reverse royalty of up to 4% on sales of future products, if Merus elects to pursue development and commercialization of products arising from the terminated programs.

In addition, in December 2016, we entered into a Share Subscription Agreement with Merus, pursuant to which we agreed to purchase 3.2 million common shares of Merus for an aggregate purchase price of \$80.0 million in cash, or \$25.00 per share. We agreed to certain standstill provisions whereby we are obligated to refrain from taking certain actions with respect to Merus or Merus' common shares during a period ending on the earliest of (i) three years from the closing date of our share purchase, (ii) the date Merus publicly announces any merger or similar business combination or another party announces an intention to acquire a substantial portion of Merus' securities, and (iii) the termination of the Collaboration and License Agreement. The standstill provisions are subject to certain exceptions, including an exception that allows us to maintain our percentage ownership following equity financings by Merus. We also agreed, subject to limited exceptions, not to sell or otherwise transfer any of our Merus shares for a period, referred to as the Lock-Up Period, ending on the earlier of 18 months after the closing date of the sale of the Shares or the end of the standstill period. In addition, if the standstill period has not been terminated earlier upon the occurrence of certain events, for a period of three years after the Lock-Up Period, we will be restricted from selling or otherwise transferring more than one-third of our Merus shares during any 12month period or 10% of our Merus shares during any three-month period, unless Merus consents otherwise. We have further agreed that during the standstill period, we will vote all of our Merus shares in accordance with the recommendation of a majority of Merus' supervisory board. However, we may vote our Merus shares at our own discretion for certain extraordinary matters, including a change in control of Merus. Merus has agreed to customary resale registration rights with respect to our Merus shares; however, any such resales will be subject to the Lock-Up Period and volume limitations on sale and transfer described above.

We completed the purchase of the shares on January 23, 2017 when the closing price on The Nasdaq Stock Market for Merus shares was \$24.50 per share. The shares we acquired were not registered under the Securities Act of 1933 on the purchase date and were subject to certain security specific restrictions for a period of time, and accordingly, we estimated a discount for lack of marketability on the shares on the issuance date of \$5.6 million, which resulted in a net fair value of the shares on the issuance date of \$72.8 million. Of the total consideration paid of \$80.0 million, \$72.8 million was allocated to our stock purchase in Merus and was recorded as a long term investment and \$7.2 million was allocated to research and development expense. The fair market value of our total long term investment in Merus at September 30, 2019 and December 31, 2018 was \$57.0 million and \$44.8 million, respectively.

We have concluded Merus is not a VIE because it has sufficient equity to finance its activities without additional subordinated financial support and its at-risk equity holders have the characteristics of a controlling financial interest. As of September 30, 2019, we owned approximately 14% of the outstanding shares of Merus common stock and conclude that we have the ability to exercise significant influence, but not control, over Merus based primarily on our ownership

interest, the level of intra-entity transactions between us and Merus related to development expenses, as well as other qualitative factors. We have elected the fair value option to account for our long term investment in Merus whereby the investment is marked to market through earnings in each reporting period. We believe the fair value option to be the most appropriate accounting method to account for securities in publicly held collaborators for which we have significant influence. For the three and nine months ended September 30, 2019, we recorded an unrealized gain of \$10.1 million and \$12.2 million, respectively, based on the change in fair value of Merus' common stock during these periods. For the three and nine months ended September 30, 2018, we recorded an unrealized loss of \$9.6 million and an unrealized gain of \$1.1 million, respectively, based on the change in fair value of Merus' common stock during these periods.

For the three and six months ended June 30, 2019, Merus reported within its Form 6-K total revenues of approximately \in 5.6 million and \in 13.3 million, respectively, and net loss of approximately \in 12.0 million and \in 18.2 million, respectively, within their condensed consolidated financial statements.

Research and development expenses for the three and nine months ended September 30, 2019 included \$1.4 million and \$5.7 million, respectively, of additional development costs incurred pursuant to the Merus agreement. Research and development expenses for the three and nine months ended September 30, 2018 included \$2.1 million and \$7.3 million, respectively, of additional development costs incurred pursuant to the Merus agreement. At September 30, 2019 and December 31, 2018, a total of \$1.5 million and \$2.9 million, respectively, of such costs were included in accrued and other liabilities on the condensed consolidated balance sheets.

Calithera

In January 2017, we entered into a Collaboration and License Agreement with Calithera Biosciences, Inc. ("Calithera"). Under this agreement, we received an exclusive, worldwide license to develop and commercialize small molecule arginase inhibitors, including CB-1158, which is currently in Phase I clinical trials, for hematology and oncology indications. We have agreed to co-fund 70% of the global development costs for the development of the licensed products for hematology and oncology indications. Calithera will have the right to conduct certain clinical development under the collaboration, including combination studies of a licensed product with a proprietary compound of Calithera. We will be entitled to 60% of the profits and losses from net sales of licensed product in the United States, and Calithera will have the right to co-detail licensed products in the United States, and we have agreed to pay Calithera tiered royalties ranging from the low to mid-double digits on net sales of licensed products outside the United States. Calithera may opt out of its co-funding obligation, in which case the U.S. profit sharing will no longer be in effect, and we have agreed to pay Calithera tiered royalties ranging from the low to mid-double digits on net sales of licensed products both in the United States and outside the United States, and additional royalties to reimburse Calithera for previously incurred development costs.

In January 2017, we paid Calithera an upfront license fee of \$45.0 million and have agreed to pay potential development, regulatory and sales milestone payments of over \$430.0 million if the profit share is in effect, or \$750.0 million if the profit share terminates. In March 2017, Calithera earned a \$12.0 million milestone payment from us for the achievement of pharmacokinetic and pharmacodynamics goals for CB-1158 which was recorded in research and development expense.

The Calithera agreement will continue on a product-by-product and country-by-country basis for so long as we are developing or commercializing products in the United States (if the parties are sharing profits in the United States) and until we have no further royalty payment obligations, unless earlier terminated according to the terms of the agreement. The agreement may be terminated in its entirety or on a product-by-product and/or a country-by-country basis by us for convenience. The agreement may also be terminated by us for Calithera's uncured material breach, by Calithera for our uncured material breach and by either party for bankruptcy or patent challenge. If the agreement is terminated early with respect to one or more products or countries, all rights in the terminated products and countries revert to Calithera.

In addition, in January 2017, we entered into a Stock Purchase Agreement with Calithera for the purchase of 1.7 million common shares of Calithera for an aggregate purchase price of \$8.0 million in cash, or \$4.65 per share. We completed the purchase of the shares on January 30, 2017 when the closing price on The Nasdaq Stock Market was \$6.75 per share. The shares we acquired were registered under the Securities Act of 1933 on the purchase date and there were no security specific restrictions for these shares, and therefore the value of the 1.7 million shares acquired by us was \$11.6

million. We paid total consideration of \$53.0 million to Calithera, composed of the \$45.0 million upfront license fee and the \$8.0 million stock purchase price. Of the \$53.0 million, \$11.6 million was allocated to our stock purchase in Calithera and was recorded within long term investments and \$41.4 million was allocated to research and development expense. The fair market value of our long term investment in Calithera at September 30, 2019 and December 31, 2018 was \$5.3 million and \$6.9 million, respectively.

We have concluded Calithera is not a VIE because it has sufficient equity to finance its activities without additional subordinated financial support and its at-risk equity holders have the characteristics of a controlling financial interest. As of September 30, 2019, we owned approximately 3% of the outstanding shares of Calithera common stock and there are several other stockholders who hold larger positions of Calithera. As we do not hold a significant position of the voting shares of Calithera and lack the qualitative characteristics associated with the ability to exercise significant influence, our ownership interest does not meet the criteria to be accounted for as an equity method investment. We intend to hold the investment in Calithera for the foreseeable future, and thereby have classified the investment within long term investments on the accompanying condensed consolidated balance sheets. Under guidance implemented by ASU No. 2016-01, the investment is marked to market through earnings in each reporting period. Prior to implementation, the unrealized gains and losses on our investment in Calithera were recorded in accumulated other comprehensive income (loss). To adopt ASU No. 2016-01, the January 1, 2018 accumulated deficit balance decreased by \$2.8 million to reflect these prior period unrealized gains. For the three and nine months ended September 30, 2019 we recorded an unrealized loss of \$1.4 million and \$1.6 million, respectively, based on the change in fair value of Calithera's common stock during these periods.

Research and development expenses for the three and nine months ended September 30, 2019 also included \$4.7 million and \$14.7 million, respectively, of additional development costs incurred pursuant to the Calithera agreement. Research and development expenses for the three and nine months ended September 30, 2018 also included \$2.4 million and \$8.2 million, respectively, of additional development costs incurred pursuant to the Calithera agreement. At September 30, 2019 and December 31, 2018, a total of \$3.4 million and \$2.6 million, respectively, of such costs were included in accrued and other liabilities on the condensed consolidated balance sheets.

MacroGenics

In October 2017, we entered into a Global Collaboration and License Agreement with MacroGenics, Inc. ("MacroGenics"). Under this agreement, we received exclusive development and commercialization rights worldwide to MacroGenics' INCMGA0012 (formerly MGA012), an investigational monoclonal antibody that inhibits PD-1. Except as set forth in the succeeding sentence, we will have sole authority over and bear all costs and expenses in connection with the development and commercialization of INCMGA0012 in all indications, whether as a monotherapy or as part of a combination regimen. MacroGenics has retained the right to develop and commercialize, at its cost and expense, its pipeline assets in combination with INCMGA0012. In addition, MacroGenics has the right to manufacture a portion of both companies' global clinical and commercial supply needs of INCMGA0012. In December 2017, we paid MacroGenics an upfront payment of \$150.0 million which was recorded in research and development expense on the consolidated statement of operations. MacroGenics will be eligible to receive up to \$420.0 million in future contingent development and regulatory milestones and up to \$330.0 million in commercial milestones as well as tiered royalties ranging from 15% to 24% of global net sales. In September 2018, we recorded \$10.0 million and in November 2018 we recorded \$5.0 million in aggregate milestones due to MacroGenics for the achievement of certain clinical milestones as part of our collaboration and license agreement, which were recorded in research and development expense.

The MacroGenics agreement will continue until we are no longer commercializing, developing or manufacturing INCMGA0012 or, if earlier, the termination of the agreement in accordance with its terms. The agreement may be terminated in its entirety or on a licensed product by licensed product basis by us for convenience. The agreement may also be terminated by either party under certain other circumstances, including material breach, as set forth in the agreement.

Research and development expenses for the three and nine months ended September 30, 2019 also included \$14.1 million and \$33.3 million, respectively, of additional development costs incurred pursuant to the MacroGenics agreement. Research and development expenses for the three and nine months ended September 30, 2018 also included \$6.3 million and \$23.7 million, respectively, of additional development costs incurred pursuant to the MacroGenics agreement. At September 30, 2019 and December 31, 2018, a total of \$2.4 million and \$3.2 million of such costs were included in accrued and other liabilities on the condensed consolidated balance sheets.

Syros

In January 2018, we entered into a target discovery, research collaboration and option agreement with Syros Pharmaceuticals, Inc. ("Syros"). Under this agreement, Syros will use its proprietary gene control platform to identify novel therapeutic targets with a focus in myeloproliferative neoplasms and we have received options to obtain exclusive worldwide rights to intellectual property resulting from the collaboration for up to seven validated targets. We will have exclusive worldwide rights to develop and commercialize any therapies under the collaboration that modulate those validated targets. We have agreed to pay Syros up to \$54.0 million in target selection and option exercise fees should we decide to exercise all of our options under the agreement. For products resulting from the collaboration against each of the seven selected and validated targets, we have agreed to pay up to \$50.0 million in potential development and regulatory milestones and up to \$65.0 million in potential commercial milestones. Syros is also eligible to receive low single-digit royalties on net sales of products resulting from the collaboration. In January 2018, we paid Syros an upfront non-refundable (except in the event of a material breach of the agreement by Syros) payment of \$10.0 million, which was recorded in research and development expense.

In addition, in January 2018, we entered into a Stock Purchase Agreement with Syros for the purchase of 0.8 million common shares of Syros for an aggregate purchase price of \$10.0 million in cash, or \$12.61 per share. We agreed to not sell or otherwise transfer any of our Syros shares for a period, referred to as the Lock-Up Period, of 12 months after the closing date of the sale. We completed the purchase of the shares on January 8, 2018 when the closing price on The Nasdaq Stock Market was \$9.77 per share. The shares we acquired were not registered on the purchase date, and accordingly, we estimated a discount for lack of marketability on the shares of \$0.1 million, which resulted in a net fair value of the shares on the issuance date of \$7.6 million. Of the \$10.0 million aggregate purchase price paid, \$7.6 million was allocated to our stock purchase in Syros and was recorded within long term investments and \$2.4 million, representing premium paid on the purchase, was allocated to research and development expense. Also in January 2018, we entered into an Amended Stock Purchase Agreement with Syros for the purchase of an additional 0.1 million common shares of Syros for an aggregate purchase price of \$1.4 million in cash, or \$9.55 per share. The shares were acquired in February 2018 and the \$1.4 million aggregate purchase price was recorded within long term investments on the condensed consolidated balance sheets. All acquired shares were subsequently registered under the Securities Act of 1933 in February 2018. The fair market value of our long term investment in Syros as of September 30, 2019 and December 31, 2018 was \$9.7 million and \$5.2 million, respectively.

We have concluded Syros is not a VIE because it has sufficient equity to finance its activities without additional subordinated financial support and its at-risk equity holders have the characteristics of a controlling financial interest. As of September 30, 2019, we owned approximately 2% of the outstanding shares of Syros common stock and there are several other stockholders who hold larger positions of Syros. As we do not hold a significant position of the voting shares of Syros and lack the qualitative characteristics associated with the ability to exercise significant influence, our ownership interest does not meet the criteria to be accounted for as an equity method investment. We intend to hold the investment in Syros for the foreseeable future and therefore, are accounting for our shares held in Syros at fair value under ASU No. 2016-01, and the investment is marked to market through earnings in each reporting period. Given our intent to hold the investment for the foreseeable future, we have classified the investment within long term investments on the accompanying condensed consolidated balance sheet. For the three and nine months ended September 30, 2019, we recorded an unrealized gain of \$1.1 million and \$4.6 million, respectively, based on the change in fair value of Syros' common stock during these periods. For the three and nine months ended September 30, 2018, we recorded an unrealized gain of \$1.6 million and \$2.2 million, respectively, based on the change in fair value of Syros' common stock during these periods.

Innovent

In December 2018, we entered into a research collaboration and licensing agreement with Innovent. Under the terms of this agreement, Innovent received exclusive development and commercialization rights to our clinical-stage product candidates pemigatinib, itacitinib and parsaclisib in hematology and oncology in mainland China, Hong Kong, Macau and Taiwan. In January 2019, we recognized an upfront payment under this agreement of \$40.0 million upon our transfer of the intellectual property related to the clinical-stage product candidates to Innovent, which was recorded in milestone and contract revenues on the condensed consolidated statement of operations for the three months ended March 31, 2019. In addition, we are eligible to receive \$20.0 million in connection with the first related IND filing in China, up to \$129.0 million in potential development and regulatory milestones, and up to \$202.5 million in potential commercial milestones. We are also eligible to receive tiered royalties from the high-teens to the low-twenties on future sales of products resulting from the collaboration. We retain an option to assist in the promotion of the three product candidates in the Innovent territories. In June 2019, we recognized the \$20.0 million milestone for the first related IND filing in China.

Research and development expenses for the three and nine months ended September 30, 2019 were net of \$3.6 million and \$4.1 million, respectively, of costs reimbursed by Innovent. At September 30, 2019, \$4.5 million of reimbursable costs were included in accounts receivable on the condensed consolidated balance sheets.

Zai Lab

In July 2019, we entered into a collaboration and license agreement with Zai Lab. Under the terms of this agreement, Zai Lab received development and exclusive commercialization rights to INCMGA0012 in hematology and oncology in mainland China, Hong Kong, Macau and Taiwan. We recognized an upfront payment under this agreement of \$17.5 million in August 2019 upon our transfer of technology related to the licensed product candidate to Zai Lab, and are eligible to receive an additional \$60.0 million in potential development, regulatory and commercial milestones, as well as tiered royalties from the low to mid-twenties. We also retain an option to assist in the promotion of INCMGA0012 in Zai Lab's licensed territories.

10. Stock compensation

We recorded \$43.4 million and \$124.6 million of stock compensation expense on our condensed consolidated statements of operations for the three and nine months ended September 30, 2019, respectively. We recorded \$38.0 million and \$110.8 million of stock compensation expense on our condensed consolidated statements of operations for the three and nine months ended September 30, 2018, respectively. For the three and nine months ended September 30, 2019, we capitalized \$0.1 million and \$0.3 million, respectively, of stock compensation expense as part of the cost of an asset. Stock compensation expense included within our condensed consolidated statements of operations included research and development expense of \$30.5 million, \$85.5 million, \$26.3 million and \$75.3 million for the three and nine months ended September 30, 2019 and 2018, respectively. Stock compensation expense included within our condensed consolidated statements of operations also included selling, general and administrative expense of \$12.8 million, \$38.6 million, \$11.7 million and \$35.5 million for the three and nine months ended September 30, 2019 and 2018, respectively. Stock compensation expense included within our condensed consolidated statements of operations also included cost of product revenues of \$0.1 million and \$0.5 million, respectively, for the three and nine months ended September 30, 2019.

We utilized the Black-Scholes valuation model for estimating the fair value of the stock compensation granted, with the following weighted-average assumptions:

	Employee Stock Options				1	Employee Sto	ck Purchase l	Plan
	For t	he Three	Fo	or the	For t	he Three	Fo	or the
	Mont	Months Ended Nine Months Ended Months Ended		hs Ended	Nine Mo	nths Ended		
	September 30,					Septe	mber 30,	
	2019	2018	2019	2018	2019	2018	2019	2018
Average risk-free interest rates	1.74 %	2.72 %	2.29 %	2.60 %	1.63 %	2.81 %	1.94 %	2.63 %
Average expected life (in years)	5.09	5.03	5.28	5.27	0.50	0.50	0.50	0.50
Volatility	45 %	45 %	45 %	45 %	34 %	27 %	34 %	45 %
Weighted-average fair value (in								
dollars)	34.83	29.32	32.38	34.41	15.04	13.56	14.53	15.91

The risk-free interest rate is derived from the U.S. Federal Reserve rate in effect at the time of grant. The expected life calculation is based on the observed and expected time to the exercise of options by our employees based on historical exercise patterns for similar type options. Expected volatility is based on the historical volatility of our common stock over the period commensurate with the expected life of the options. A dividend yield of zero is assumed based on the fact that we have never paid cash dividends and have no present intention to pay cash dividends. Nonemployee awards are measured on the grant date by estimating the fair value of the equity instruments to be issued using the expected term, similar to our employee awards.

Option activity under the 2010 Stock Plan was as follows:

	Shares Subject to Outstanding Options			
	Shares	l Average se Price		
Balance at December 31, 2018	12,285,159	\$	74.39	
Options granted	3,334,747	\$	76.37	
Options exercised	(1,506,665)	\$	28.22	
Options cancelled	(671,712)	\$	90.93	
Balance at September 30, 2019	13,441,529	\$	79.23	

In July 2016, we revised the terms of our annual stock option grants to provide that new option grants would generally have a 10-year term and vest over four years, with 25% vesting after one year and the remainder vesting in 36 equal monthly installments. Previously, our option grants generally had 7-year terms and vested over three years, with 33% vesting after one year and the remainder vesting in 24 equal monthly installments.

RSU award and PSU activity under the 2010 Stock Plan was as follows:

	Shares Subject to Outstanding Awards			
	Shares	Grant I	Date Value	
Balance at December 31, 2018	2,043,337	\$	80.35	
RSUs granted	1,132,673	\$	83.20	
PSUs granted	231,915	\$	79.32	
RSUs released	(572,102)	\$	87.67	
PSUs released	(13,325)	\$	68.62	
RSUs cancelled	(117,233)	\$	84.83	
PSUs cancelled	(23,514)	\$	66.42	
Balance at September 30, 2019	2,681,751	\$	79.66	

In January 2014, we began granting RSUs and PSUs to our employees at the share price on the date of grant. Each RSU represents the right to acquire one share of our common stock. Each RSU granted prior to July 2016 was subject to cliff vesting after three years. In July 2016, we revised the terms of our RSU grants to provide that the awards will vest 25% annually over four years.

Also, in January 2014, Hervé Hoppenot, our President and Chief Executive Officer, was granted a one-time grant of 400,000 RSUs outside of our 2010 Stock Incentive Plan. Vesting of the RSUs will be subject to Mr. Hoppenot's continued employment on the applicable vesting dates, with one-sixth of the RSUs vesting at the end of each of the calendar years 2014 through 2019, subject to earlier acceleration of vesting upon the occurrence of certain events in accordance with the terms of his employment agreement. As of September 30, 2019, a cumulative total of 333,334 RSUs granted to Mr. Hoppenot had vested and were released, leaving 66,666 RSUs outstanding.

In June 2018, we granted 190,000 RSUs and 446,500 PSUs under long term incentive plans with performance and/or service-based milestones with graded and/or cliff vesting over three to four years. In April 2019, we granted an additional 100,000 PSUs under the existing long term incentive plan with performance based milestones and cliff vesting. For one of the long term incentive plans, under which 106,500 PSUs were granted, the actual number of shares of our common stock into which each PSU may convert was subject to a multiplier of up to 267% based on the level at which the performance conditions were achieved. The actual number of shares of our common stock into which each PSU converted was at a multiplier of 142% based on the performance conditions being achieved as of March 31, 2019. Compensation expense for the performance-based awards is recorded over the estimated service period for each milestone when the performance conditions are deemed probable of achievement. For the three and nine months ended September 30, 2019, the stock compensation expense recorded during the period was for service-based awards and performance conditions deemed probable of achievement and/or achieved. For PSUs containing performance conditions which were not deemed probable of achievement at September 30, 2019, no stock compensation expense was recognized.

In July 2018, we granted 77,243 PSUs to executives with performance milestones and graded vesting over four years. The shares of our common stock into which each PSU may convert is subject to a multiplier up to 150% based on the level at which the performance condition is achieved. Compensation expense for the performance-based awards is recorded over the estimated service period when the performance condition is deemed probable of achievement. The actual number of shares of our common stock into which each PSU converted was at a multiplier of 83% based on the performance condition being achieved as of December 31, 2018.

The following table summarizes our shares available for grant:

	Shares Available for Grant
Balance at December 31, 2018	7,023,328
Additional authorization	7,700,000
Options, RSUs and PSUs granted	(5,847,561)
Options, RSUs and PSUs cancelled	825,589
Balance at September 30, 2019	9,701,356

Based on our historical experience of employee turnover, we have assumed an annualized forfeiture rate of 5% for our options, RSUs and PSUs. Under the true-up provisions of the stock compensation guidance, we will record additional expense if the actual forfeiture rate is lower than we estimated, and will record a recovery of prior expense if the actual forfeiture is higher than we estimated.

Total compensation cost of options granted but not yet vested, as of September 30, 2019, was \$114.4 million, which is expected to be recognized over the weighted average period of approximately 1.6 years. Total compensation cost of RSUs granted but not yet vested, as of September 30, 2019, was \$102.0 million, which is expected to be recognized over the weighted average period of approximately 1.9 years. Total compensation cost of PSUs granted but not yet vested, as of September 30, 2019, was \$34.4 million, which is expected to be recognized over the weighted average period of 2.4 years, should the underlying performance conditions be deemed probable of achievement.

11. Accrued and other current liabilities

Accrued and other current liabilities consisted of the following (in thousands):

	Sept	tember 30, 2019	1	December 31, 2018
Royalties	\$	52,861	\$	25,087
Clinical related costs		68,914		98,607
Sales allowances		59,348		44,770
Construction in progress		4,614		7,673
Financing lease liability		_		18,696
Operating lease liabilities		10,372		_
Other current liabilities		53,612		34,568
Total accrued and other current liabilities	\$	249,721	\$	229,401

12. Debt

The components of the convertible notes are as follows (in thousands):

			Carrying A			Amount,		
Debt	Interest Rates September 30, 2019	Maturities	Sep	tember 30, 2019	Dec	cember 31, 2018		
1.25% Convertible Senior Notes due 2020	1.25 %	2020	\$	18,080	\$	17,434		
				18,080		17,434		
Less current portion								
			\$	18,080	\$	17,434		

The carrying amount and fair value of our convertible notes are as follows (in thousands):

	September 30, 2019		19 December 31, 2018	
	Carrying		Carrying	
	Amount	Fair Value	Amount	Fair Value
1.25% Convertible Senior Notes due 2020	\$ 18,080	\$ 28,427	\$ 17,434	\$ 25,073
	\$ 18,080	\$ 28,427	\$ 17,434	\$ 25,073

The fair value of the 1.25% Convertible Senior Notes due November 15, 2020 (the "2020 Notes") is based on data from readily available pricing sources which utilize market observable inputs and other characteristics for similar types of instruments, and, therefore, is classified within Level 2 in the fair value hierarchy.

Prior to May 14, 2014, the 2020 Notes were not convertible except in connection with a make-whole fundamental change, as defined in the indenture. Beginning on, and including, May 15, 2014, the 2020 Notes are convertible prior to the close of business on the business day immediately preceding May 15, 2020 only under the following circumstances: (i) during any calendar quarter commencing after the calendar quarter ending on March 31, 2014 (and only during such calendar quarter), if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price for the 2020 Notes on each applicable trading day; (ii) during the five business day period after any five consecutive trading day period (the "measurement period") in which the trading price per \$1,000 principal amount of the 2020 Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate for the 2020 Notes on each such trading day; or (iii) upon the occurrence of specified corporate events. On or after May 15, 2020 until the close of business on the second scheduled trading day immediately preceding the relevant maturity date, the 2020 Notes are convertible at any time, regardless of the foregoing circumstances. Upon conversion we will pay or deliver, as the case may be, cash, shares of common stock or a combination of cash and shares of common stock, at our election.

On October 1, 2019, the 2020 Notes became convertible through at least December 31, 2019, based on meeting the conversion criteria related to the sale price of our common stock during the calendar quarter ended September 30, 2019 as described in (i) above. The 2020 Notes are reflected in long term liabilities on the condensed consolidated balance sheet as of September 30, 2019 as management's intent is to settle any conversions of the 2020 Notes during this period in shares of our common stock.

13. Employee benefit plans

Defined Contribution Plans

We have a defined contribution plan qualified under Section 401(k) of the Internal Revenue Code covering all U.S. employees and defined contribution plans for other Incyte employees in Europe. Employees may contribute a portion of their compensation, which is then matched by us, subject to certain limitations. Defined contribution expense for the three and nine months ended September 30, 2019 was \$3.0 million and \$9.0 million, respectively. Defined contribution expense for the three and nine months ended September 30, 2018 was \$2.6 million and \$8.1 million, respectively.

Defined Benefit Pension Plans

We have defined benefit pension plans for our employees in Europe which provide benefits to employees upon retirement, death or disability. The assets of the pension plans are held in collective investment accounts represented by the cash surrender value of an insurance policy and are classified as Level 2 within the fair value hierarchy.

The net periodic benefit cost was as follows (in thousands):

	Three Mor Septem		Nine Mor Septen	
	2019	2018	2019	2018
Service cost	\$ 1,263	\$ 1,041	\$ 3,813	\$ 3,152
Interest cost	84	69	253	208
Expected return on plan assets	(60)	(48)	(180)	(145)
Amortization of prior service cost	54	45	161	135
Amortization of actuarial losses	74	66	186	198
Net periodic benefit cost	\$ 1,415	\$ 1,173	\$ 4,233	\$ 3,548

The components of net periodic benefit cost other than the service cost component are included in other income (expense), net on the condensed consolidated statements of operations. We expect to contribute a total of \$3.5 million to the pension plans in 2019 inclusive of the amounts contributed to the plan during the current period. As of September 30, 2019 and December 31, 2018, \$16.6 million and \$15.7 million, respectively, of accrued pension obligation is recorded in other long term liabilities on the condensed consolidated balance sheets.

14. Income taxes

For the three and nine months ended September 30, 2019, we recorded income tax expense of approximately \$19.7 million and \$24.9 million, respectively. For the three and nine months ended September 30, 2018, we recorded income tax expense of approximately \$1.8 million and \$4.2 million, respectively. The increased tax expense for the three and nine months ended September 30, 2019 is primarily the result of estimating U.S. tax liabilities that are not fully sheltered by net operating losses or research and development tax credit carryforwards. This is partially offset by higher discrete tax benefits associated with stock-based compensation.

As of September 30, 2019, a full valuation allowance continues to be recorded against our U.S. and Swiss net deferred tax assets. This position is based on an analysis of positive and negative evidence, including analyzing three-year cumulative pre-tax income or loss, projections of future taxable income as well as other quantitative and qualitative information. We may release all or a portion of the valuation allowance in the near-term; however the exact timing and amount of such release continues to be based on our assessment of the factors mentioned above. In the period of a release

of the valuation allowance, we would recognize a non-cash increase to net income and a corresponding deferred tax asset on our consolidated balance sheet. Following the release, we would continue to utilize research and development tax credits to offset our tax liabilities, but would begin recognizing a significant provision for income taxes. The majority of this provision would be a non-cash expense until our research and development tax credit carryforwards are fully utilized.

The balance of our unrecognized tax benefits (including penalties and interest) increased by approximately \$1.8 million during the nine months ended September 30, 2019, of which only \$0.1 million was recorded as an increase to noncurrent other liabilities on the condensed consolidated balance sheet. The increase is primarily driven by unrecognized tax benefits related to current year operations and research and development tax credits.

15. Net income per share

Net income per share was calculated as follows for the periods indicated below:

	Three Months En September 30,							
(in thousands, except per share data)		2019		2018		2019		2018
Basic Net Income Per Share								
Basic net income	\$ 1	128,271	\$	29,176	\$	335,901	\$	40,430
Weighted average common shares outstanding	2	215,199		212,627		214,628		212,172
Basic net income per share	\$	0.60	\$	0.14	\$	1.57	\$	0.19
•								
Diluted Net Income Per Share								
Diluted net income	\$ 1	128,271	\$	29,176	\$	335,901	\$	40,430
Weighted average common shares outstanding	2	215,199		212,627		214,628		212,172
Dilutive stock options and awards		2,592		3,337		2,765		3,344
•								
Weighted average shares used to compute diluted net income per share	2	217,791		215,964		217,393		215,516
Diluted net income per share	\$	0.59	\$	0.14	\$	1.55	\$	0.19
1	_		_		_			

The following potential common shares were excluded from the calculations as their effect would be anti-dilutive:

	Three Mont Septemb		Nine Montl Septemb	
	2019	2018	2019	2018
Outstanding stock options and awards	8,893,596	9,055,004	9,457,441	7,254,774
Common shares issuable upon conversion of the 2018				
Notes	_	148,741	_	148,741
Common shares issuable upon conversion of the 2020				
Notes	368,939	368,939	368,939	368,939
Total potential common shares excluded from diluted	0.262.525	0.572.604	0.027.200	7.772.454
net income (loss) per share computation	9,262,535	9,572,684	9,826,380	7,772,454

16. Contingencies

In December 2018, we received a civil investigative demand from the U.S. Department of Justice for documents and information relating to our speaker programs and patient assistance programs, including our support of non-profit organizations that provide financial assistance to eligible patients. We are cooperating with this inquiry. Given that the investigation is still ongoing and that we have not yet been made aware of the substance of any civil claims, we cannot predict the outcome of the investigation, the timing of the ultimate resolution of this matter, or reasonably estimate the

possible range of loss, if any, that may result from this matter. Accordingly, no reserve has been made with respect to this matter as of September 30, 2019.

17. Subsequent event

In October 2019, we entered into an agreement with Wilmington Friends School Inc., to purchase property for \$50.0 million to expand our global headquarters. Per the agreement, closing of the purchase is subject to certain standard closing conditions including an initial diligence period and a subsequent approval period.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations as of and for the three and nine months ended September 30, 2019 should be read in conjunction with the unaudited condensed consolidated financial statements and notes to those statements included elsewhere in this Quarterly Report on Form 10-Q and our audited consolidated financial statements as of and for the year ended December 31, 2018 included in our Annual Report on Form 10-K for the year ended December 31, 2018 previously filed with the SEC.

This report contains forward-looking statements that involve risks and uncertainties. These statements relate to future periods, future events or our future operating or financial plans or performance. Often, these statements include the words "believe," "expect," "target," "anticipate," "intend," "plan," "seek," "estimate," "potential," or words of similar meaning, or future or conditional verbs such as "will," "would," "should," "could," "might," or "may," or the negative of these terms, and other similar expressions. These forward-looking statements include statements as to:

- the discovery, development, formulation, manufacturing and commercialization of our compounds, our drug candidates and JAKAFI®/JAKAVI® (ruxolitinib) and ICLUSIG® (ponatinib);
- the expected benefits from our acquisition of ARIAD Pharmaceuticals (Luxembourg) S.à.r.l. and our plans to further develop our European operations;
- conducting clinical trials internally, with collaborators, or with clinical research organizations;
- our collaboration and strategic relationship strategy; anticipated benefits and disadvantages of entering into collaboration agreements;
- our licensing, investment and commercialization strategies, including our plans to commercialize JAKAFI and ICLUSIG:
- the regulatory approval process, including obtaining U.S. Food and Drug Administration and other international health authorities approval for our products in the United States and abroad;
- the safety, effectiveness and potential benefits and indications of our drug candidates and other compounds under development;
- the timing and size of our clinical trials; the compounds expected to enter clinical trials; timing of clinical trial results;
- our ability to manage expansion of our drug discovery and development operations;
- future required expertise relating to clinical trials, manufacturing, sales and marketing;
- obtaining and terminating licenses to products, drug candidates or technology, or other intellectual property rights;
- the receipt from or payments pursuant to collaboration or license agreements resulting from milestones or royalties;
- plans to develop and commercialize products on our own;
- plans to use third-party manufacturers;
- expected expenses and expenditure levels; expected uses of cash; expected revenues and sources of revenues, including milestone payments; expectations with respect to inventory;

- expectations with respect to reimbursement for our products;
- the expected impact of recent accounting pronouncements and changes in U.S. tax laws;
- expected losses; fluctuation of losses; currency translation impact associated with collaboration royalties;
- our profitability; the adequacy of our capital resources to continue operations;
- the need to raise additional capital;
- the costs associated with resolving matters in litigation;
- our expectations regarding competition;
- expectations relating to our new European headquarters, including the anticipated date we take possession of the building and construction activities and expected lease accounting effects, and the anticipated completion date for our large molecule production facility;
- our investments, including anticipated expenditures, losses and expenses; and
- our patent prosecution and maintenance efforts.

These forward-looking statements reflect our current views with respect to future events, are based on assumptions and are subject to risks and uncertainties. These risks and uncertainties could cause actual results to differ materially from those projected and include, but are not limited to:

- our ability to successfully commercialize JAKAFI and ICLUSIG;
- our ability to maintain at anticipated levels reimbursement for our products from government health administration authorities, private health insurers and other organizations;
- our ability to establish and maintain effective sales, marketing and distribution capabilities;
- the risk of reliance on other parties to manufacture our products, which could result in a short supply of our products, increased costs, and withdrawal of regulatory approval;
- our ability to maintain regulatory approvals to market our products;
- our ability to achieve a significant market share in order to achieve or maintain profitability;
- the risk of civil or criminal penalties if we market our products in a manner that violates health care fraud and abuse and other applicable laws, rules and regulations;
- our ability to discover, develop, formulate, manufacture and commercialize our drug candidates;
- the risk of unanticipated delays in, or discontinuations of, research and development efforts;
- the risk that previous preclinical testing or clinical trial results are not necessarily indicative of future clinical trial results;
- risks relating to the conduct of our clinical trials;
- changing regulatory requirements;
- the risk of adverse safety findings;

- the risk that results of our clinical trials do not support submission of a marketing approval application for our drug candidates;
- the risk of significant delays or costs in obtaining regulatory approvals;
- risks relating to our reliance on third-party manufacturers, collaborators, and clinical research organizations;
- risks relating to the development of new products and their use by us and our current and potential collaborators;
- risks relating to our inability to control the development of out-licensed compounds or drug candidates;
- risks relating to our collaborators' ability to develop and commercialize drug candidates;
- costs associated with prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights;
- our ability to maintain or obtain adequate product liability and other insurance coverage;
- the risk that our drug candidates may not obtain or maintain regulatory approval;
- the impact of technological advances and competition, including potential generic competition;
- our ability to compete against third parties with greater resources than ours;
- risks relating to changes in pricing and reimbursement in the markets in which we may compete;
- risks relating to governmental healthcare reform efforts, including efforts to control, set or cap pricing for our commercial drugs in the U.S and abroad;
- competition to develop and commercialize similar drug products;
- our ability to obtain and maintain patent protection and freedom to operate for our discoveries and to continue to be effective in expanding our patent coverage;
- the impact of changing laws on our patent portfolio;
- developments in and expenses relating to litigation;
- our ability to in-license drug candidates or other technology;
- unanticipated construction, other delays or changes in plans relating to our new European headquarters and large molecule production facility;
- our ability to integrate successfully acquired businesses, development programs or technology;
- our ability to obtain additional capital when needed;
- fluctuations in net cash provided and used by operating, financing and investing activities;
- our ability to analyze the effects of new accounting pronouncements and apply new accounting rules;

- our history of operating losses; and
- the risks set forth under "Risk Factors."

Given these risks and uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by federal securities laws, we undertake no obligation to update any forward-looking statements for any reason, even if new information becomes available or other events occur in the future.

In this report all references to "Incyte," "we," "us," "our" or the "Company" mean Incyte Corporation and our subsidiaries, except where it is made clear that the term means only the parent company.

Incyte and JAKAFI are our registered trademarks. We also refer to trademarks of other corporations and organizations in this Quarterly Report on Form 10-Q.

Overview

Incyte is a biopharmaceutical company focused on the discovery, development and commercialization of proprietary therapeutics. Our global headquarters is located in Wilmington, Delaware. We conduct our European clinical development operations from our offices in Geneva, Switzerland, and Lausanne, Switzerland; our Japanese office is in Tokyo.

Marketed Indications - JAKAFI (ruxolitinib)

JAKAFI (ruxolitinib) is our first product to be approved for sale in the United States. It was approved by the U.S. Food and Drug Administration (FDA) in November 2011 for the treatment of adults with intermediate or high-risk myelofibrosis, in December 2014 for the treatment of adults with polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea and in May 2019 for the treatment of steroid-refractory acute graft-versus-host disease (GVHD) in adult and pediatric patients 12 years and older. Myelofibrosis and polycythemia vera are both rare blood cancers, and GVHD is an adverse immune response to an allogeneic hematopoietic stem cell transplant (HSCT). Under our collaboration agreement with Novartis International Pharmaceutical Ltd., Novartis received exclusive development and commercialization rights to ruxolitinib outside of the United States for all hematologic and oncologic indications and sells ruxolitinib outside of the United States under the name JAKAVI.

In 2003, we initiated a research and development program to explore the inhibition of enzymes called janus associated kinases (JAK). The JAK family is composed of four tyrosine kinases—JAK1, JAK2, JAK3 and Tyk2—that are involved in the signaling of a number of cytokines and growth factors. JAKs are central to a number of biologic processes, including the formation and development of blood cells and the regulation of immune functions. Dysregulation of the JAK-STAT signaling pathway has been associated with a number of diseases, including myeloproliferative neoplasms, other hematological malignancies, rheumatoid arthritis and other chronic inflammatory diseases. Myeloproliferative neoplasms are a closely related group of blood diseases in which blood cells, specifically platelets, white blood cells, and red blood cells, grow or act abnormally. These diseases include myelofibrosis (MF), polycythemia vera (PV) and essential thrombocythemia (ET).

We have discovered multiple potent, selective and orally bioavailable JAK inhibitors that are selective for JAK1 or JAK1 and JAK2. JAKAFI is the most advanced compound in our JAK program. It is an oral JAK1 and JAK2 inhibitor.

JAKAFI is marketed in the United States through our own specialty sales force and commercial team. JAKAFI was the first FDA-approved JAK inhibitor for any indication and was the first and remains the only product approved by the FDA for use in MF, PV and steroid-refractory acute GVHD. The FDA has granted JAKAFI orphan drug status for MF, PV, ET, acute lymphoblastic leukemia (ALL) and GVHD.

To help ensure that all eligible patients have access to JAKAFI, we have established a patient assistance program called IncyteCARES (CARES stands for Connecting to Access, Reimbursement, Education and Support). IncyteCARES helps ensure that any patient with intermediate or high-risk MF, uncontrolled PV or steroid-refractory acute GVHD who

meets certain eligibility criteria and is prescribed JAKAFI has access to the product regardless of ability to pay and has access to ongoing support and educational resources during treatment.

JAKAFI is distributed primarily through a network of specialty pharmacy providers and wholesalers that allow for efficient delivery of the medication by mail directly to patients or direct delivery to the patient's pharmacy. Our distribution process uses a model that is well-established and familiar to physicians who practice within the oncology field.

To further support appropriate use and future development of JAKAFI, our U.S. Medical Affairs department is responsible for providing appropriate scientific and medical education and information to physicians, preparing scientific presentations and publications, and overseeing the process for supporting investigator sponsored trials.

Myelofibrosis. Myelofibrosis is a rare, life-threatening condition. MF, considered the most serious of the myeloproliferative neoplasms, can occur either as primary MF, or as secondary MF that develops in some patients who previously had polycythemia vera or essential thrombocythemia. We estimate there are between 16,000 and 18,500 patients with MF in the United States. Based on the modern prognostic scoring systems referred to as International Prognostic Scoring System and Dynamic International Prognostic Scoring System, we believe intermediate and high-risk patients represent 80% to 90% of all patients with MF in the United States and encompass patients over the age of 65, or patients who have or have ever had any of the following: anemia, constitutional symptoms, elevated white blood cell or blast counts, or platelet counts less than 100,000 per microliter of blood.

Most MF patients have enlarged spleens and many suffer from debilitating symptoms, including abdominal discomfort, pruritus (itching), night sweats and cachexia (involuntary weight loss). There were no FDA approved therapies for MF until the approval of JAKAFI.

The FDA approval was based on results from two randomized Phase III trials (COMFORT-I and COMFORT-II), which demonstrated that patients treated with JAKAFI experienced significant reductions in splenomegaly (enlarged spleen). COMFORT-I also demonstrated improvements in symptoms. The most common hematologic adverse reactions in both trials were thrombocytopenia and anemia. These events rarely led to discontinuation of JAKAFI treatment. The most common non-hematologic adverse reactions were bruising, dizziness and headache.

In August 2014, the FDA approved supplemental labeling for JAKAFI to include Kaplan-Meier overall survival curves as well as additional safety and dosing information. The overall survival information is based on three-year data from COMFORT-I and II, and shows that at three years the probability of survival for patients treated with JAKAFI in COMFORT-I was 70% and for those patients originally randomized to placebo it was 61%. In COMFORT-II, at three years the probability of survival for patients treated with JAKAFI was 79% and for patients originally randomized to best available therapy it was 59%. In December 2016, we announced an exploratory pooled analysis of data from the five-year follow-up of the COMFORT-II trials of patients treated with JAKAFI, which further supported previously published overall survival findings.

In September 2016, we announced that JAKAFI had been included as a recommended treatment in the latest National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology for myelofibrosis, underscoring the important and long-term clinical benefits seen in patients treated with JAKAFI.

In October 2017, the FDA approved updated labeling for JAKAFI to include the addition of new patient-reported outcome (PRO) data from the COMFORT-I study, as well as updating the warning related to progressive multifocal leukoencephalopathy. An exploratory analysis of PRO data of patients with myelofibrosis receiving JAKAFI showed improvement in fatigue-related symptoms at Week 24. Fatigue response (defined as a reduction of 4.5 points or more from baseline in the PROMIS® Fatigue total score) was reported in 35% of patients treated with JAKAFI versus 14% of the patients treated with placebo.

Polycythemia Vera. PV is a myeloproliferative neoplasm typically characterized by elevated hematocrit, the volume percentage of red blood cells in whole blood, which can lead to a thickening of the blood and an increased risk of blood clots, as well as an elevated white blood cell and platelet count. When phlebotomy can no longer control PV, chemotherapy such as hydroxyurea, or interferon, is utilized. Approximately 25,000 patients with PV in the United States

are considered uncontrolled because they have an inadequate response to or are intolerant of hydroxyurea, the most commonly used chemotherapeutic agent for the treatment of PV.

In December 2014, the FDA approved JAKAFI for the treatment of patients with PV who have had an inadequate response to or are intolerant of hydroxyurea. The approval of JAKAFI for PV was based on data from the pivotal Phase III RESPONSE trial. In this trial, patients treated with JAKAFI demonstrated superior hematocrit control and reductions in spleen volume compared to best available therapy. In addition, a greater proportion of patients treated with JAKAFI achieved complete hematologic remission—which was defined as achieving hematocrit control, and lowering platelet and white blood cell counts. In the RESPONSE trial, the most common hematologic adverse reactions (incidence > 20%) were thrombocytopenia and anemia. The most common non-hematologic adverse events (incidence >10%) were headache, abdominal pain, diarrhea, dizziness, fatigue, pruritus, dyspnea and muscle spasms.

In March 2016, the FDA approved supplemental labeling for JAKAFI to include additional safety data as well as efficacy analyses from the RESPONSE trial to assess the durability of response in JAKAFI treated patients after 80 weeks. At this time, 83% patients were still on treatment, and 76% of the responders at 32 weeks maintained their response through 80 weeks.

In June 2016, we announced data from the Phase III RESPONSE-2 study of JAKAFI in patients with inadequately controlled PV that was resistant to or intolerant of hydroxyurea who did not have an enlarged spleen. These data showed that JAKAFI was superior to best available therapy in maintaining hematocrit control (62.2% vs. 18.7%, respectively; P<0.0001) without the need for phlebotomy.

In August 2017, we announced that JAKAFI had been included as a recommended treatment in the latest NCCN Guidelines for patients with polycythemia vera who have had an inadequate response to first-line therapies, such as hydroxyurea.

Graft-versus-host disease. GVHD is a condition that can occur after an allogeneic HSCT (the transfer of genetically dissimilar stem cells or tissue). In GVHD, the donated bone marrow or peripheral blood stem cells view the recipient's body as foreign and attack various tissues. 12-month survival rates in patients with Grade III or IV steroid-refractory acute GVHD are 50% or less, and the incidence of newly diagnosed acute and de novo chronic GVHD is approximately 15,000 per year across the United States, Europe and Japan.

In June 2016, we announced that the FDA granted Breakthrough Therapy designation for ruxolitinib in patients with acute GVHD. In May 2019, the FDA approved JAKAFI for the treatment of steroid-refractory acute GVHD in adult and pediatric patients 12 years and older. The approval was based on data from REACH1, an open-label, single-arm, multicenter study of Jakafi in combination with corticosteroids in patients with steroid-refractory grade II-IV acute GVHD. The overall response rate (ORR) in patients refractory to steroids alone was 57% with a complete response (CR) rate of 31%. The most frequently reported adverse reactions among all study participants were infections (55%) and edema (51%), and the most common laboratory abnormalities were anemia (75%), thrombocytopenia (75%) and neutropenia (58%).

We have retained all development and commercialization rights to JAKAFI in the United States and are eligible to receive development and commercial milestones as well as royalties from product sales outside the United States. We hold patents that cover the composition of matter and use of ruxolitinib which patents, including applicable extensions, expire in late 2027.

Marketed Indications - ICLUSIG (ponatinib)

In June 2016, we acquired the European operations of ARIAD Pharmaceuticals, Inc. (ARIAD) and obtained an exclusive license to develop and commercialize ICLUSIG (ponatinib) in Europe and other select countries. ICLUSIG is a kinase inhibitor. The primary target for ICLUSIG is BCR-ABL, an abnormal tyrosine kinase that is expressed in chronic myeloid leukemia (CML) and Philadelphia-chromosome positive acute lymphoblastic leukemia (Ph+ ALL).

In the European Union, ICLUSIG is approved for the treatment of adult patients with chronic phase, accelerated phase or blast phase CML who are resistant to dasatinib or nilotinib; who are intolerant to dasatinib or nilotinib and for

whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation, or the treatment of adult patients with Ph+ ALL who are resistant to dasatinib; who are intolerant to dasatinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation.

Clinical Programs in Oncology

We believe that the future of cancer treatment lies in the use of targeted therapies, which aim to block the effects of cancer-causing mutations, and immune therapies, which seek to recruit the patient's own immune system to tackle cancer. Our most advanced programs are detailed below.

JAK Inhibition

As part of our development program to improve and expand therapeutic options for patients with MF, we are currently recruiting Phase II trials combining ruxolitinib with our investigational agents such as itacitinib (JAK1), parsaclisib (PI3Kδ), and INCB53914 (PIM) in patients with refractory MF.

Following positive proof-of-concept data, we initiated a pivotal program investigating ruxolitinib for the treatment of patients with ET. ET is a Philadelphia chromosome negative myeloproliferative neoplasm, characterized by the overproduction of platelets in the bone marrow. The pivotal RESET trial is enrolling ET patients that are refractory to or intolerant of hydroxyurea, the current standard of care for first-line treatment of these patients.

The REACH clinical program evaluates ruxolitinib in patients with steroid-refractory GVHD and includes REACH2, a Novartis-sponsored Phase III trial in steroid-refractory acute GVHD, and REACH3, a Phase III trial in steroid-refractory chronic GVHD that is co-sponsored by Incyte and Novartis.

In October 2019, we and Novartis announced that REACH2 met its primary endpoint of superior overall response rate (ORR) at Day 28 with ruxolitinib treatment compared to best available therapy. No new safety signals were observed, and the ruxolitinib safety profile in REACH2 was consistent with that seen in previously reported studies in steroid-refractory acute GVHD. In addition, in October 2019, we also announced that an interim efficacy and safety analysis conducted by an Independent Data Monitoring Committee (IDMC) recommended that REACH3 should continue without modification. The result of REACH3 is expected to be available in 2020.

Based on data from a proof-of-concept trial of itacitinib, a selective JAK1 inhibitor, in patients with acute GVHD, a pivotal trial (GRAVITAS-301) investigating itacitinib for the treatment of patients with treatment-naïve acute GVHD was initiated in July 2017 and we announced completion of enrollment in April 2019. A second pivotal trial of itacitinib, GRAVITAS-309, was initiated in January 2019 for patients with treatment-naïve chronic GVHD. The FDA has granted itacitinib orphan drug status for GVHD.

FGFR1/2/3 Inhibition

Pemigatinib is a potent and selective inhibitor of the fibroblast growth factor receptor (FGFR) isoforms 1, 2 and 3 with demonstrated activity in preclinical studies. The FGFR family of receptor tyrosine kinases can act as oncogenic drivers in a number of liquid and solid tumor types. We initiated the FIGHT clinical program to evaluate pemigatinib across a spectrum of cancers that are driven by FGF/FGFR alterations. The program initially included three Phase II trials – FIGHT-201 in patients with bladder cancer, FIGHT-202 in patients with cholangiocarcinoma, and FIGHT-203 in patients with 8p11 myeloproliferative syndrome (8p11 MPN). Based on data generated from these ongoing trials, we are currently initiating additional trials, including FIGHT-207, a Phase II solid tumor-agnostic trial evaluating pemigatinib in patients with driver-activations of FGF/FGFR.

In September 2019, we announced positive updated data from the FIGHT-202 trial evaluating pemigatinib in patients with advanced/metastatic or surgically unresectable cholangiocarcinoma who failed at least one previous treatment. In February 2019, we announced that the FDA granted Breakthrough Therapy designation for pemigatinib in patients with previously treated, advanced/metastatic or unresectable FGFR2 translocated cholangiocarcinoma. FIGHT-

302, a Phase III trial of pemigatinib for the first-line treatment of patients with cholangiocarcinoma and FGFR2 fusions or rearrangements was initiated in June 2019.

Cholangiocarcinoma is a cancer that arises from the cells within the bile ducts. It is often diagnosed late (stages III and IV) and the prognosis is poor. The incidence of cholangiocarcinoma with FGFR2 fusions or rearrangements is increasing, and is currently estimated at 2,000-3,000 patients in the U.S., Europe and Japan.

PD-1 Antagonism

In October 2017, we and MacroGenics, Inc. announced an exclusive global collaboration and license agreement for MacroGenics' INCMGA0012, an investigational monoclonal antibody that inhibits PD-1. Under this collaboration, we obtained exclusive worldwide rights for the development and commercialization of INCMGA0012 in all indications. Enrollment in the dose escalation portion of the Phase I study of INCMGA0012 has been completed and the molecule is currently being evaluated as monotherapy across four solid tumor types in the dose expansion portion of the study. Registration-directed trials in MSI-high endometrial cancer, Merkel cell carcinoma, and anal cancer were initiated in 2018.

PI3K-delta Inhibition

The PI3K-delta pathway mediates oncogenic signaling in B cell malignancies. Parsaclisib (formerly INCB50465) is a PI3K-delta inhibitor that has demonstrated potency and selectivity in preclinical studies and has potential therapeutic utility in the treatment of patients with lymphoma. We initiated the CITADEL clinical program to evaluate parsaclisib in non-Hodgkin lymphomas, and we are currently running Phase II trials in follicular lymphoma, marginal zone lymphoma and mantle cell lymphoma.

	Indication and status
Ruxolitinib (JAK1/JAK2)	Steroid-refractory acute GVHD: Phase III (REACH2) met primary endpoint Steroid-refractory chronic GVHD: Phase III (REACH3) Essential thrombocythemia: Phase II (RESET) Refractory myelofibrosis: Phase II with PI3Kδ, PIM or JAK1 inhibition
Itacitinib (JAK1)	Treatment-naïve acute GVHD: Phase III (GRAVITAS-301) Treatment-naïve chronic GVHD: Phase III (GRAVITAS-309)
Pemigatinib (FGFR1/2/3)	Cholangiocarcinoma: Phase II (FIGHT-202), Phase III (FIGHT-302) Bladder cancer: Phase II (FIGHT-201) 8p11 MPN: Phase II (FIGHT-203) Tumor agnostic: Phase II (FIGHT-207)
Parsaclisib (PI3Kδ)	Follicular lymphoma: Phase II (CITADEL-203) Marginal zone lymphoma: Phase II (CITADEL-204) Mantle cell lymphoma: Phase II (CITADEL-205)
INCMGA0012 (PD-1)1	MSI-high endometrial cancer: Phase II (POD1UM-101) Merkel cell carcinoma: Phase II (POD1UM-201) Anal cancer: Phase II (POD1UM-202)

^{1.} INCMGA0012 licensed from MacroGenics.

Earlier-Stage Programs

We also have a number of other earlier-stage clinical programs, as detailed in the table below. We intend to describe these programs more fully if we obtain clinical proof-of-concept and establish that a program warrants further development in a specific indication or group of indications.

Modality	Candidates
Small molecules	INCB01158 (ARG) ¹ , INCB81776 (AXL/MER), INCB62079 (FGFR4), epacadostat (IDO1), INCB59872 (LSD1), INCB53914 (PIM), INCB86550 (PD-L1)
Monoclonal antibodies ²	INCAGN1876 (GITR), INCAGN2385 (LAG-3), INCAGN1949 (OX40), INCAGN2390 (TIM-3)
Bispecific antibodies	MCLA-145 (PD-L1xCD137) ³

- ¹ INCB01158 development in collaboration with Calithera Biosciences, Inc.
- ² Discovery collaboration with Agenus Inc.
- ³ MCLA-145 development in collaboration with Merus N.V.

Clinical Programs outside Oncology

In June 2018, we announced that a Phase II trial of ruxolitinib cream for the topical treatment of atopic dermatitis showed a significant benefit over vehicle control and a global, pivotal Phase III program was initiated in December 2018. Atopic dermatitis is a skin disorder that causes the skin to become red, scaly, and itchy. Onset can occur at any age, but is much more common in infants and children. United States and European prevalence are estimated at 10.3 million patients and 6.5 million patients, respectively.

In June 2019, primary endpoint data after 6 months of therapy from the Phase II trial of ruxolitinib cream in patients with vitiligo showed a significant benefit over vehicle control, and a global, pivotal Phase III program was initiated in September 2019. In October 2019, updated data from the Phase II trial showed, after 12 months of therapy, additional improvement in the repigmentation of vitiligo lesions. Vitiligo is a long-term skin condition characterized by patches of the skin losing their pigment. It is estimated that there are 2-3 million patients in the United States with this disorder, and there are no FDA approved treatments.

A Phase II trial of INCB54707, a JAK1 selective inhibitor, is ongoing in patients with hidradenitis suppurativa, an inflammatory skin disease.

A Phase II trial of itacitinib, a JAK1 selective inhibitor, is ongoing in patients with ulcerative colitis.

Phase II trials of parsaclisib, a PI3K δ inhibitor, in autoimmune hemolytic anemia and Sjögren's syndrome are underway.

	Indication and status
Ruxolitinib cream ¹ (JAK1/JAK2)	Atopic dermatitis: Phase III (TRuE-AD) Vitiligo: Phase III (TRuE-V)
INCB54707 (JAK1)	Hidradenitis suppurativa: Phase II
Itacitinib (JAK1)	Ulcerative colitis: Phase II

ParsaclisibAutoimmune hemolytic anemia: Phase II(PI3Kδ)Sjögren's syndrome: Phase II

Partnered Programs

Baricitinib

We have a second JAK1 and JAK2 inhibitor, baricitinib, which is subject to our collaboration agreement with Eli Lilly and Company, in which Lilly received exclusive worldwide development and commercialization rights to the compound for inflammatory and autoimmune diseases. The Phase III program of baricitinib in patients with rheumatoid arthritis incorporated all three rheumatoid arthritis populations (methotrexate naïve, biologic naïve, and tumor necrosis factor (TNF) inhibitor inadequate responders); used event rates to fully power the baricitinib program for structural comparison and non-inferiority vs. adalimumab; and evaluated patient-reported outcomes. All four Phase III trials met their respective primary endpoints.

In January 2016, Lilly submitted a New Drug Application (NDA) to the FDA and a Marketing Authorization Application (MAA) to the European Medicines Agency for baricitinib as treatment for rheumatoid arthritis. In February 2017, we and Lilly announced that the European Commission approved baricitinib as OLUMIANT for the treatment of moderate-to-severe rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to, one or more disease-modifying antirheumatic drugs (DMARDs). In July 2017, Japan's Ministry of Health, Labor and Welfare (MHLW) granted marketing approval for OLUMIANT for the treatment of rheumatoid arthritis (including the prevention of structural injury of joints) in patients with inadequate response to standard-of-care therapies. In June 2018, the FDA approved the 2mg dose of OLUMIANT for the treatment of adults with moderately-to-severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more tumor necrosis factor (TNF) inhibitor therapies.

Rheumatoid Arthritis. Rheumatoid arthritis is an autoimmune disease characterized by aberrant or abnormal immune mechanisms that lead to joint inflammation and swelling and, in some patients, the progressive destruction of joints. Rheumatoid arthritis can also affect connective tissue in the skin and organs of the body.

Current rheumatoid arthritis treatments include the use of non-steroidal anti-inflammatory drugs, disease-modifying anti-rheumatic drugs, such as methotrexate, and the newer biological response modifiers that target pro-inflammatory cytokines, such as tumor necrosis factor, implicated in the pathogenesis of rheumatoid arthritis. None of these approaches to treatment is curative; therefore, there remains an unmet need for new safe and effective treatment options for these patients. Rheumatoid arthritis is estimated to affect about 1% of the world's population.

Atopic Dermatitis. Atopic dermatitis (AtD) is a condition that makes the skin red and itchy and which is common in children but can occur at any age. Atopic dermatitis is long lasting and tends to flare periodically and then subside. Lilly has conducted a Phase IIa trial to evaluate the safety and efficacy of baricitinib in patients with moderate-to-severe atopic dermatitis. The JAK-STAT pathway has been shown to play an essential role in the dysregulation of immune responses in atopic dermatitis. Therefore, we believe that inhibiting cytokine pathways dependent on JAK1 and JAK2 may lead to positive clinical outcomes in atopic dermatitis.

A Phase III program to evaluate the safety and efficacy of baricitinib in patients with moderate to severe AtD is ongoing. In February 2019, we and Lilly announced that baricitinib met the primary endpoint in BREEZE-AD1 and BREEZE-AD2, two Phase III studies evaluating the efficacy and safety of baricitinib monotherapy for the treatment of adult patients with moderate to severe AtD and, in August 2019, we and Lilly announced that baricitinib met the primary endpoint in BREEZE-AD7, a Phase III study evaluating the efficacy and safety of baricitinib in combination with standard-of-care topical corticosteroids in patients with moderate to severe AtD. These are three of five studies that are expected to be part of the placebo-controlled data program intended to support global registrations.

¹ Novartis' rights for ruxolitinib outside of the United States under our Collaboration and License Agreement with Novartis do not include topical administration.

Systemic Lupus Erythematosus. Systemic lupus erythematosus (SLE) is a chronic disease that causes inflammation. In addition to affecting the skin and joints, it can affect other organs in the body such as the kidneys, the tissue lining the lungs and heart, and the brain. Lilly has conducted a Phase II trial to evaluate the safety and efficacy of baricitinib in patients with SLE. Baricitinib's activity profile suggests that it inhibits cytokines implicated in SLE such as type I interferon (IFN), type II IFN-γ, IL-6, and IL-23 as well as other cytokines that may have a role in SLE, including granulocyte macrophage colony stimulating factor (GM-CSF) and IL-12. The potential impact of baricitinib on the IFN pathway is highly relevant to SLE, as clinical and preclinical studies have established that this pathway is involved in the pathogenesis of SLE. Lilly is currently running a Phase III trial of baricitinib in patients with SLE.

Alopecia Areata. Alopecia areata is an autoimmune disorder in which the immune system attacks the hair follicles, causing hair loss in patches. Lilly has initiated the Phase III portion of the ongoing Phase II/III trial designed to evaluate the safety and efficacy of baricitinib in patients with severe alopecia areata.

Capmatinib

Capmatinib is a potent and highly selective MET inhibitor. The investigational compound has demonstrated inhibitory activity in cell-based biochemical and functional assays that measure MET signaling and MET dependent cell proliferation, survival and migration. Under our agreement, Novartis received worldwide exclusive development and commercialization rights to capmatinib and certain back-up compounds in all indications. Capmatinib is being evaluated in patients with hepatocellular carcinoma, non-small cell lung cancer and other solid tumors, and may have potential utility as a combination agent.

MET is a clinically validated receptor kinase cancer target. Abnormal MET activation in cancer correlates with poor prognosis. Dysregulation of the MET pathway triggers tumor growth, formation of new blood vessels that supply the tumor with nutrients, and causes cancer to spread to other organs. Dysregulation of the MET pathway is seen in many types of cancers, including lung, kidney, liver, stomach, breast and brain.

In October 2018, we and Novartis announced positive preliminary results of the GEOMETRY mono-1 Phase II clinical trial of capmatinib in patients with advanced non-small cell lung cancer (NSCLC) harboring MET exon 14 skipping mutations. In June 2019, we and Novartis announced updated results from the GEOMETRY mono-1 trial, as well as the granting of Breakthrough Therapy designation by the FDA for capmatinib as a treatment for patients with metastatic NSCLC harboring MET exon-14 skipping mutation with disease progression on or after platinum-based chemotherapy.

NSCLC is the most common type of lung cancer, impacting more than 2 million people per year. Approximately 3-4 percent of all patients with NSCLC have an identified MET mutation. Though rare, this mutation is an indicator of especially poor prognosis and there is currently no approved therapy designed to target this mutation.

	Indication and status
Baricitinib (JAK1/JAK2) ¹	Atopic dermatitis: Phase III (BREEZE-AD) Systemic lupus erythematosus: Phase III Severe alopecia areata: Phase III
Capmatinib (MET) ²	NSCLC (with MET exon 14 skipping mutations): NDA expected in Q4 2019 (by Novartis)

^{1.} Baricitinib licensed to Lilly

License Agreements and Business Relationships

We establish business relationships, including collaborative arrangements with other companies and medical research institutions to assist in the clinical development and/or commercialization of certain of our drugs and drug candidates and to provide support for our research programs. We also evaluate opportunities for acquiring products or

² Capmatinib licensed to Novartis

rights to products and technologies that are complementary to our business from other companies and medical research institutions

Below is a brief description of our significant business relationships and collaborations and related license agreements that expand our pipeline and provide us with certain rights to existing and potential new products and technologies.

Novartis

In November 2009, we entered into a Collaboration and License Agreement with Novartis. Under the terms of the agreement, Novartis received exclusive development and commercialization rights outside of the United States to ruxolitinib and certain back-up compounds for hematologic and oncology indications, including all hematological malignancies, solid tumors and myeloproliferative diseases. We retained exclusive development and commercialization rights to JAKAFI (ruxolitinib) in the United States and in certain other indications. Novartis also received worldwide exclusive development and commercialization rights to our MET inhibitor compound capmatinib and certain back-up compounds in all indications. We retained options to co-develop and to co-promote capmatinib in the United States.

Under this agreement, we received an upfront payment and immediate milestone payment totaling \$210.0 million and were initially eligible to receive additional payments of up to approximately \$1.2 billion if defined development and commercialization milestones are achieved. We are also eligible to receive tiered, double-digit royalties ranging from the upper-teens to the mid-twenties percent on future ruxolitinib net sales outside of the United States, and tiered, worldwide royalties on future capmatinib net sales that range from 12% to 14%. In addition, Novartis has received reimbursement and pricing approval for ruxolitinib in a specified number of countries, and we are now obligated to pay to Novartis tiered royalties in the low single-digits on future ruxolitinib net sales within the United States. Each company is responsible for costs relating to the development and commercialization of ruxolitinib in its respective territories, with costs of collaborative studies shared equally. Novartis is also responsible for all costs relating to the development and commercialization of capmatinib.

In April 2016, we amended this agreement to provide that Novartis has exclusive research, development and commercialization rights outside of the United States to ruxolitinib (excluding topical formulations) in the GVHD field. Under this amendment, we received a \$5.0 million payment in exchange for the development and commercialization rights to ruxolitinib in GVHD outside of the United States and became eligible to receive up to \$75.0 million of additional potential development and regulatory milestones relating to GVHD. In March 2017, we recognized a \$25.0 million milestone for the first patient first visit in a GVHD study and in December 2017, we recognized a \$40.0 million milestone for Novartis achieving annual net sales of a JAK licensed product of \$600.0 million. In December 2018, we recognized a \$60.0 million milestone for Novartis achieving annual net sales of a JAK licensed product of \$900.0 million.

The Novartis agreement will continue on a program-by-program basis until Novartis has no royalty payment obligations with respect to such program or, if earlier, the termination of the agreement or any program in accordance with the terms of the agreement. Royalties are payable by Novartis on a product-by-product and country-by-country basis until the latest to occur of (i) the expiration of the last valid claim of the licensed patent rights covering the licensed product in the relevant country, (ii) the expiration of regulatory exclusivity for the licensed product in such country and (iii) a specified period from first commercial sale in such country of the licensed product by Novartis or its affiliates or sublicensees. The agreement may be terminated in its entirety or on a program-by-program basis by Novartis for convenience. The agreement may also be terminated by either party under certain other circumstances, including material breach.

Lilly

In December 2009, we entered into a License, Development and Commercialization Agreement with Lilly. Under the terms of the agreement, Lilly received exclusive worldwide development and commercialization rights to baricitinib and certain back-up compounds for inflammatory and autoimmune diseases. We received an initial payment of \$90.0 million, and were initially eligible to receive additional payments of up to \$665.0 million based on the achievement of defined development, regulatory and commercialization milestones.

We retained options to co-develop our JAK1/JAK2 inhibitors with Lilly on a compound-by-compound and indication-by-indication basis. Lilly is responsible for all costs relating to the development and commercialization of the compounds unless we elect to co-develop any compounds or indications. If we elect to co-develop any compounds and/or indications, we would be responsible for funding 30% of the associated future global development costs from the initiation of a Phase IIb trial through regulatory approval, including post-launch studies required by a regulatory authority. We would receive an incremental royalty rate increase across all tiers resulting in effective royalty rates ranging up to the high twenties on potential future global net sales for compounds and/or indications that we elect to co-develop. For indications that we elect not to co-develop, we would receive tiered, double-digit royalty payments on future global net sales with rates ranging up to 20% if the product is successfully commercialized. If we have started co-development funding for any indication, we can at any time opt out and stop future co-development cost sharing. If we elect to do this we would still be eligible for our base royalties plus an incremental pro-rated royalty commensurate with our contribution to the total co-development cost for those indications for which we co-funded. We previously had retained an option to co-promote products in the United States but, in March 2016, we waived our co-promotion option as part of an amendment to the agreement.

In July 2010, we elected to co-develop baricitinib with Lilly in rheumatoid arthritis, and subsequently in several additional indications, and became responsible for funding 30% of the associated global development costs for such indications from the initiation of the Phase IIb trial through regulatory approval, including post-launch studies required by a regulatory authority. In April 2019, we elected to end additional co-funding of the development of baricitinib in all indications, effective as of January 1, 2019. Pursuant to the terms of the Lilly agreement, we will continue to receive base tiered royalties on global net sales of OLUMIANT in all indications, as well as pro-rated incremental royalties, as described above.

In March 2016, we entered into an amendment to the agreement with Lilly that allows us to engage in the development and commercialization of ruxolitinib in the GVHD field. We paid Lilly an upfront payment of \$35.0 million and Lilly is eligible to receive up to \$40.0 million in additional regulatory milestone payments relating to ruxolitinib in the GVHD field. In May 2019, the approval of JAKAFI in steroid-refractory acute GVHD triggered a \$20.0 million milestone payment to Lilly.

In February 2017, the European Commission announced the approval of baricitinib as OLUMIANT, triggering a \$65.0 million milestone payment from Lilly. In July 2017, Japan's MHLW granted marketing approval for OLUMIANT, triggering a \$15.0 million milestone payment from Lilly. In December 2017, we recognized a \$30.0 million milestone payment for the first patient treated in the atopic dermatitis Phase III program for baricitinib. In June 2018, the FDA approved the 2mg dose of OLUMIANT, triggering a \$100.0 million milestone payment from Lilly. In September 2018, we recognized a \$20.0 million milestone payment for the first patient treated in the systemic lupus erythematosus Phase III program for baricitinib.

The Lilly agreement will continue until Lilly no longer has any royalty payment obligations or, if earlier, the termination of the agreement in accordance with its terms. Royalties are payable by Lilly on a product-by-product and country-by-country basis until the latest to occur of (i) the expiration of the last valid claim of the licensed patent rights covering the licensed product in the relevant country, (ii) the expiration of regulatory exclusivity for the licensed product in such country and (iii) a specified period from first commercial sale in such country of the licensed product by Lilly or its affiliates or sublicensees. The agreement may be terminated by Lilly for convenience, and may also be terminated under certain other circumstances, including material breach.

Agenus

In January 2015, we entered into a License, Development and Commercialization Agreement with Agenus Inc. and its wholly-owned subsidiary, 4-Antibody AG (now known as Agenus Switzerland Inc.), which we collectively refer to as Agenus. Under this agreement, the parties have agreed to collaborate on the discovery of novel immuno-therapeutics using Agenus' antibody discovery platforms. In February 2017, we and Agenus amended this agreement.

Under the terms of this agreement, as amended, we received exclusive worldwide development and commercialization rights to four checkpoint modulators directed against GITR, OX40, LAG-3 and TIM-3. In addition to the initial four program targets, we and Agenus have the option to jointly nominate and pursue additional targets within

the framework of the collaboration, and in November 2015, three more targets were added. Targets may be designated profitshare programs, where all costs and profits are shared equally by us and Agenus, or royalty-bearing programs, where we are responsible for all costs associated with discovery, preclinical, clinical development and commercialization activities. The programs relating to GITR and OX40 and two of the undisclosed targets were profit-share programs until February 2017, while the other targets currently under collaboration are royalty-bearing programs. The February 2017 amendment converted the programs relating to GITR and OX40 to royalty-bearing programs and removed from the collaboration the profit-share programs relating to the two undisclosed targets, with one reverting to us and one reverting to Agenus. Should any of those removed programs be successfully developed by a party, the other party will be eligible to receive the same milestone payments as the royalty-bearing programs and royalties at a 15% rate on global net sales. There are currently no profit-share programs. For each royalty-bearing product other than GITR and OX40, Agenus will be eligible to receive tiered royalties on global net sales ranging from 6% to 12%. For GITR and OX40, Agenus will be eligible to receive 15% royalties on global net sales. Under the February 2017 amendment, we paid Agenus \$20.0 million in accelerated milestones relating to the clinical development of the GITR and OX40 programs. Agenus is eligible to receive up to an additional \$510.0 million in future contingent development, regulatory and commercialization milestones across all programs in the collaboration. The agreement may be terminated by us for convenience upon 12 months' notice and may also be terminated under certain other circumstances, including material breach.

Takeda (ARIAD)

In June 2016, we acquired from ARIAD Pharmaceuticals, Inc. all of the outstanding shares of ARIAD Pharmaceuticals (Luxembourg) S.à.r.l., the parent company of ARIAD's European subsidiaries responsible for the development and commercialization of ICLUSIG in the European Union and other countries. We obtained an exclusive license to develop and commercialize ICLUSIG in Europe and other select countries. ARIAD was subsequently acquired by Takeda Pharmaceutical Company Limited in 2017. As such, Takeda will be eligible to receive from us tiered royalties on net sales of ICLUSIG in our territory and up to \$135.0 million in potential future oncology development and regulatory approval milestone payments, together with additional milestone payments for non-oncology indications, if approved, in our territory.

Merus

In December 2016, we entered into a Collaboration and License Agreement with Merus N.V. Under this agreement, which became effective in January 2017, the parties have agreed to collaborate with respect to the research, discovery and development of bispecific antibodies utilizing Merus' technology platform. The collaboration encompasses up to eleven independent programs.

The most advanced collaboration program is MCLA-145, a bispecific antibody targeting PD-L1 and CD137, for which we received exclusive development and commercialization rights outside of the United States. Merus retained exclusive development and commercialization rights in the United States to MCLA-145. Each party will share equally the costs of mutually agreed global development activities for MCLA-145, and fund itself any independent development activities in its territory. Merus will be responsible for commercializing MCLA-145 in the United States and we will be responsible for commercializing it outside of the United States.

In addition to receiving rights to MCLA-145 outside of the United States, we received worldwide exclusive development and commercialization rights to up to ten additional programs. Of these ten additional programs, Merus retained the option, subject to certain conditions, to co-fund development of up to two such programs. If Merus exercises its co-funding option for a program, Merus would be responsible for funding 35% of the associated future global development costs and, for certain of such programs, would be responsible for reimbursing us for certain development costs incurred prior to the option exercise. Merus will also have the right to participate in a specified proportion of detailing activities in the United States for one of those co-developed programs. All costs related to the co-funded collaboration programs are subject to joint research and development plans and overseen by a joint development committee, but we will have final determination as to such plans in cases of dispute. We will be responsible for all research, development and commercialization costs relating to all other programs.

In February 2017, we paid Merus an upfront non-refundable payment of \$120.0 million. For each program as to which Merus does not have commercialization or development co-funding rights, Merus will be eligible to receive up to \$100.0 million in future contingent development and regulatory milestones, and up to \$250.0 million in commercialization milestones as well as tiered royalties ranging from 6% to 10% of global net sales. For each program as to which Merus exercises its option to co-fund development, Merus will be eligible to receive a 50% share of profits (or sustain 50% of any losses) in the United States and be eligible to receive tiered royalties ranging from 6% to 10% of net sales of products outside of the United States. If Merus opts to cease co-funding a program as to which it exercised its co-development option, then Merus will no longer receive a share of profits in the United States but will be eligible to receive the same milestones from the co-funding termination date and the same tiered royalties described above with respect to programs where Merus does not have a right to co-fund development and, depending on the stage at which Merus chose to cease co-funding development costs, Merus will be eligible to receive additional royalties ranging up to 4% of net sales in the United States. For MCLA-145, we and Merus will each be eligible to receive tiered royalties on net sales in the other party's territory at rates ranging from 6% to 10%.

The Merus agreement will continue on a program-by-program basis until we have no royalty payment obligations with respect to such program or, if earlier, the termination of the agreement or any program in accordance with the terms of the agreement. The agreement may be terminated in its entirety or on a program-by-program basis by us for convenience. The agreement may also be terminated by either party under certain other circumstances, including material breach, as set forth in the agreement. If the agreement is terminated with respect to one or more programs, all rights in the terminated programs revert to Merus, subject to payment to us of a reverse royalty of up to 4% on sales of future products, if Merus elects to pursue development and commercialization of products arising from the terminated programs.

Calithera

In January 2017, we entered into a Collaboration and License Agreement with Calithera Biosciences, Inc. Under this agreement, we received an exclusive, worldwide license to develop and commercialize small molecule arginase inhibitors, including INCB01158 (CB-1158), which is currently in Phase I clinical trials, for hematology and oncology indications. We have agreed to co-fund 70% of the global development costs for the development of the licensed products for hematology and oncology indications. Calithera will have the right to conduct certain clinical development under the collaboration, including combination studies of a licensed product with a proprietary compound of Calithera. We will be entitled to 60% of the profits and losses from net sales of licensed product in the United States, and Calithera will have the right to co-detail licensed products in the United States, and we have agreed to pay Calithera tiered royalties ranging from the low to middouble digits on net sales of licensed products outside the United States. Calithera may opt out of its co-funding obligation, in which case the U.S. profit sharing will no longer be in effect, and we have agreed to pay Calithera tiered royalties ranging from the low to mid-double digits on net sales of licensed products both in the United States and outside the United States, and additional royalties to reimburse Calithera for previously incurred development costs.

Calithera retains rights to certain arginase inhibitors that are not part of the collaboration for specific orphan indications outside of hematology and oncology, subject to our rights to negotiate a license for any such programs under specified circumstances if Calithera elects to out-license them.

In January 2017, we paid Calithera an upfront license fee of \$45.0 million and have agreed to pay potential development, regulatory and sales milestone payments of over \$430.0 million if the profit share is in effect, or \$750.0 million if the profit share terminates.

The Calithera agreement will continue on a product-by-product and country-by-country basis for so long as we are developing or commercializing products in the United States (if the parties are sharing profits in the United States) and until we have no further royalty payment obligations, unless earlier terminated according to the terms of the agreement. The agreement may be terminated in its entirety or on a product-by-product and/or a country-by-country basis by us for convenience. The agreement may also be terminated by us for Calithera's uncured material breach, by Calithera for our uncured material breach and by either party for bankruptcy or patent challenge. If the agreement is terminated early with respect to one or more products or countries, all rights in the terminated products and countries revert to Calithera.

MacroGenics

In October 2017, we entered into a Global Collaboration and License Agreement with MacroGenics. Under this agreement, we received exclusive development and commercialization rights worldwide to MacroGenics' INCMGA0012, an investigational monoclonal antibody that inhibits PD-1. Except as set forth in the succeeding sentence, we will have sole authority over and bear all costs and expenses in connection with the development and commercialization of INCMGA0012 in all indications, whether as a monotherapy or as part of a combination regimen. MacroGenics has retained the right to develop and commercialize, at its cost and expense, its pipeline assets in combination with INCMGA0012. In addition, MacroGenics has the right to manufacture a portion of both companies' global clinical and commercial supply needs of INCMGA0012. In December 2017, we paid MacroGenics an upfront payment of \$150.0 million. MacroGenics will be eligible to receive up to \$420.0 million in future contingent development and regulatory milestones, and up to \$330.0 million in commercial milestones as well as tiered royalties ranging from 15% to 24% of global net sales.

The MacroGenics agreement will continue until we are no longer commercializing, developing or manufacturing INCMGA0012 or, if earlier, the termination of the agreement in accordance with its terms. The agreement may be terminated in its entirety or on a licensed product by licensed product basis by us for convenience. The agreement may also be terminated by either party under certain other circumstances, including material breach, as set forth in the agreement.

Syros

In January 2018, we entered into a target discovery, research collaboration and option agreement with Syros Pharmaceuticals, Inc. Under this agreement, Syros will use its proprietary gene control platform to identify novel therapeutic targets with a focus in myeloproliferative neoplasms and we have received options to obtain exclusive worldwide rights to intellectual property resulting from the collaboration for up to seven validated targets. We will have exclusive worldwide rights to develop and commercialize any therapies under the collaboration that modulate those validated targets. We paid Syros \$2.5 million in cash for access to proprietary technology and \$7.5 million in cash for research and development services. We have agreed to pay Syros up to \$54.0 million in target selection and option exercise fees should we decide to exercise all of our options under the agreement. For products resulting from the collaboration against each of the seven selected and validated targets, we have agreed to pay up to \$50.0 million in potential development and regulatory milestones and up to \$65.0 million in potential commercial milestones. Syros is also eligible to receive low single-digit royalties on net sales of products resulting from the collaboration.

Innovent

In December 2018, we entered into a research collaboration and licensing agreement with Innovent Biologics, Inc. Under the terms of this agreement, Innovent received exclusive development and commercialization rights to our clinical-stage product candidates pemigatinib, itacitinib and parsaclisib in hematology and oncology in mainland China, Hong Kong, Macau and Taiwan. In January 2019, we recognized an upfront payment under this agreement of \$40.0 million upon our transfer of the intellectual property related to the clinical-stage product candidates to Innovent. In addition, we are eligible to receive \$20.0 million in connection with the first related IND filing in China, up to \$129.0 million in potential development and regulatory milestones, and up to \$202.5 million in potential commercial milestones. We are also eligible to receive tiered royalties from the high-teens to the low-twenties on future sales of products resulting from the collaboration. We retain an option to assist in the promotion of the three product candidates in the Innovent territories. In June 2019, we recognized the \$20.0 million milestone for the first related IND filing in China.

Zai Lab

In July 2019, we entered into a collaboration and license agreement with a subsidiary of Zai Lab Limited. Under the terms of this agreement, Zai Lab received development and exclusive commercialization rights to INCMGA0012 in hematology and oncology in mainland China, Hong Kong, Macau and Taiwan. We recognized an upfront payment under this agreement of \$17.5 million in August 2019 upon our transfer of technology related to the licensed product candidate to Zai Lab, and are eligible to receive an additional \$60.0 million in potential development, regulatory and commercial

milestones, as well as tiered royalties from the low to mid-twenties. We also retain an option to assist in the promotion of INCMGA0012 in Zai Lab's licensed territories.

Critical Accounting Policies and Significant Estimates

The preparation of financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances, the results of which form our basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates under different assumptions or conditions. We believe the following critical accounting policies reflect the more significant judgments and estimates used in the preparation of our condensed consolidated financial statements. See Note 2 of Notes to the Condensed Consolidated Financial Statements for a complete list of our significant accounting policies.

Revenue Recognition. We recognize revenue only when we have satisfied a performance obligation through transferring control of the promised good or service to a customer. Control, in this instance, may mean the ability to prevent other entities from directing the use of, and receiving benefit from, a good or service. The standard indicates that an entity must determine at contract inception whether it will transfer control of a promised good or service over time or satisfy the performance obligation at a point in time through analysis of the following criteria: (i) the entity has a present right to payment, (ii) the customer has legal title, (iii) the customer has physical possession, (iv) the customer has the significant risks and rewards of ownership and (v) the customer has accepted the asset. We assess collectability based primarily on the customer's payment history and on the creditworthiness of the customer.

Product Revenues

Our product revenues consist of U.S. sales of JAKAFI and European sales of ICLUSIG. Product revenues are recognized once we satisfy the performance obligation at a point in time under the revenue recognition criteria as described above. We recognize revenues for product received by our customers net of allowances for customer credits, including estimated rebates, chargebacks, discounts, returns, distribution service fees, patient assistance programs, and government rebates, such as Medicare Part D coverage gap reimbursements in the U.S. These sales allowances and accruals are recorded based on estimates which are described in detail below. Estimates are assessed as of the end of each reporting period and are updated to reflect current information. We believe that our sales allowances and accruals are reasonable and appropriate based on current facts and circumstances.

Customer Credits: Our customers are offered various forms of consideration, including allowances, service fees and prompt payment discounts. We expect our customers will earn prompt payment discounts and, therefore, we deduct the full amount of these discounts from total product sales when revenues are recognized. Service fees are also deducted from total product sales as they are earned.

Rebates and Discounts: We accrue rebates for mandated discounts under the Medicaid Drug Rebate Program in the U.S. and mandated discounts in Europe in markets where government-sponsored healthcare systems are the primary payers for healthcare. These accruals are based on statutory discount rates and expected utilization as well as historical data we have accumulated since product launch. Our estimates for expected utilization of rebates are based on data received from our customers. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarters' unpaid rebates. In addition to actual rebates received, we maintain an accrual for the estimated rebates on the inventory levels on hand in our distribution channel. If actual future rebates vary from estimates, we may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

Chargebacks: Chargebacks are discounts that occur when certain contracted customers purchase directly from our wholesalers at a discounted price. The wholesalers, in turn, charges back to us the difference between the price initially paid by the wholesalers and the discounted price paid by the contracted customers. In addition to actual chargebacks received, we maintain an accrual for chargebacks based on the estimated contractual discounts on the inventory levels on

hand in our distribution channel. If actual future chargebacks vary from these estimates, we may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

Medicare Part D Coverage Gap: Medicare Part D prescription drug benefit mandates manufacturers to fund 70% of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients. Our estimates for the expected Medicare Part D coverage gap are based on historical invoices received and in part from data received from our customers. Funding of the coverage gap is generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarters. In addition, we maintain an accrual for the estimated coverage gap on the inventory levels on hand in our distribution channel. If actual future funding varies from estimates, we may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

Co-payment Assistance: Patients who have commercial insurance and meet certain eligibility requirements may receive co-payment assistance. We accrue a liability for co-payment assistance based on actual program participation and estimates of program redemption using data provided by third-party administrators and we accrue for estimated co-payment assistance on the inventory levels on hand in our distribution channel.

Product Royalty Revenues

Royalty revenues on commercial sales for JAKAVI by Novartis are estimated based on information provided by Novartis. Royalty revenues on commercial sales for OLUMIANT by Lilly are estimated based on information provided by Lilly. We exercise judgment in determining whether the information provided is sufficiently reliable for us to base our royalty revenue recognition thereon. If actual royalties vary from estimates, we may need to adjust the prior period, which would affect royalty revenue and receivable in the period of adjustment.

Milestone and Contract Revenues

At the inception of the contract, the transaction price reflects the amount of consideration we expect to be entitled to in exchange for transferring promised goods or services to our collaborator. We review our estimate of the transaction price each period, and make revisions to such estimates as necessary. Milestone and contract revenues from collaborative agreements with multiple performance obligations is determined based upon assessment of each distinct promised good or service's estimated fair value and recognized based upon the transfer of the promised good or service to our collaborator.

Our license agreements often include contractual milestones, which typically relate to the achievement of prespecified development, regulatory and commercialization events outside of our control, such as regulatory approval of a compound, first patient dosing or achievement of sales-based thresholds. As such, milestones associated with our collaborations involve a substantial degree of uncertainty and risk that they may never be received. Given the uncertainty associated with achieving these milestones, a constraint on the allocated consideration is assessed each reporting period. Revenues are recognized when achievement is probable, which may not be until achieved.

Stock Compensation. Share-based payment transactions with employees, which include stock options, restricted stock units (RSUs) and performance shares (PSUs), are recognized as compensation expense over the requisite service period based on their estimated fair values at the date of grant as well as expected forfeiture rates based on actual experience. The stock compensation process requires significant judgment and the use of estimates, particularly surrounding Black-Scholes assumptions such as stock price volatility over the option term and expected option lives, as well as expected forfeiture rates and the probability of PSUs vesting. The fair value of stock options, which are subject to graded vesting, are recognized as compensation expense over the requisite service period using the accelerated attribution method. The fair value of RSUs that are subject to cliff vesting are recognized as compensation expense over the requisite service period using the accelerated attribution method. The fair value of PSUs are recognized as compensation expense beginning at the time in which the performance conditions are deemed probable of achievement. We assess the probability of achievement of performance conditions, including projected product revenues and clinical development milestones, as of the end of each reporting period. Once a performance condition is considered probable, we record compensation expense based on the portion of the service period elapsed to

date with respect to that award, with a cumulative catch-up, net of estimated forfeitures, and recognize any remaining compensation expense, if any, over the remaining requisite service period using the straight-line attribution method for PSUs that are subject to cliff vesting and using the accelerated attribution method for PSUs that are subject to graded vesting.

Income Taxes. We account for income taxes using an asset and liability approach to financial accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax bases of assets and liabilities using enacted tax rates in effect for years in which the basis differences are expected to reverse. We periodically assess the likelihood of the realization of deferred tax assets, and reduce the carrying amount of these deferred tax assets to an amount that is considered to be more-likely-than-not to be realizable. Our assessment considers recent cumulative earnings experience, projections of future taxable income (losses) and ongoing prudent and feasible tax planning strategies. When performing our assessment on projections of future taxable income (losses), we consider factors such as the likelihood of regulatory approval and commercial success of products currently under development, among other factors. Significant judgment is required in making this assessment and, to the extent that a reversal of any portion of our valuation allowance against our deferred tax assets is deemed appropriate, a tax benefit will be recognized against our income tax provision in the period of such reversal.

We recognize the tax benefit from an uncertain tax position only if it is more-likely-than-not that the position will be sustained upon examination by the taxing authorities, including resolutions of any related appeals or litigation processes, based on the technical merits of the position. The tax benefit that is recorded for these positions is measured at the largest amount of benefit that is greater than 50 percent likely of being realized upon ultimate settlement. We adjust the level of the liability to reflect any subsequent changes in the relevant facts surrounding the uncertain positions. Any interest and penalties on uncertain tax positions are included within the tax provision.

We record estimates and prepare and file tax returns in various jurisdictions across the U.S., Europe, and Asia based upon our interpretation of local tax laws and regulations. While we exercise significant judgment when applying complex tax laws and regulations in these various taxing jurisdictions, many of our tax returns are open to audit, and may be subject to future tax, interest, and penalty assessments.

We believe our estimates for the valuation allowances against certain deferred tax assets and the amount of benefits associated with uncertain tax positions recognized in our financial statements are appropriate based upon our assessment of the factors mentioned above.

Acquisition-related contingent consideration. Acquisition-related contingent consideration, which consists of our future royalty and certain potential milestone obligations to ARIAD/Takeda, was recorded on the acquisition date at the estimated fair value of the obligation, in accordance with the acquisition method of accounting. The fair value of the contingent consideration was determined using an income approach based on estimated ICLUSIG revenues in the European Union and other countries. As the fair value measurement is based on significant inputs that are unobservable in the market, this represents a Level 3 measurement.

The fair value of the acquisition-related contingent consideration is remeasured each reporting period, with changes in fair value recorded in the consolidated statements of operations. The assumptions used to determine the fair value of the acquisition-related contingent consideration include projected ICLUSIG revenues and discount rates which, require significant judgement and are analyzed on a quarterly basis. While we use the best available information to prepare our projected ICLUSIG revenues and discount rate assumptions, actual ICLUSIG revenues and/or market conditions could differ significantly. Changes to one or multiple inputs could have a material impact on the amount of acquisition-related contingent consideration expense recorded during the reporting period.

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASC 842, Leases, that requires lessees to recognize assets and liabilities on the balance sheet for most leases including operating leases. Additionally, the FASB issued clarifying guidance to the topic in ASUs No. 2018-10, No. 2018-11, No. 2018-20 and No. 2019-01 which clarified certain aspects of the new leases standard and provided an optional transition method. The guidance requires that

the lessees classify leases as either a finance or operating lease and lessors classify all leases as sales-type, direct financing or operating leases. The statement of operations presentation and expense recognition for lessees for finance leases is similar to that of capital leases under ASC 840, with separate interest and amortization expense with higher interest expense in the earlier periods of a lease. For operating leases, the statement of operations presentation and expense recognition is similar to that of operating leases under ASC 840, with a single lease cost recognized on a straight-line basis. We implemented a third-party information technology application to facilitate activities for the new accounting and disclosure requirements and implemented new internal control procedures to support the new accounting and reporting processes associated with adopting the guidance. We elected the package of practical expedients and adopted utilizing the optional transition method as defined within ASU No. 2018-11. Accordingly, prior periods will not be restated to reflect the adopted standard. We did not elect the hindsight expedient.

As a result of adoption on January 1, 2019, we recorded \$23.6 million of lease right-of-use assets, \$23.7 million of lease liabilities and an adjustment to retained earnings of \$0.1 million. In addition, our capital lease assets and liabilities are now classified as finance lease right-of-use assets and liabilities. The capital asset and financing liability of \$18.7 million recorded in 2018 related to the Morges office building and construction, described more fully in Note 7, was derecognized upon adoption. The adoption of the standard did not materially impact our consolidated net income and had no impact on our consolidated cash flows.

In June 2016, the FASB issued ASU No. 2016-13, "Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments." This guidance applies to all entities and impacts how entities account for credit losses for most financial assets and other instruments. ASU 2016-13 requires financial assets measured at amortized cost to be presented at the net amount expected to be collected. The measurement of expected credit losses is based on relevant information about past events, including historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amounts. An entity must use judgment in determining the relevant information and estimation methods that are appropriate in its circumstances. For trade receivables, loans and held-to-maturity debt securities, entities will be required to estimate expected credit losses over the lifetime of the asset. For available-for-sale debt securities, entities will be required to recognize an allowance for credit losses rather than an other-than-temporary impairment that reduces the cost basis of the investment. Further, an entity will recognize any improvements in estimated credit losses on its available-for-sale debt securities immediately in earnings.

The FASB also released clarifying guidance in April 2019 within ASU No. 2019-04, "Codification Improvements to Topic 326, Financial Instruments – Credit Losses," and in May 2019 within ASU No. 2019-05, "Financial Instruments – Credit Losses (Topic 326): Targeted Transition Relief." The updates provide guidance on estimating credit losses, including transition relief by allowing for election of the fair value methodology on an instrument-by-instrument basis for eligible financial instruments within the scope of ASC 825-10. This guidance is effective for fiscal years beginning after December 15, 2019 and interim periods therein. Elections under ASU 2019-05 require a modified retrospective application through a cumulative-effect adjustment in the opening balance of retained earnings upon adoption. We are currently analyzing the impact of the ASUs on our condensed consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, "Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting." This guidance expanded the scope of ASC 718 to include share-based payments granted to nonemployees in exchange for goods or services and supersedes the guidance in ASC 505-50. Under this new standard, nonemployee awards are measured on the grant date by estimating the fair value of the equity instruments to be issued rather than the fair value of the goods or services received. Entities may use the expected term when estimating the fair value of a nonemployee option or elect to use the contractual term as the expected term, on an award-by-award basis. The cumulative effect of the transition adjustment is to be recorded as an adjustment to retained earnings as of the beginning of the annual period of adoption. We adopted this standard for the period beginning January 1, 2019 and concluded there to be no change in our previous accounting for nonemployee awards and no impact on our condensed consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-14, "Compensation – Retirement Benefits – Defined Benefit Plans – General," an update to Subtopic ASC 715-20. The guidance amended year-end disclosure requirements related to defined benefit pension plans, and does not affect interim disclosures. The guidance is effective for fiscal years ending after December 15, 2020, and is permitted for early adoption. The standard is to be applied on a retrospective basis. Incyte

sponsors defined benefit plans for employees located in Europe. We are currently analyzing the impact of ASU No. 2018-14 on our consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-15, "Intangibles – Goodwill and Other – Internal-Use Software," an update to Subtopic ASC 350-40. The guidance directs accounting for service contracts for cloud computing arrangements to follow guidance within ASC 350-40 to determine capitalization of implementation costs. The guidance is effective for fiscal years beginning after December 15, 2019, and is permitted for early adoption. The standard may be applied on either a retrospective or prospective basis. We are currently analyzing the impact of ASU No. 2018-15 on our condensed consolidated financial statements.

In August 2018, the SEC issued a final rule Release No. 33-10532, "Disclosure Update and Simplification," to amend certain disclosure requirements now seen as redundant, duplicative, overlapping, outdated or superseded in the wake of recent accounting pronouncements. The amended rules became effective November 5, 2018. We analyzed the release in preparation of our Form 10-Q during the first interim period in 2019, which resulted in the additional disclosure of changes to stockholders' equity during interim periods, as presented within the condensed consolidated statements of stockholders' equity. We note that many of the amended requirements under this Release are not applicable to the Company, as we do not make dividend payments to stockholders, currently report our activities under a single business segment, and already provided all other significant disclosure requirements.

In November 2018, the FASB issued ASU No. 2018-18, "Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606." The guidance clarifies the interactions between Topic 808 and Topic 606, including clarifications on revenue recognition, unit of account, and reporting disclosure requirements. The guidance is effective for fiscal years beginning after December 15, 2019, and is permitted for early adoption. The standard is to be applied on a retrospective basis to the date of the initial application of Topic 606. We utilize collaborative arrangements as described in our license agreements footnote and are currently analyzing the impact of ASU No. 2018-18 on our condensed consolidated financial statements.

Results of Operations

We recorded net income of \$128.3 million and basic net income per share of \$0.60 and diluted net income per share of \$0.59 for the three months ended September 30, 2019, as compared to net income of \$29.2 million and basic and diluted net income per share of \$0.14 in the corresponding period in 2018. We recorded net income of \$335.9 million and basic net income per share of \$1.57 and diluted net income per share of \$1.55 for the nine months ended September 30, 2019, as compared to net income of \$40.4 million and basic and diluted net income per share of \$0.19 in the corresponding period in 2018

Revenues.

	F	or the Three Septen			For the Nine I Septen	,		
		2019 2018				2019		2018
		(in m)	-	(in mi	llions)		
JAKAFI revenues, net	\$	433.4	\$	347.6	\$	1,218.5	\$	1,006.9
ICLUSIG revenues, net		20.6		20.1		65.6		60.8
Total product revenues, net	_	454.0		367.7		1,284.1		1,067.7
JAKAVI product royalty revenues		58.4		50.9		160.9		139.4
OLUMIANT product royalty revenues		21.6		11.0		56.8		26.2
Total product royalty revenues		80.0		61.9	-	217.7		165.6
Milestone and contract revenues		17.5		20.0		77.5		120.0
Other revenues		_		0.1				0.2
Total revenues	\$	551.5	\$	449.7	\$	1,579.3	\$	1,353.5

The increase in JAKAFI product revenues for the three months ended September 30, 2019 as compared to the corresponding period in 2018 was comprised of a volume increase of \$61.9 million and a price increase of \$23.9 million. The increase in JAKAFI product revenues for the nine months ended September 30, 2019 as compared to the corresponding

period in 2018 was comprised of a volume increase of \$147.3 million and a price increase of \$64.3 million. Our product revenues may fluctuate from quarter to quarter due to our customers' purchasing patterns over the course of the year, including as a result of increased inventory building by customers in advance of expected or announced price increases. Product revenues are recorded net of estimated product returns, pricing discounts including rebates offered pursuant to mandatory federal and state government programs and chargebacks, prompt pay discounts and distribution fees and co-pay assistance. Our revenue recognition policies require estimates of the aforementioned sales allowances each period.

The following table provides a summary of activity with respect to our sales allowances and accruals (in thousands):

Nine Months Ended September 30, 2019	scounts and istribution Fees	R	Sovernment Rebates and hargebacks	a	Co-Pay Assistance and Other Discounts	Product Returns	Total
Balance at January 1, 2019	\$ 5,125	\$	39,737	\$	547	\$ 2,270	\$ 47,679
Allowances for current period sales	36,603		189,732		6,808	654	233,797
Allowances for prior period sales	(306)		1,184		_	(164)	714
Credits/payments for current period sales	(31,311)		(153,896)		(6,508)	_	(191,715)
Credits/payments for prior period sales	(4,310)		(22,754)		(170)	(704)	(27,938)
Balance at September 30, 2019	\$ 5,801	\$	54,003	\$	677	\$ 2,056	\$ 62,537

Government rebates and chargebacks are the most significant component of our sales allowances. Increases in certain government reimbursement rates are limited to a measure of inflation, and when the price of a drug increases faster than this measure of inflation it will result in a penalty adjustment factor that causes a larger sales allowance to those government related entities. We expect government rebates and chargebacks as a percentage of our gross product sales will continue to increase in connection with any future JAKAFI price increases greater than the rate of inflation, and any such increase in these government rebates and chargebacks will have a negative impact on our reported product revenues, net. We adjust our estimates for government rebates and chargebacks based on new information regarding actual rebates as it becomes available. Claims by third-party payors for rebates and chargebacks are frequently submitted after the period in which the related sales occurred, which may result in adjustments to prior period accrual balances in the period in which the new information becomes available. We also adjust our allowance for product returns based on new information regarding actual returns as it becomes available.

We expect our sales allowances to fluctuate from quarter to quarter as a result of the Medicare Part D Coverage Gap, the volume of purchases eligible for government mandated discounts and rebates as well as changes in discount percentages which are impacted by potential future price increases, rate of inflation, and other factors.

Product royalty revenues on commercial sales of JAKAVI by Novartis are based on net sales of licensed products in licensed territories as provided by Novartis. Product royalty revenues on commercial sales of OLUMIANT by Lilly are based on net sales of licensed products in licensed territories as provided by Lilly.

Our milestone and contract revenues for the nine months ended September 30, 2019, were derived from a \$40.0 million upfront payment and a \$20.0 million milestone under the Innovent research collaboration and licensing agreement and a \$17.5 million upfront payment under the Zai Lab collaboration and license agreement. During the nine months ended September 30, 2018, under the Lilly agreement, we recognized a \$20.0 million development milestone for the first patient treated in systemic lupus erythematosus Phase III program for baricitinib and a \$100.0 million regulatory milestone for the approval of the 2mg dose of OLUMIANT for the treatment of moderately-to-severely active rheumatoid arthritis in adult patients by the FDA.

Cost of Product Revenues.

	For	the Three Septen	Month nber 30			Ended,		
	2	2019		2018		2019		2018
		(in m	illions)			(in m	illions)	
Product costs	\$	2.7	\$	2.4	\$	8.7	\$	7.3
Salary and benefits related		0.6		_		1.9		_
Stock compensation		0.1		_		0.5		_
Royalty expense		21.2		17.0		54.7		44.3
Amortization of definite-lived intangible assets		5.4		5.4		16.2		16.2
Total cost of product revenues	\$	30.0	\$	24.8	\$	82.0	\$	67.8

Cost of product revenues includes all JAKAFI and ICLUSIG related product costs, employee personnel costs, including stock compensation, for those employees dedicated to the production of our commercial products, low single-digit royalties to Novartis on all sales of JAKAFI in the United States and amortization of our licensed intellectual property rights for ICLUSIG using the straight-line method over the estimated useful life of 12.5 years. The increase in cost of product revenues for the three and nine months ended September 30, 2019 as compared to the same periods in 2018 is due primarily to increased royalties to Novartis on all JAKAFI sales in the United States.

Operating Expenses.

Research and development expenses.

	For	the Three Septer		For	r the Nine l Septen			
		2019		2018		2019		2018
	(in millions)					(in m	nillions)	
Salary and benefits related	\$	64.9	\$	51.9	\$	185.6	\$	159.1
Stock compensation		30.5		26.3		85.5		75.3
Clinical research and outside services		157.5		190.0		488.7		585.1
Occupancy and all other costs		28.4		24.3		81.4		74.2
Total research and development expenses	\$	281.3	\$	292.5	\$	841.2	\$	893.7

We account for research and development costs by natural expense line and not costs by project. Salary and benefits related expense increased from the three and nine months ended September 30, 2018 to the three and nine months ended September 30, 2019 due primarily to increased development headcount to sustain our development pipeline. Stock compensation expense may fluctuate from period to period based on the number of awards granted, stock price volatility and expected award lives, as well as expected award forfeiture rates which are used to value equity-based compensation.

The decrease in clinical research and outside services expense from the nine months ended September 30, 2018 to the nine months ended September 30, 2019 was primarily due to upfront and milestone expenses related to our collaborative agreements recorded during 2018 and the election to end additional co-funding of the development of baricitinib with Lilly effective as of January 1, 2019. Research and development expenses include upfront and milestone expenses related to our collaborative agreements of \$0.0 million and \$25.3 million for the three and nine months ended September 30, 2019. Research and development expenses include upfront and milestone expenses related to our collaborative agreements of \$15.0 million and \$47.4 million for the three and nine months ended September 30, 2018. For the three and nine months ended September 30, 2019, we recorded no research and development expense under the Lilly agreement for co-funding the development of baricitinib. For the three and nine months ended September 30, 2018, we recorded \$18.9 million and \$45.6 million, respectively, in research and development expenses under the Lilly agreement representing 30% of the global development costs for baricitinib for the treatment of rheumatoid arthritis, psoriatic arthritis and atopic dermatitis. Research and development expenses for the three and nine months ended September 30, 2019 and 2018 were net of \$5.3 million, \$11.6 million, \$2.4 million and \$7.0 million, respectively, of costs reimbursed by our collaborative partners.

In addition to one-time expenses resulting from upfront fees in connection with the entry into any new or amended collaboration agreements and payment of milestones under those agreements, research and development expenses may fluctuate from period to period depending upon the stage of certain projects and the level of pre-clinical and clinical trial related activities. Many factors can affect the cost and timing of our clinical trials, including requests by regulatory agencies for more information, inconclusive results requiring additional clinical trials, slow patient enrollment, adverse side effects among patients, insufficient supplies for our clinical trials and real or perceived lack of effectiveness or safety of our investigational drugs in our clinical trials. In addition, the development of all of our products will be subject to extensive governmental regulation. These factors make it difficult for us to predict the timing and costs of the further development and approval of our products.

Selling, general and administrative expenses.

	Fo	For the Three Months Ended, September 30,					For the Nine Months End September 30,			
		2019	2018		2019			2018		
		(in m	illions)		(in r		nillions)			
Salary and benefits related	\$	33.2	\$	26.9	\$	96.0	\$	85.0		
Stock compensation		12.8		11.7		38.6		35.5		
Other contract services and outside costs		56.6		57.9		197.9		205.5		
Total selling, general and administrative expenses	\$	102.6	\$	96.5	\$	332.5	\$	326.0		

Salary and benefits related expense increased from the three and nine months ended September 30, 2018 to the three and nine months ended September 30, 2019 due to increased headcount. This increased headcount was due primarily to the ongoing commercialization efforts related to JAKAFI for intermediate or high-risk myelofibrosis and uncontrolled polycythemia vera. Stock compensation expense may fluctuate from period to period based on the number of awards granted, stock price volatility and expected award lives, as well as expected award forfeiture rates which are used to value equity-based compensation.

Change in fair value of acquisition-related contingent consideration

Acquisition-related contingent consideration, which consists of our future royalty and certain potential milestone obligations to Takeda, was recorded on the acquisition date, June 1, 2016, at the estimated fair value of the obligation, in accordance with the acquisition method of accounting. The fair value of the acquisition-related contingent consideration is remeasured quarterly. The change in fair value of the acquisition-related contingent consideration for the three and nine months ended September 30, 2019 was \$3.3 million and \$16.6 million, respectively, which is recorded in change in fair value of acquisition-related contingent consideration on the condensed consolidated statements of operations. The change in fair value of the acquisition-related contingent consideration for the three and nine months ended September 30, 2018 was \$4.7 million and \$18.7 million, respectively, which is recorded in change in fair value of acquisition-related contingent consideration on the condensed consolidated statements of operations. The change in fair value for the three and nine months ended September 30, 2019 and 2018 was due primarily to the passage of time as there were no other significant changes in the key assumptions during the periods.

Other income (expense).

Other income (expense), net. Other income (expense), net for the three and nine months ended September 30, 2019 was \$12.0 million and \$36.3 million, respectively. Other income (expense), net for the three and nine months ended September 30, 2018 was \$10.2 million and \$20.5 million, respectively. The increase in other income (expense), net primarily relates to interest income.

Interest expense. Interest expense for the three and nine months ended September 30, 2019 was \$0.6 million and \$1.2 million, respectively. Interest expense for the three and nine months ended September 30, 2018 was \$0.4 million and \$1.2 million, respectively. Included in interest expense for the three and nine months ended September 30, 2019 was \$0.2 million and \$0.6 million, respectively, of non-cash charges to amortize the discount on the 2020 Notes. Included in interest

expense for the three and nine months ended September 30, 2018 was \$0.3 million and \$0.9 million, respectively, of non-cash charges to amortize the discounts on the 2018 and 2020 convertible senior notes.

Unrealized gain (loss) on long term investments. Unrealized gains and losses on long term investments will fluctuate from period to period, based on the change in fair value of the securities we hold in our publicly held collaboration partners. The following table provides a summary of those unrealized gains and (losses):

	For	For the Three Months Ended, September 30,					For the Nine Months Ended, September 30,			
		2019		2018		2019		2018		
		(in millions)				(in millions)				
Agenus	\$	(7.5)	\$	(2.3)	\$	3.5	\$	(19.9)		
Calithera		(1.4)		0.4		(1.6)		(5.3)		
Merus		10.1		(9.6)		12.2		1.1		
Syros		1.1		1.6		4.6		2.2		
Total unrealized gain (loss) on long term investments	\$	2.3	\$	(9.9)	\$	18.7	\$	(21.9)		

Provision for income taxes.

For the three and nine months ended September 30, 2019, we recorded income tax expense of approximately \$19.7 million and \$24.9 million, respectively. For the three and nine months ended September 30, 2018, we recorded income tax expense of approximately \$1.8 million and \$4.2 million, respectively. The increased tax expense for the three and nine months ended September 30, 2019 is primarily the result of estimating U.S. tax liabilities that are not fully sheltered by net operating losses or research and development tax credit carryforwards. This is partially offset by higher discrete tax benefits associated with stock-based compensation.

Liquidity and Capital Resources

Due to historical net losses, we had an accumulated deficit of \$1.5 billion as of September 30, 2019. We have funded our research and development operations through sales of equity securities, the issuance of convertible notes, cash received from customers, and collaborative arrangements. At September 30, 2019, we had available cash, cash equivalents and marketable securities of \$2.0 billion. Our cash and marketable securities balances are held in a variety of interest-bearing instruments, including money market accounts, corporate debt securities and U.S. government securities. Available cash is invested in accordance with our investment policy's primary objectives of liquidity, safety of principal and diversity of investments.

Net cash provided by operating activities was \$579.0 million and \$252.4 million, respectively, for the nine months ended September 30, 2019 and 2018. The \$326.6 million increase in cash provided by operating activities was due primarily to changes in working capital.

Our investing activities, other than purchases, sales and maturities of marketable securities, have consisted predominantly of capital expenditures and purchases of long term investments. Net cash used by investing activities was \$57.4 million for the nine months ended September 30, 2019, which represented purchases of marketable securities of \$222.2 million and capital expenditures of \$48.7 million, offset in part by the sale and maturity of marketable securities of \$213.5 million. Net cash used in investing activities was \$50.3 million for the nine months ended September 30, 2018, which represented purchases of marketable securities of \$104.2 million, capital expenditures of \$48.2 million and purchases of long term equity investments of \$8.9 million, offset in part by the sale and maturity of marketable securities of \$111.0 million. In the future, net cash used by investing activities may fluctuate significantly from period to period due to the timing of strategic equity investments, acquisitions, and capital expenditures and maturities/sales and purchases of marketable securities.

Net cash provided by financing activities was \$16.4 million and \$10.6 million, respectively, for the nine months ended September 30, 2019 and 2018, primarily representing proceeds from the issuance of common stock under our stock plans, offset in part by cash paid to ARIAD/Takeda for contingent consideration.

The following summarizes our significant contractual obligations as of September 30, 2019 and the effect those obligations are expected to have on our liquidity and cash flow in future periods (in millions):

	Total		Less Than 1 Year		Years 2 - 3		Years 4 - 5		Over 5 Years	
Contractual Obligations:										
Principal on convertible senior debt	\$	19.1	\$	_	\$	19.1	\$	_	\$	_
Interest on convertible senior debt		0.3		0.2		0.1		_		_
Finance lease liabilities		44.0		0.8		4.6		5.4		33.2
Operating lease liabilities		25.1		11.3		10.3		2.5		1.0
Other non-cancelable obligations		2.3		1.0		1.0		0.3		_
Total contractual obligations	\$	90.8	\$	13.3	\$	35.1	\$	8.2	\$	34.2

We have entered into and may in the future seek to license additional rights relating to technologies or drug development candidates in connection with our drug discovery and development programs. Under these licenses, we may be required to pay upfront fees, milestone payments, and royalties on sales of future products, which are not reflected in the table above.

In October 2019, we entered into an agreement with Wilmington Friends School Inc., to purchase property for \$50.0 million to expand our global headquarters. Per the agreement, closing of the purchase is subject to certain standard closing conditions including an initial diligence period and a subsequent approval period.

We believe that our cash flow from operations, together with our cash, cash equivalents and marketable securities, will be adequate to satisfy our capital needs for the foreseeable future. Our cash requirements depend on numerous factors, including our expenditures in connection with our drug discovery and development programs and commercialization operations; expenditures in connection with litigation or other legal proceedings; costs for future facility requirements; our receipt of any milestone or other payments under any collaborative agreements we may enter into, including the agreements with Novartis, Lilly, Innovent and Zai Lab; and expenditures in connection with strategic relationships and license agreements, including our agreements with Agenus, ARIAD/Takeda, Calithera, Lilly, MacroGenics, Merus and Syros, strategic equity investments or potential acquisitions. To the extent we seek to augment our existing cash resources and cash flow from operations to satisfy our cash requirements for future acquisitions or other strategic purposes, we expect that additional funding can be obtained through equity or debt financings or from other sources. The sale of equity or additional convertible debt securities in the future may be dilutive to our stockholders, and may provide for rights, preferences or privileges senior to those of our holders of common stock. Debt financing arrangements may require us to pledge certain assets or enter into covenants that could restrict our operations or our ability to incur further indebtedness.

Off Balance Sheet Arrangements

We have no off-balance sheet arrangements other than those that are discussed above.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our investments in marketable securities, which are composed primarily of corporate debt securities and U.S. government securities, are subject to default, changes in credit rating and changes in market value. These investments are also subject to interest rate risk and will decrease in value if market interest rates increase. As of September 30, 2019, marketable securities were \$284.2 million. Due to the nature of these investments, if market interest rates were to increase immediately and uniformly by 10% from levels as of September 30, 2019, the decline in fair value would not be material.

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures. We maintain "disclosure controls and procedures," as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act"), that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and

forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Our disclosure controls and procedures have been designed to meet reasonable assurance standards. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Based on their evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in internal control over financial reporting. There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) for the three months ended September 30, 2019, that materially affected or are reasonably likely to materially affect our internal control over financial reporting.

PART II: OTHER INFORMATION

Item 1A. Risk Factors

RISKS RELATING TO COMMERCIALIZATION OF OUR PRODUCTS

We depend heavily on our lead product, JAKAFI (ruxolitinib), which is marketed as JAKAVI outside the United States. If we are unable to successfully commercialize JAKAFI in its approved indications or to successfully obtain regulatory approval for and commercialize ruxolitinib for the treatment of additional indications, or if we are significantly delayed or limited in doing so, our business may be materially harmed.

JAKAFI is our first and, currently, only product marketed by us that is approved for sale in the United States. It was approved by the U.S. Food and Drug Administration, or FDA, in November 2011 for the treatment of patients with intermediate or high-risk myelofibrosis and in December 2014 for the treatment of patients with polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea, which we refer to as uncontrolled polycythemia vera. Although we have received regulatory approval for these indications, such approval does not guarantee future revenues. While in June 2016 we acquired exclusive rights to develop and commercialize ICLUSIG in the European Union, or EU, and other countries and in June 2018 the FDA approved for sale OLUMIANT (baricitinib), which we exclusively licensed to Eli Lilly and Company, for the treatment of specified rheumatoid arthritis indications, we anticipate that JAKAFI product sales will continue to contribute a significant percentage of our total revenues over the next several years.

The commercial success of JAKAFI and our ability to generate and maintain revenues from the sale of JAKAFI will depend on a number of factors, including:

- the number of patients with intermediate or high-risk myelofibrosis or uncontrolled polycythemia vera who are diagnosed with the disease and the number of such patients that may be treated with JAKAFI;
- the acceptance of JAKAFI by patients and the healthcare community;
- whether physicians, patients and healthcare payors view JAKAFI as therapeutically effective and safe relative to cost and any alternative therapies;
- the ability to obtain and maintain sufficient coverage or reimbursement by third-party payors;

- the ability of our third-party manufacturers to manufacture JAKAFI in sufficient quantities that meet all
 applicable quality standards;
- the ability of our company and our third-party providers to provide marketing and distribution support for JAKAFI;
- the label and promotional claims allowed by the FDA;
- the maintenance of regulatory approval for the approved indications in the United States; and
- our ability to develop, obtain regulatory approval for and commercialize ruxolitinib in the United States for additional indications.

If we are not successful in commercializing JAKAFI in the United States, or are significantly delayed or limited in doing so, our business may be materially harmed and we may need to delay other drug discovery and development initiatives or even significantly curtail operations.

In addition, our receipt of royalties under our collaboration agreements with Novartis for sales of JAKAVI outside the United States and with Lilly for worldwide sales of OLUMIANT will depend on factors similar to those listed above, with similar regulatory issues driven by applicable regulatory authorities affecting jurisdictions outside the United States.

If we are unable to obtain, or maintain at anticipated levels, reimbursement for our products from government health administration authorities, private health insurers and other organizations, our pricing may be affected or our product sales, results of operations or financial condition could be harmed.

We may not be able to sell our products on a profitable basis or our profitability may be reduced if we are required to sell our products at lower than anticipated prices or reimbursement is unavailable or limited in scope or amount. JAKAFI and ICLUSIG are expensive and almost all patients will require some form of third-party coverage to afford their cost. Our future revenues and profitability will be adversely affected if we cannot depend on government and other third-party payors to defray the cost of our products to the patient. Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country-by-country basis. Reimbursement in the EU must be negotiated on a country-by-country basis and in many countries the product cannot be commercially launched until reimbursement is approved. The timing to complete the negotiation process in each country is highly uncertain, and in some countries, we expect that it may exceed 12 months. Risks related to pricing and reimbursement are described below under "-Other Risks Relating to our Business- Health care reform measures could impact the pricing and profitability of pharmaceuticals, and adversely affect the commercial viability of our products and drug candidates. Our ability to generate revenues will be diminished if we are unable to obtain an adequate level of reimbursement from private insurers, government insurance programs or other third-party payors of health care costs, which could be affected by current and potential healthcare reform legislation." If government and other third-party payors refuse to provide coverage and reimbursement with respect to our products, determine to provide a lower level of coverage and reimbursement than anticipated, or reduce previously approved levels of coverage and reimbursement, then our pricing or reimbursement for our products may be affected and our product sales, results of operations or financial condition could be harmed.

We depend upon a limited number of specialty pharmacies and wholesalers for a significant portion of any revenues from JAKAFI, and the loss of, or significant reduction in sales to, any one of these specialty pharmacies or wholesalers could adversely affect our operations and financial condition.

We sell JAKAFI primarily to specialty pharmacies and wholesalers. Specialty pharmacies dispense JAKAFI to patients in fulfillment of prescriptions and wholesalers sell JAKAFI to hospitals and physician offices. We do not promote JAKAFI to specialty pharmacies or wholesalers, and they do not set or determine demand for JAKAFI. Our ability to successfully commercialize JAKAFI will depend, in part, on the extent to which we are able to provide adequate distribution of JAKAFI to patients. Although we have contracted with a number of specialty pharmacies and wholesalers, they are expected generally to carry a very limited inventory and may be reluctant to be part of our distribution network in

the future if demand for the product does not increase. Further, it is possible that these specialty pharmacies and wholesalers could decide to change their policies or fees, or both, at some time in the future. This could result in their refusal to carry smaller volume products such as JAKAFI, or lower margins or the need to find alternative methods of distributing our product. Although we believe we can find alternative channels to distribute JAKAFI on relatively short notice, our revenue during that period of time may suffer and we may incur additional costs to replace any such specialty pharmacy or wholesaler. The loss of any large specialty pharmacy or wholesaler as part of our distribution network, a significant reduction in sales we make to specialty pharmacies or wholesalers, or any failure to pay for the products we have shipped to them could materially and adversely affect our results of operations and financial condition.

If we are unable to establish and maintain effective sales, marketing and distribution capabilities, or to enter into agreements with third parties to do so, we will not be able to successfully commercialize our products.

Prior to our commercialization of JAKAFI, we had no experience selling and marketing drug products and with pricing and obtaining adequate third-party reimbursement for drug products. Under our collaboration and license agreement with Novartis, we have retained commercialization rights to JAKAFI in the United States. We have established commercial capabilities in the United States, but cannot guarantee that we will be able to enter into and maintain any marketing, distribution or third-party logistics agreements with third-party providers on acceptable terms, if at all. In connection with our June 2016 acquisition from ARIAD Pharmaceuticals, Inc. we licensed rights to develop and commercialize ICLUSIG in certain countries and we acquired the European sales, marketing and distribution operations of ARIAD. We may not be able to maintain those operations or retain their personnel or distribution arrangements. We may not be able to correctly judge the size and experience of the sales and marketing force and the scale of distribution capabilities necessary to successfully market and sell our products. Establishing and maintaining sales, marketing and distribution capabilities are expensive and time-consuming. Competition for personnel with experience in sales and marketing can be high. Our expenses associated with building and maintaining the sales force and distribution capabilities may be disproportional compared to the revenues we may be able to generate on sales of our products.

If we fail to comply with applicable laws and regulations, we could lose our approval to market our products or be subject to other governmental enforcement activity.

We cannot guarantee that we will be able to maintain regulatory approval to market our products in the jurisdictions in which they are currently marketed. If we do not maintain our regulatory approval to market our products, in particular JAKAFI, our results of operations will be materially harmed. We and our collaborators, third-party manufacturers and suppliers are subject to rigorous and extensive regulation by the FDA and other federal and state agencies as well as foreign governmental agencies. These regulations continue to apply after product marketing approval, and cover, among other things, testing, manufacturing, quality control and assurance, labeling, advertising, promotion, risk mitigation, and adverse event reporting requirements.

The commercialization of our products is subject to post-regulatory approval product surveillance, and our products may have to be withdrawn from the market or subject to restrictions if previously unknown problems occur. Regulatory agencies may also require additional clinical trials or testing for our products, and our products may be recalled or may be subject to reformulation, additional studies, changes in labeling, warnings to the public and negative publicity. For example, from late 2013 through 2014, ICLUSIG was subject to review by the European Medicines Agency, or EMA, of the benefits and risks of ICLUSIG to better understand the nature, frequency and severity of events obstructing the arteries or veins, the potential mechanism that leads to these side effects and whether there needed to be a revision in the dosing recommendation, patient monitoring and a risk management plan for ICLUSIG. This review was completed in January 2015, with additional warnings in the product information but without any change in the approved indications. The EMA could take additional actions in the future that reduce the commercial potential of ICLUSIG.

Failure to comply with the laws and regulations administered by the FDA or other agencies could result in:

- administrative and judicial sanctions, including warning letters;
- fines and other civil penalties;

- suspension or withdrawal of regulatory approval to market or manufacture our products;
- interruption of production;
- operating restrictions;
- product recall or seizure;
- injunctions; and
- criminal prosecution.

The occurrence of any such event may have a material adverse effect on our business.

If the use of our products harms patients, or is perceived to harm patients even when such harm is unrelated to our products, our regulatory approvals could be revoked or otherwise negatively impacted or we could be subject to costly and damaging product liability claims.

The testing of JAKAFI and ICLUSIG, the manufacturing, marketing and sale of JAKAFI and the marketing and sale of ICLUSIG expose us to product liability and other risks. Side effects and other problems experienced by patients from the use of our products could:

- lessen the frequency with which physicians decide to prescribe our products;
- encourage physicians to stop prescribing our products to their patients who previously had been prescribed our products;
- cause serious harm to patients that may give rise to product liability claims against us; and
- result in our need to withdraw or recall our products from the marketplace.

If our products are used by a wide patient population, new risks and side effects may be discovered, the rate of known risks or side effects may increase, and risks previously viewed as less significant could be determined to be significant.

Previously unknown risks and adverse effects of our products may also be discovered in connection with unapproved, or off-label, uses of our products. We are prohibited by law from promoting or in any way supporting or encouraging the promotion of our products for off-label uses, but physicians are permitted to use products for off-label purposes. In addition, we are studying and expect to continue to study JAKAFI in diseases for potential additional indications in controlled clinical settings, and independent investigators are doing so as well. In the event of any new risks or adverse effects discovered as new patients are treated for intermediate or high-risk myelofibrosis or uncontrolled polycythemia vera and as JAKAFI is studied in or used by patients for off-label indications, regulatory authorities may delay or revoke their approvals, we may be required to conduct additional clinical trials, make changes in labeling of JAKAFI, reformulate JAKAFI or make changes and obtain new approvals. We may also experience a significant drop in the sales of JAKAFI, experience harm to our reputation and the reputation of JAKAFI in the marketplace or become subject to lawsuits, including class actions. Any of these results could decrease or prevent sales of JAKAFI or substantially increase the costs and expenses of commercializing JAKAFI. Similar results could occur with respect to our commercialization of ICLUSIG.

Patients who have been enrolled in our clinical trials or who may use our products in the future often have severe and advanced stages of disease and known as well as unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may or may not be related to our products. Such events could subject us to costly litigation, require us to pay substantial amounts

of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our products, the investigation into the circumstance may be time consuming or inconclusive. These investigations may interrupt our sales efforts, impact and limit the type of regulatory approvals our products receive or maintain, or delay the regulatory approval process in other countries.

Factors similar to those listed above also apply to our collaboration partner Novartis and to ICLUSIG for jurisdictions outside the United States.

If we market our products in a manner that violates various laws and regulations, we may be subject to civil or criminal penalties.

In addition to FDA and related regulatory requirements, we are subject to health care "fraud and abuse" laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally- or state-financed health care programs. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities.

Although physicians are permitted, based on their medical judgment, to prescribe products for indications other than those approved by the FDA, manufacturers are prohibited from promoting their products for such off-label uses. We market JAKAFI for intermediate or high-risk myelofibrosis and uncontrolled polycythemia vera and provide promotional materials to physicians regarding the use of JAKAFI for these indications. Although we believe that our promotional materials for physicians do not constitute off-label promotion of JAKAFI, the FDA or other agencies may disagree. If the FDA or another agency determines that our promotional materials or other activities constitute off-label promotion of JAKAFI, it could request that we modify our promotional materials or other activities or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they believe that the alleged improper promotion led to the submission and payment of claims for an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. Even if it is later determined we are not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our position and have to divert significant management resources from other matters.

The European Union and member countries, as well as governmental authorities in other countries, impose similar strict restrictions on the promotion and marketing of drug products. The off-label promotion of medicinal products is prohibited in the EU and in other territories. The promotion of medicinal products that are not subject to a marketing authorization is also prohibited in the EU. Violations of the rules governing the promotion of medicinal products in the EU and in other territories could be penalized by administrative measures, fines and imprisonment.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. In recent years, several states and localities, including California, Connecticut, the District of Columbia, Massachusetts, Minnesota, Nevada, New Mexico, Texas, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar legislation is being considered in other states. Additionally, as part of the Patient Protection and Affordable Care Act, the federal government has enacted the Physician Payment Sunshine provisions. The Sunshine provisions and similar laws and regulations in other jurisdictions where we do business require manufacturers to publicly report certain payments or other transfers of value made to physicians and teaching hospitals. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity. See

also "—Other Risks Relating to our Business—If we fail to comply with the extensive legal and regulatory requirements affecting the health care industry, we could face increased costs, penalties and a loss of business" below.

Competition for our products could harm our business and result in a decrease in our revenue.

Present and potential competitors for JAKAFI could include major pharmaceutical and biotechnology companies, as well as specialty pharmaceutical firms. For example, in January 2019, Celgene Corporation announced that it had submitted an NDA for fedratinib, a drug candidate for the treatment of myelofibrosis, and expected FDA approval by year-end 2019. See "-Other Risks Relating to our Business- We face significant competition for our drug discovery and development efforts, and if we do not compete effectively, our commercial opportunities will be reduced or eliminated" for a description of risks relating to this type of competition. In addition, JAKAFI could face competition from generic products. As a result of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, in the United States, generic manufacturers may seek approval of a generic version of an innovative pharmaceutical by filing with the FDA an Abbreviated New Drug Application, or ANDA. The Hatch-Waxman Act provides significant incentives to generic manufacturers to challenge U.S. patents on successful innovative pharmaceutical products. In February 2016, we received a notice letter regarding an ANDA that requested approval to market a generic version of JAKAFI and purported to challenge patents covering ruxolitinib phosphate and its use that expire in 2028. The notice letter does not challenge the ruxolitinib composition of matter patent, which expires in December 2027. To date, to our knowledge, the FDA has taken no action with respect to this ANDA. Separately, in January 2018 the Patent Trial and Appeal Board of United States Patent and Trademark Office denied a petition challenging our patent covering deuterated ruxolitinib analogs, although the challenging party retains the right to challenge the validity of the patent in federal court. There can be no assurance that our patents will be upheld or that any litigation in which we might engage with any such generic manufacturer would be successful in protecting JAKAFI's exclusivity. The entry of a generic version of JAKAFI could result in a decrease in JAKAFI sales and materially harm our business, operating results and financial condition.

ICLUSIG currently competes with existing therapies that are approved for the treatment of patients with chronic myeloid leukemia, or CML, who are resistant or intolerant to prior tyrosine kinase inhibitor, or TKI, therapies, on the basis of, among other things, efficacy, cost, breadth of approved use and the safety and side-effect profile. In addition, a generic version of imatinib was launched in the United States in February 2016, and generic versions are expected to be launched in other markets. Although we currently believe that generic versions of imatinib will not materially impact our commercialization of ICLUSIG, given ICLUSIG's various indication statements globally that are currently focused on resistant or intolerant CML, we cannot be certain how physicians, payors, patients, regulatory authorities and other market participants will respond to the availability of generic versions of imatinib.

OTHER RISKS RELATING TO OUR BUSINESS

We may be unsuccessful in our efforts to discover and develop drug candidates and commercialize drug products.

None of our drug candidates, other than JAKAFI/JAKAVI, has received regulatory approval. Our ability to discover and develop drug candidates and to commercialize additional drug products will depend on our ability to:

- hire and retain key employees;
- identify high quality therapeutic targets;
- identify potential drug candidates;
- develop products internally or license drug candidates from others;
- identify and enroll suitable human subjects, either in the United States or abroad, for our clinical trials;
- complete laboratory testing;

- commence, conduct and complete safe and effective clinical trials on humans;
- obtain and maintain necessary intellectual property rights to our products;
- obtain and maintain necessary regulatory approvals for our products, both in the United States and abroad;
- enter into arrangements with third parties to provide services or to manufacture our products on our behalf;
- deploy sales and marketing resources effectively or enter into arrangements with third parties to provide these functions in compliance with all applicable laws;
- obtain appropriate coverage and reimbursement levels for the cost of our products from governmental authorities, private health insurers and other third-party payors;
- lease facilities at reasonable rates to support our growth; and
- enter into arrangements with third parties to license and commercialize our products.

We have limited experience with many of the activities listed above and may not be successful in discovering, developing, or commercializing additional drug products. Discovery and development of drug candidates are expensive, uncertain and time-consuming, and we do not know if our efforts will lead to discovery of any drug candidates that can be successfully developed and marketed. Of the compounds or biologics that we identify as potential drug products or that we may in-license from other companies, including potential products for which we are conducting clinical trials, only a few, if any, are likely to lead to successful drug development programs and commercialized drug products.

We depend heavily on the success of our most advanced drug candidates. We might not be able to commercialize any of our drug candidates successfully, and we may spend significant time and money attempting to do so.

We have invested significant resources in the development of our most advanced drug candidates. Ruxolitinib is in Phase III clinical trials for the treatment of patients with steroid-refractory graft-versus-host disease and is in other clinical trials. Itacitinib is in a Phase III clinical trial for the treatment of patients with acute graft-versus-host disease. Further, we have a number of drug candidates in Phase I and Phase II clinical trials. Our ability to generate product revenues will depend on the successful development and eventual commercialization of our most advanced drug candidates. We, or our collaborators or licensees, may decide to discontinue development of any or all of our drug candidates at any time for commercial, scientific or other reasons. For example: in early 2016, we decided to discontinue the clinical trials of ruxolitinib in pancreatic cancer and solid tumors and itacitinib in pancreatic cancer; and, in April 2018, we along with Merck stopped the ECHO-301 study with epacadostat, and we also significantly downsized the epacadostat development program. If a product is developed but not approved or marketed, we may have spent significant amounts of time and money on it, which could adversely affect our operating results and financial condition as well as our business plans.

If we or our collaborators are unable to obtain regulatory approval for our drug candidates in the United States and foreign jurisdictions, we or our collaborators will not be permitted to commercialize products resulting from our research.

In order to commercialize drug products in the United States, drug candidates will have to obtain regulatory approval from the FDA. Satisfaction of regulatory requirements typically takes many years. To obtain regulatory approval, we or our collaborators, as the case may be, must first show that our drug candidates are safe and effective for target indications through preclinical testing (animal testing) and clinical trials (human testing). Preclinical testing and clinical development are long, expensive and uncertain processes, and we do not know whether the FDA will allow us or our collaborators to undertake clinical trials of any drug candidates in addition to our compounds currently in clinical trials. If regulatory approval of a product is granted, this approval will be limited to those disease states and conditions for which the product is demonstrated through clinical trials to be safe and effective.

Completion of clinical trials may take several years and failure may occur at any stage of testing. The length of time required varies substantially according to the type, complexity, novelty and intended use of the drug candidate. Interim results of a preclinical test or clinical trial do not necessarily predict final results, and acceptable results in early clinical trials may not be repeated in later clinical trials. For example, a drug candidate that is successful at the preclinical level may cause harmful or dangerous side effects when tested at the clinical level. Our rate of commencement and completion of clinical trials may be delayed, and existing clinical trials with our drug candidates may be stopped, due to many potential factors, including:

- the high degree of risk and uncertainty associated with drug development;
- our inability to formulate or manufacture sufficient quantities of materials for use in clinical trials;
- variability in the number and types of patients available for each study;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- unforeseen safety issues or side effects;
- poor or unanticipated effectiveness of drug candidates during the clinical trials; or
- government or regulatory delays.

Data obtained from clinical trials are susceptible to varying interpretation, which may delay, limit or prevent regulatory approval. Many companies in the pharmaceutical and biopharmaceutical industry, including our company, have suffered significant setbacks in advanced clinical trials, even after achieving promising results in earlier clinical trials. In addition, regulatory authorities may refuse or delay approval as a result of other factors, such as changes in regulatory policy during the period of product development and regulatory agency review. For example, the FDA has in the past required, and could in the future require, that we or our collaborators conduct additional trials of any of our drug candidates, which would result in delays. In April 2017, we and our collaborator Lilly announced that the FDA had issued a complete response letter for the New Drug Application, or NDA, of OLUMIANT as a once-daily oral medication for the treatment of moderate-to-severe rheumatoid arthritis. The letter indicated that additional clinical data were needed to determine the most appropriate doses and to further characterize safety concerns across treatment arms. In June 2018, after a resubmission of the NDA, the FDA approved the 2mg dose of OLUMIANT for the treatment of adults with moderately-to-severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor inhibitor therapies. The FDA did not at that time approve any higher dose of OLUMIANT and required a warning label in connection with its approval.

Compounds or biologics developed by us or with or by our collaborators and licensees may not prove to be safe and effective in clinical trials and may not meet all of the applicable regulatory requirements needed to receive marketing approval. For example, in January 2016, a Phase II trial that was evaluating ruxolitinib in combination with regorafenib in patients with relapsed or refractory metastatic colorectal cancer and high C-reactive protein was stopped early after a planned analysis of interim efficacy data determined that the likelihood of the trial meeting its efficacy endpoint was insufficient. In addition, in February 2016, we made a decision to discontinue our JANUS 1 study, our JANUS 2 study, our other studies of ruxolitinib in colorectal, breast and lung cancer, and our study of INCB39110 in pancreatic cancer after a planned analysis of interim efficacy data of JANUS 1 demonstrated that ruxolitinib plus capecitabine did not show a sufficient level of efficacy to warrant continuation. Also, in April 2018, we along with Merck announced that the ECHO-301 study had been stopped and we also significantly downsized the epacadostat development program. If clinical trials of any of our compounds or biologics are stopped for safety, efficacy or other reasons or fail to meet their respective endpoints, our overall development plans, business, prospects, expected operating results and financial condition could be materially harmed and the value of our company could be negatively affected.

Outside the United States, our and our collaborators' ability to market a product is contingent upon receiving a marketing authorization from the appropriate regulatory authorities. This foreign regulatory approval process typically

includes all of the risks associated with the FDA approval process described above and may also include additional risks. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country and may require us to perform additional testing and expend additional resources. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA.

Health care reform measures could impact the pricing and profitability of pharmaceuticals, and adversely affect the commercial viability of our products and drug candidates. Our ability to generate revenues will be diminished if we are unable to obtain an adequate level of reimbursement from private insurers, government insurance programs or other third-party payors of health care costs, which could be affected by current and potential healthcare reform legislation and diminished revenues could adversely affect our ability to conduct our research and development operations.

Our ability to commercialize our current and any future approved products successfully will depend in part on the prices we are able to charge for our approved products and the extent to which adequate reimbursement levels for the cost of our products and related treatment are obtained from third-party payors, such as private insurers, government insurance programs, including Medicare and Medicaid, health maintenance organizations (HMOs) and other health care related organizations in the U.S. and abroad.

In recent years, through legislative and regulatory actions, the U.S. federal government has made substantial changes to various payment systems under the Medicare and other federal health care programs. Comprehensive reforms to the U.S. healthcare system were enacted, including changes to the methods for, and amounts of, Medicare reimbursement. While there is currently significant uncertainty regarding the implementation of some of these reforms or the scope of amended or additional reforms, the implementation of reforms could significantly reduce payments from Medicare and Medicaid. Reforms or other changes to these payment systems may change the availability, methods and rates of reimbursements from Medicare, private insurers and other third-party payors for our current and any future approved products. Some of these changes and proposed changes could result in reduced reimbursement rates or in eliminating dual sources of payment, which could reduce the price that we or any of our collaborators or licensees receive for any products in the future, and which would adversely affect our business strategy, operations and financial results.

In addition, there has been an increasing legislative and enforcement interest in the United States with respect to drug pricing practices. This has resulted in several recent federal and state proposals to regulate prices of pharmaceutical products and other health care reforms, any of which could limit the prices that we can charge for our products and may further limit the commercial viability of our products and drug candidates. Specifically, there have been several federal congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, reform government program reimbursement methodologies for prescription drugs, allow importation of drugs into the U.S. from other countries and limit allowable prices for drugs to a function of an average international reference price which may be substantially lower than what we currently or would otherwise charge. In certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. We expect that the health care reform measures that have been adopted in the United States and in foreign markets, and further reforms that may be adopted in the future, could result in more rigorous coverage criteria and additional downward pressure on the prices that we may receive for our approved products. If reimbursement for our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed, including by our revenue potentially being materially adversely affected and our research and development efforts potentially being materially curtailed or, in some cases, ceasing. There may be future changes that result in reductions in current coverage and reimbursement levels for our current or any future approved products, and we cannot predict the scope of any future changes or the impact that those changes would have on our operations.

Further, if we become the subject of any governmental or other regulatory hearing or investigation with respect to the pricing of our products or other business practices, we could incur significant expenses and could be distracted from the operation of our business and execution of our business strategy. Any such hearing or investigation could also result in significant negative publicity and harm to our reputation, reduced market acceptance and demand, which could adversely affect our financial results and growth prospects.

Third-party payors are increasingly challenging the prices charged for medical products and services. Also, the trend toward managed health care in the United States, the organizations for which could control or significantly influence the purchase of health care services and products, as well as legislative and regulatory proposals to reform health care or reduce government insurance programs, may all result in lower prices for or rejection of our products. Adoption of our products by the medical community may be limited without adequate reimbursement for those products. Cost control initiatives may decrease coverage and payment levels for our products and, in turn, the price that we will be able to charge for any product. Our products may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a profitable basis. We are unable to predict all changes to the coverage or reimbursement methodologies that will be applied by private or government payors to our current and any future approved products.

The continuing efforts of legislatures, health agencies and third-party payors to contain or reduce the costs of health care, any denial of private or government payor coverage or inadequate reimbursement for our drug candidates could materially and adversely affect our business strategy, operations, future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers, collaborators and licensees and the availability of capital. The same risks apply to our compounds developed and marketed by our collaborators, and our future potential milestone and royalty revenues could be affected in a similar manner.

We depend on our collaborators and licensees for the future development and commercialization of some of our drug candidates. Conflicts may arise between our collaborators and licensees and us, or our collaborators and licensees may choose to terminate their agreements with us, which may adversely affect our business.

We have licensed to Novartis rights to ruxolitinib outside of the United States and worldwide rights to our MET inhibitor compounds and licensed to Lilly worldwide rights to baricitinib. In addition, we have licensed to Innovent and to Zai Lab certain Asian rights to some of our clinical stage compounds. Under the terms of our agreements with these collaborators, we have no or limited control over the further clinical development of these drug candidates in the relevant territories and any revenues we may receive if these drug candidates receive regulatory approval and are commercialized in the relevant territories will depend primarily on the development and commercialization efforts of others. While OLUMIANT was approved by the European Commission in February 2017 for the treatment of moderate-to-severe rheumatoid arthritis in adult patients and by Japan's Ministry of Health, Labor and Welfare in July 2017 for the treatment of rheumatoid arthritis in patients with inadequate response to standard-of-care therapies, the NDA for OLUMIANT for the treatment of moderate-to-severe rheumatoid arthritis was approved in June 2018, and only in the lower dosage tablet and with a warning label. Delays in any marketing approval by the FDA, European or other regulatory authorities, or any label modifications or restrictions in connection with any such approval, or the existence of other risks relating to approved drug products, including those described under "Risks Relating to Commercialization of Our Products," could delay the receipt of and reduce resulting potential royalty and milestone revenue from baricitinib or any of our other out-licensed drug candidates.

Conflicts may arise with our collaborators and licensees if they pursue alternative technologies or develop alternative products either on their own or in collaboration with others as a means for developing treatments for the diseases that we have targeted. Competing products and product opportunities may lead our collaborators and licensees to withdraw their support for our drug candidates. Any failure of our collaborators and licensees to perform their obligations under our agreements with them or otherwise to support our drug candidates could negatively impact the development of our drug candidates, lead to our loss of potential revenues from product sales and milestones and delay our achievement, if any, of profitability. Additionally, conflicts may arise if, among other things, there is a dispute about the achievement and payment of a milestone amount or the ownership of intellectual property that is developed during the course of a collaborative relationship.

Our existing collaborative and license agreements can be terminated by our collaborators and licensees for convenience, among other circumstances. If any of our collaborators or licensees terminates its agreement with us, or terminates its rights with respect to certain indications or drug candidates, we may not be able to find a new collaborator for them, and our business could be adversely affected. Should an agreement be terminated before we have realized the benefits of the collaboration or license, our reputation could be harmed, we may not obtain revenues that we anticipated receiving, and our business could be adversely affected.

The success of our drug discovery and development efforts may depend on our ability to find suitable collaborators to fully exploit our capabilities. If we are unable to establish collaborations or if these future collaborations are unsuccessful in the development and commercialization of our drug candidates, our research, development and commercialization efforts may be unsuccessful, which could adversely affect our results of operations and financial condition.

An element of our business strategy is to enter into collaborative or license arrangements with other parties, under which we license our drug candidates to those parties for development and commercialization or under which we study our drug candidates in combination with other parties' compounds or biologics. For example, in addition to our Novartis, Lilly, Innovent and Zai Lab collaborations, we have entered into clinical study relationships with respect to several of our programs, including epacadostat, and are evaluating strategic relationships with respect to several of our other programs. However, because collaboration and license arrangements are complex to negotiate, we may not be successful in our attempts to establish these arrangements. Also, we may not have drug candidates that are desirable to other parties, or we may be unwilling to license a drug candidate to a particular party because such party interested in it is a competitor or for other reasons. The terms of any such arrangements that we establish may not be favorable to us. Alternatively, potential collaborators may decide against entering into an agreement with us because of our financial, regulatory or intellectual property position or for scientific, commercial or other reasons. If we are not able to establish collaboration or license arrangements, we may not be able to develop and commercialize a drug product, which could adversely affect our business and our revenues.

We will likely not be able to control the amount and timing of resources that our collaborators or licensees devote to our programs or drug candidates. If our collaborators or licensees prove difficult to work with, are less skilled than we originally expected, do not devote adequate resources to the program, are unable to obtain regulatory approval of our drug candidates, pursue alternative technologies or develop alternative products, or do not agree with our approach to development or manufacturing of the drug candidate, the relationship could be unsuccessful. Our collaborations with respect to epacadostat involved the study of our collaborators' drugs used in combination with epacadostat on a number of indications or tumor types, many of which were the same across multiple collaborations. We cannot assure you that potential conflicts will not arise or be alleged among these collaborations. If a business combination involving a collaborator or licensee and a third-party were to occur, the effect could be to terminate or cause delays in development of a drug candidate.

If we fail to enter into additional licensing agreements or if these arrangements are unsuccessful, our business and operations might be adversely affected.

In addition to establishing collaborative or license arrangements under which other parties license our drug candidates for development and commercialization or under which we study our drug candidates in combination with such parties' compounds or biologics, we may explore opportunities to develop our clinical pipeline by in-licensing drug candidates or therapeutics targets that fit within our focus on oncology, such as our collaborations with Agenus Inc., Calithera Biosciences, Inc., MacroGenics, Inc., Merus N.V., and Syros Pharmaceuticals, Inc., or explore additional opportunities to further develop and commercialize existing drug candidates in specific jurisdictions, such as our June 2016 acquisition of the development and commercialization rights to ICLUSIG in certain countries. We may be unable to enter into any additional in-licensing agreements because suitable drug candidates that are within our expertise may not be available to us on terms that are acceptable to us or because competitors with greater resources seek to in-license the same drug candidates. Drug candidates that we would like to develop or commercialize may not be available to us because they are controlled by competitors who are unwilling to license the rights to the drug candidate to us. In addition, we may enter into license agreements that are unsuccessful and our business and operations might be adversely affected if we are unable to realize the expected economic benefits of a collaboration or other licensing arrangement, by the termination of a drug candidate and termination and winding down of the related license agreement, or due to other business or regulatory issues, including financial difficulties, that may adversely affect a licensor's ability to continue to perform its obligations under an in-license agreement. As discussed above under "We depend on our collaborators and licensees for the future development and commercialization of some of our drug candidates. Conflicts may arise between our collaborators and licensees and us, or our collaborators and licensees may choose to terminate their agreements with us, which may adversely affect our business," conflicts or other issues may arise with our licensors. Those conflicts could result in delays in our plans to develop drug candidates or result in the expenditure of additional funds to resolve those conflicts that could have

an adverse effect on our results of operations. We may also need to license drug delivery or other technology in order to continue to develop our drug candidates. If we are unable to enter into additional agreements to license drug candidates, drug delivery technology or other technology or if these arrangements are unsuccessful, our research and development efforts could be adversely affected.

Even if a drug candidate that we develop receives regulatory approval, we may decide not to commercialize it if we determine that commercialization of that product would require more money and time than we are willing to invest.

Even if any of our drug candidates receives regulatory approval, it could be subject to post-regulatory surveillance, and may have to be withdrawn from the market or subject to restrictions if previously unknown problems occur. Regulatory agencies may also require additional clinical trials or testing, and the drug product may be recalled or may be subject to reformulation, additional studies, changes in labeling, warnings to the public and negative publicity. As a result, we may not continue to commercialize a product even though it has obtained regulatory approval. Further, we may decide not to continue to commercialize a product if the market does not accept the product because it is too expensive or because third parties such as insurance companies or Medicare, have not approved it for substantial reimbursement. In addition, we may decide not to continue to commercialize a product if competitors develop and commercialize similar or superior products or have proprietary rights that preclude us from ultimately marketing our products.

Any approved drug product that we bring to the market may not gain market acceptance by physicians, patients, healthcare payors and others in the medical community.

Even if we are successful in gaining regulatory approval of any of our drug candidates in addition to JAKAFI or acquire rights to approved drug products in addition to ICLUSIG, we may not generate significant product revenues and we may not become profitable if these drug products do not achieve an adequate level of acceptance. Physicians may not recommend our drug products until longer-term clinical data or other factors demonstrate the safety and efficacy of our drug products as compared to other alternative treatments. Even if the clinical safety and efficacy of our drug products is established, physicians may elect not to prescribe these drug products for a variety of reasons, including the reimbursement policies of government and other third-party payors and the effectiveness of our competitors in marketing their products.

Market acceptance of our drug products, if approved for commercial sale, will depend on a number of factors, including:

- the willingness and ability of patients and the healthcare community to use our drug products;
- the ability to manufacture our drug products in sufficient quantities that meet all applicable quality standards and to offer our drug products for sale at competitive prices;
- the perception of patients and the healthcare community, including third-party payors, regarding the safety, efficacy and benefits of our drug products compared to those of competing products or therapies;
- the label and promotional claims allowed by the FDA;
- the pricing and reimbursement of our drug products relative to existing treatments; and
- marketing and distribution support for our drug products.

We have limited capacity to conduct preclinical testing and clinical trials, and our resulting dependence on other parties could result in delays in and additional costs for our drug development efforts.

We have limited internal resources and capacity to perform preclinical testing and clinical trials. As part of our development strategy, we often hire clinical research organizations, or CROs, to perform preclinical testing and clinical trials for drug candidates. If the CROs that we hire to perform our preclinical testing and clinical trials do not meet deadlines, do not follow proper procedures, or a conflict arises between us and our CROs, our preclinical testing and

clinical trials may take longer than expected, may cost more, may be delayed or may be terminated. If we were forced to find a replacement entity to perform any of our preclinical testing or clinical trials, we may not be able to find a suitable entity on favorable terms, or at all. Even if we were able to find another company to perform a preclinical test or clinical trial, the delay in the test or trial may result in significant additional expenditures. Events such as these may result in delays in our obtaining regulatory approval for our drug candidates or our ability to commercialize our products and could result in increased expenditures that would adversely affect our operating results.

We face significant competition for our drug discovery and development efforts, and if we do not compete effectively, our commercial opportunities will be reduced or eliminated.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our drug discovery and development efforts may target diseases and conditions that are already subject to existing therapies or that are being developed by our competitors, many of which have substantially greater resources, larger research and development staffs and facilities, more experience in completing preclinical testing and clinical trials, and formulation, marketing and manufacturing capabilities. As a result of these resources, our competitors may develop drug products that render our products obsolete or noncompetitive by developing more effective drugs, developing their products more efficiently or pricing their products more competitively. Our ability to develop competitive products would be limited if our competitors succeeded in obtaining regulatory approvals for drug candidates more rapidly than we were able to or in obtaining patent protection or other intellectual property rights that limited our drug development efforts. Any drug products resulting from our research and development efforts, or from our joint efforts with collaborators or licensees, might not be able to compete successfully with our competitors' existing and future products, or obtain regulatory approval in the United States or elsewhere. The development of products or processes by our competitors with significant advantages over those that we are developing could harm our future revenues and profitability.

Our reliance on other parties to manufacture our drug products and drug candidates could result in a short supply of the drugs, delays in clinical trials or drug development, increased costs, and withdrawal or denial of a regulatory authority's approval.

We do not currently operate manufacturing facilities for clinical or commercial production of JAKAFI and our other drug candidates or for ICLUSIG. We currently hire third parties to manufacture the raw materials, active pharmaceutical ingredient, or API, and finished drug product of JAKAFI, ICLUSIG and our other drug candidates for clinical trials. In addition, we expect to continue to rely on third parties for the manufacture of commercial supplies of raw materials, API and finished drug product for any drugs that we successfully develop. We also hire third parties to package and label the finished product. The FDA requires that the raw materials, API and finished product for JAKAFI and our other drug candidates be manufactured according to its current Good Manufacturing Practices regulations and regulatory authorities in other countries have similar requirements. There are only a limited number of manufacturers that comply with these requirements. Failure to comply with current Good Manufacturing Practices and the applicable regulatory requirements of other countries in the manufacture of our drug candidates and products could result in the FDA or a foreign regulatory authority halting our clinical trials, withdrawing or denying regulatory approval of our drug product, enforcing product recalls or other enforcement actions, which could have a material adverse effect on our business.

We may not be able to obtain sufficient quantities of our drug candidates or any drug products we may develop if our designated manufacturers do not have the capacity or capability to manufacture them according to our schedule and specifications. Manufacturers of pharmaceutical products often encounter difficulties in production, especially in scaling up initial production. These problems include difficulties with production costs and yields, quality control and assurance and shortages of qualified personnel. In addition, we may not be able to arrange for our drug candidates or any drug products that we may develop to be manufactured by one of these parties on reasonable terms, if at all. We generally have a single source or a limited number of suppliers that are qualified to supply each of the API and finished product of JAKAFI, ICLUSIG and our other drug candidates and, in the case of JAKAFI, we only have a single source for its raw materials. If any of these suppliers were to become unable or unwilling to supply us with raw materials, API or finished product that complies with applicable regulatory requirements, we could incur significant delays in our clinical trials or interruption of commercial supply that could have a material adverse effect on our business. If we have promised delivery of a drug candidate or drug product and are unable to meet the delivery requirement due to manufacturing difficulties, our development programs could be delayed, we may have to expend additional sums in order to ensure that manufacturing

capacity is available when we need it even if we do not use all of the manufacturing capacity, and our business and operating results could be harmed.

We may not be able to adequately manage and oversee the manufacturers we choose, they may not perform as agreed or they may terminate their agreements with us. Foreign manufacturing approval processes typically include all of the risks associated with the FDA approval process for manufacturing and may also include additional risks.

A number of our collaborations involve the manufacture of antibodies. Either we or our collaborators have primary responsibility for manufacturing activities, and we are currently using third-party contract manufacturing organizations. Manufacturing antibodies and products containing antibodies is a more complex process than manufacturing small molecule drugs and subject to additional risks. The process of manufacturing antibodies and products containing antibodies is highly susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics, and difficulties in scaling up the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

If we fail to comply with the extensive legal and regulatory requirements affecting the health care industry, we could face increased costs, penalties and a loss of business.

Our activities, and the activities of our collaborators, partners and third-party providers, are subject to extensive government regulation and oversight both in the United States and in foreign jurisdictions. The FDA and comparable agencies in other jurisdictions directly regulate many of our most critical business activities, including the conduct of preclinical and clinical studies, product manufacturing, advertising and promotion, product distribution, adverse event reporting and product risk management. States increasingly have been placing greater restrictions on the marketing practices of healthcare companies. In addition, pharmaceutical and biotechnology companies have been the target of lawsuits and investigations alleging violations of government regulations, including claims asserting submission of incorrect pricing information, impermissible off-label promotion of pharmaceutical products, payments intended to influence the referral of federal or state healthcare business, submission of false claims for government reimbursement, antitrust violations, violations of the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act and similar anti-bribery or anti-corruption laws, or violations related to environmental matters. There is also enhanced scrutiny of company-sponsored patient assistance programs, including insurance premium and co-pay assistance programs and donations to third-party charities that provide such assistance. In December 2018, we received a civil investigative demand from the U.S. Department of Justice for documents and information relating to our speaker programs and patient assistance programs, including our support of non-profit organizations that provide financial assistance to eligible patients. Violations of governmental regulation by us, our vendors or donation recipients may be punishable by criminal and civil sanctions, including damages, fines and penalties and exclusion from participation in government programs, including Medicare and Medicaid. In addition to damages, fines and penalties for violation of laws and regulations, we could be required to repay amounts we received from government payors, or pay additional rebates and interest if we are found to have miscalculated the pricing information we have submitted to the government. Actions taken by federal or local governments, legislative bodies and enforcement agencies with respect to these legal and regulatory compliance matters could also result in reduced demand for our products, reduced coverage of our products by health care payors, or both. We cannot ensure that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, collaborators, partners or third-party providers that would violate the laws or regulations of the jurisdictions in which we operate. Whether or not we have complied with the law, an investigation into alleged unlawful conduct could increase our expenses, damage our reputation, divert management time and attention and adversely affect our business. Risks relating to compliance with laws and regulations may be heightened as we continue to expand our global operations and enter new therapeutic areas with different patient populations, which due to different product distribution methods, marketing programs or patient assistance programs may result in additional regulatory burdens and obligations.

As our drug discovery and development operations are conducted at our headquarters in Wilmington, Delaware, the loss of access to this facility would negatively impact our business.

Our facility in Wilmington, Delaware is our headquarters and is also where we conduct all of our drug discovery, research, development and marketing activities. In addition, natural disasters or actions of activists opposed to aspects of pharmaceutical research may disrupt our experiments or our ability to access or use our facility. The loss of access to or use of our Wilmington, Delaware facility, either on a temporary or permanent basis would result in an interruption of our business and, consequently, would adversely affect our overall business.

We depend on key employees in a competitive market for skilled personnel, and the loss of the services of any of our key employees or our inability to attract and retain additional personnel would affect our ability to expand our drug discovery and development programs and achieve our objectives.

We are highly dependent on the members of our executive management team and principal members of our commercial, development, medical, operations and scientific staff. We experience intense competition for qualified personnel. Our future success also depends in part on the continued service of our executive management team and key personnel and our ability to recruit, train and retain essential personnel for our drug discovery and development programs, and for our medical affairs and commercialization activities. If we lose the services of any of these people or if we are unable to recruit sufficient qualified personnel, our research and product development goals, and our commercialization efforts could be delayed or curtailed. We do not maintain "key person" insurance on any of our employees.

If we fail to manage our growth effectively, our ability to develop and commercialize products could suffer.

We expect that if our drug discovery efforts continue to generate drug candidates, our clinical drug candidates continue to progress in development, and we continue to build our development, medical and commercial organizations, we will require significant additional investment in personnel, management and resources. Our ability to achieve our research, development and commercialization objectives depends on our ability to respond effectively to these demands and expand our internal organization, systems, controls and facilities to accommodate additional anticipated growth. If we are unable to manage our growth effectively, our business could be harmed and our ability to execute our business strategy could suffer.

We may acquire businesses or assets, form joint ventures or make investments in other companies that may be unsuccessful, divert our management's attention and harm our operating results and prospects.

As part of our business strategy, we may pursue additional acquisitions of what we believe to be complementary businesses or assets or seek to enter into joint ventures. We also may pursue strategic alliances in an effort to leverage our existing infrastructure and industry experience to expand our product offerings or distribution, or make investments in other companies. For example, in June 2016, we completed the acquisition of the European operations of ARIAD and obtained the exclusive license to develop and commercialize ICLUSIG in Europe and other countries. The success of our acquisitions, joint ventures, strategic alliances and investments will depend on our ability to identify, negotiate, complete and, in the case of acquisitions, integrate those transactions and, if necessary, obtain satisfactory debt or equity financing to fund those transactions. We may not realize the anticipated benefits of any acquisition, joint venture, strategic alliance or investment. We may not be able to integrate acquisitions successfully into our existing business, achieve planned synergies or cost savings, maintain the key business relationships of businesses we acquire, or retain key personnel of an acquired business, and we could assume unknown or contingent liabilities or incur unanticipated expenses. Integration of acquired companies or businesses also may require management resources that otherwise would be available for ongoing development of our existing business. Any acquisitions or investments made by us also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. For example, in the year ended December 31, 2018, we recorded unrealized losses related to our investments in Agenus Inc., Calithera Biosciences, Inc., Merus N.V. and Syros Pharmaceuticals, Inc., and we may in the future experience additional losses related to our investments. In addition, if we choose to issue shares of our stock as consideration for any acquisition, dilution to our stockholders could result.

Risks associated with the expansion of our operations outside of the United States could adversely affect our business.

Our acquisition of ARIAD's European operations significantly expanded our operations in Europe, and we plan to continue to expand our operations and conduct certain development activities outside of the United States, including our recent expansion in Japan. We have limited experience with conducting activities outside of the United States. International operations and business expansion plans are subject to numerous additional risks, including:

- multiple, conflicting and changing laws and regulations such as tax laws, privacy regulations, tariffs, export and
 import restrictions, employment, immigration and labor laws, regulatory requirements, and other governmental
 approvals, permits and licenses;
- difficulties in staffing and managing foreign operations and difficulties in connection with assimilating and integrating any operations and personnel we might acquire into our company;
- risks associated with obtaining and maintaining, or the failure to obtain or maintain, regulatory approvals for the sale or use of our products in various countries;
- complexities associated with managing government payor systems, multiple payor-reimbursement regimes or patient self-pay systems;
- financial risks, such as longer payment cycles, difficulty obtaining financing in foreign markets, difficulty enforcing contracts and intellectual property rights, difficulty collecting accounts receivable and exposure to foreign currency exchange rate fluctuations;
- general political and economic conditions in the countries in which we operate, including terrorism and political unrest, curtailment of trade and other business restrictions, and uncertainties associated with the future relationship between the United Kingdom and the European Union; and
- regulatory and compliance risks that relate to maintaining accurate information and control over activities that
 may fall within the purview of the U.S. Foreign Corrupt Practices Act, its books and records provisions or its
 anti-bribery provisions, or similar anti-bribery or anti-corruption laws and regulations, such as the U.K. AntiBribery Act and the U.K. Criminal Finances Act.

Any of the risks described above, if encountered, could significantly increase our costs of operating internationally, prevent us from operating in certain jurisdictions, or otherwise significantly harm our future international expansion and operations, which could have a material adverse effect on our business, financial condition and results of operations.

If product liability lawsuits are brought against us, we could face substantial liabilities and may be required to limit commercialization of our products and our results of operations could be harmed.

In addition to the risks described above under "—Risks Relating to Commercialization of Our Products—If the use of our products harms patients, or is perceived to harm patients even when such harm is unrelated to our products, our regulatory approvals could be revoked or otherwise negatively impacted or we could be subject to costly and damaging product liability claims," the conduct of clinical trials of medical products that are intended for human use entails an inherent risk of product liability. If any product that we or any of our collaborators or licensees develops causes or is alleged to cause injury during clinical trials or commercialization, we may be held liable. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities, including substantial damages to be paid to the plaintiffs and legal costs, or we may be required to limit further development and commercialization of our products. Additionally, any product liability lawsuit could cause injury to our reputation, participants and investigators to withdraw from clinical trials, and potential collaborators or licensees to seek other partners, any of which could impact our results of operations.

Our product liability insurance policy may not fully cover our potential liabilities. In addition, we may determine that we should increase our coverage, and this insurance may be prohibitively expensive to us or our collaborators or licensees and may not fully cover our potential liabilities. Since December 30, 2017, we elected to self-insure a portion of our exposure to product liability risks through our wholly-owned captive insurance subsidiary, in tandem with third-party insurance policies. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the development or commercialization of our drug candidates and products, and if our liabilities from any such claims exceed our third-party insurance limits and self-insurance reserves, our results of operations, cash flows and financial condition could be adversely impacted.

Because our activities involve the use of hazardous materials, we may be subject to claims relating to improper handling, storage or disposal of these materials that could be time consuming and costly.

We are subject to various environmental, health and safety laws and regulations governing, among other things, the use, handling, storage and disposal of regulated substances and the health and safety of our employees. Our research and development processes involve the controlled use of hazardous and radioactive materials and biological waste resulting in the production of hazardous waste products. We cannot completely eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. If any injury or contamination results from our use or the use by our collaborators or licensees of these materials, we may be sued and our liability may exceed our insurance coverage and our total assets. Further, we may be required to indemnify our collaborators or licensees against all damages and other liabilities arising out of our development activities or products produced in connection with these collaborations or licenses. Compliance with the applicable environmental and workplace laws and regulations is expensive. Future changes to environmental, health, workplace and safety laws could cause us to incur additional expense or may restrict our operations or impair our research, development and production efforts.

RISKS RELATING TO OUR FINANCIAL RESULTS

We may incur losses in the future, and we expect to continue to incur significant expenses to discover and develop drugs, which may make it difficult for us to achieve sustained profitability on a quarterly or annual basis in the future.

Due to historical net losses, we had an accumulated deficit of \$1.5 billion as of September 30, 2019. We intend to continue to spend significant amounts on our efforts to discover and develop drugs. As a result, we may incur losses in future periods as well. Our revenues, expenses and net income (loss) may fluctuate, even significantly, due to the risks described in these "Risk Factors" and factors discussed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" as well as the timing of charges and expenses that we may take, including those relating to transactions such as acquisitions and the entry into collaborative agreements.

We anticipate that our drug discovery and development efforts and related expenditures will increase as we focus on the studies, including preclinical tests and clinical trials prior to seeking regulatory approval, that are required before we can sell a drug product.

The development of drug products will require us to spend significant funds on research, development, testing, obtaining regulatory approvals, manufacturing and marketing. To date, we do not have any drug products that have generated significant revenues other than from sales of JAKAFI and we cannot assure you that we will generate significant revenues from the drug candidates that we license or develop, including ICLUSIG, for several years, if ever.

We cannot be certain whether or when we will achieve sustained or increased profitability on a quarterly or annual basis because of the factors discussed above and the significant uncertainties relating to our ability to generate commercially successful drug products. Even if we are successful in obtaining regulatory approvals for manufacturing and commercializing drug products in addition to JAKAFI and ICLUSIG, we may incur losses if our drug products do not generate significant revenues.

We may need additional capital in the future. If we are unable to generate sufficient funds from operations, the capital markets may not permit us to raise additional capital at the time that we require it, which could result in limitations on our research and development or commercialization efforts or the loss of certain of our rights in our technologies or drug candidates.

Our future funding requirements will depend on many factors and we anticipate that we may need to raise additional capital to fund our business plan and research and development efforts going-forward.

Additional factors that may affect our future funding requirements include:

- the amount of revenues generated from our business activities;
- any changes in the breadth of our research and development programs;
- the results of research and development, preclinical testing and clinical trials conducted by us or our current or future collaborators or licensees, if any;
- our exercise of any co-development options with collaborators that may require us to fund future development;
- the acquisition of businesses, technologies, or drug candidates, or the licensing of technologies or drug candidates, if any;
- costs for future facility requirements;
- our ability to maintain and establish new corporate relationships and research collaborations;
- competing technological and market developments;
- the time and costs involved in filing, prosecuting, defending and enforcing patent and intellectual property claims;
- the receipt of contingent licensing or milestone fees or royalties on product sales from our current or future collaborative and license arrangements, if established; and
- the timing of regulatory approvals, if any.

If we require additional capital at a time when investment in companies such as ours, or in the marketplace generally, is limited due to the then prevailing market or other conditions, we may have to scale back our operations, eliminate one or more of our research or development programs, or attempt to obtain funds by entering into an agreement with a collaborator or licensee that would result in terms that are not favorable to us or relinquishing our rights in certain of our proprietary technologies or drug candidates. If we are unable to raise funds at the time that we desire or at any time thereafter on acceptable terms, we may not be able to continue to develop our drug candidates. The sale of equity or additional convertible debt securities in the future may be dilutive to our stockholders and may provide for rights, preferences or privileges senior to those of our holders of common stock, and debt financing arrangements may require us to pledge certain assets or enter into covenants that could restrict our operations or our ability to incur further indebtedness.

Our marketable securities and long term investments are subject to risks that could adversely affect our overall financial position.

We invest our cash in accordance with an established internal policy and customarily in instruments, corporate bonds and money market funds which historically have been highly liquid and carried relatively low risk. In recent periods, similar types of investments and money market funds have experienced losses in value or liquidity issues that differ from their historical pattern.

Should a portion of our cash or marketable securities lose value or have their liquidity impaired, it could adversely affect our overall financial position by imperiling our ability to fund our operations and forcing us to seek additional financing sooner than we would otherwise. Such financing, if available, may not be available on commercially attractive terms.

As discussed under "Other Risks Relating to Our Business— We may acquire businesses or assets, form joint ventures or make investments in other companies that may be unsuccessful, divert our management's attention and harm our operating results and prospects," any investments that we may make in companies with which we have strategic alliances, such as Agenus and Merus, could result in our recognition of losses on those investments. In addition, to the extent we may seek to sell or otherwise monetize those investments, we may not be able to do so at our desired price or valuation levels, or at all, due to the limited liquidity of some or all of those investments.

Any loss in value of our long term investments could adversely affect our financial position on the consolidated balance sheets and consolidated statements of operations.

Our current revenues are derived from JAKAFI and ICLUSIG product sales, JAKAVI and OLUMIANT product royalties, collaborations and from licensing our intellectual property. If we are unable to achieve milestones, develop products or renew or enter into new collaborations, our revenues may decrease, and future milestone and royalty payments may not contribute significantly to revenues for several years, and may never result in revenues.

We derived substantially all of our revenues for the nine months ended September 30, 2019 from JAKAFI and ICLUSIG product revenues, JAKAVI and OLUMIANT product royalties and our collaborations and licensing our intellectual property to others. Future revenues from research and development collaborations depend upon continuation of the collaborations, the achievement of milestones and royalties we earn from any future products developed from our research. If we are unable to successfully achieve milestones or our collaborators fail to develop successful products, we will not earn the future revenues contemplated under our collaborative agreements. For example, delays in or other limitations with respect to the approval of baricitinib in the United States for the treatment of moderate-to-severe rheumatoid arthritis, or the failure to obtain such approval, as discussed under "—We depend on our collaborators and licensees for the future development and commercialization of some of our drug candidates. Conflicts may arise between our collaborators and licensees and us, or our collaborators and licensees may choose to terminate their agreements with us, which may adversely affect our business." would affect potential future royalty and milestone and contract revenue. In addition, our revenues are subject to foreign currency exchange rate fluctuations due to the global nature of our operations. To the extent that our non-U.S. source revenues represent a more significant portion of our total revenues, these fluctuations could materially affect our operating results.

RISKS RELATING TO INTELLECTUAL PROPERTY AND LEGAL MATTERS

If we are subject to arbitration, litigation and infringement claims, they could be costly and disrupt our drug discovery and development efforts.

The technology that we use to make and develop our drug products, the technology that we incorporate in our products, and the products we are developing may be subject to claims that they infringe the patents or proprietary rights of others. The success of our drug discovery and development efforts will also depend on our ability to develop new compounds, drugs and technologies without infringing or misappropriating the proprietary rights of others. We are aware of patents and patent applications filed in certain countries claiming intellectual property relating to some of our drug discovery targets and drug candidates. While the validity of issued patents, patentability of pending patent applications and applicability of any of them to our programs are uncertain, if any of these patents are asserted against us or if we choose to license any of these patents, our ability to commercialize our products could be harmed or the potential return to us from any product that may be successfully commercialized could be diminished.

From time to time we have received, and we may in the future receive, notices from third parties offering licenses to technology or alleging patent, trademark, or copyright infringement, claims regarding trade secrets or other contract claims. Receipt of these notices could result in significant costs as a result of the diversion of the attention of management from our drug discovery and development efforts. Parties sending these notices may have brought and in the future may bring litigation against us or seek arbitration relating to contract claims.

We may be involved in future lawsuits or other legal proceedings alleging patent infringement or other intellectual property rights or contract violations. In addition, litigation or other legal proceedings may be necessary to:

- assert claims of infringement;
- enforce our patents or trademarks;
- protect our trade secrets or know-how; or
- determine the enforceability, scope and validity of the proprietary rights of others.

We may be unsuccessful in defending or pursuing these lawsuits, claims or other legal proceedings. Regardless of the outcome, litigation or other legal proceedings can be very costly and can divert management's efforts. An adverse determination may subject us to significant liabilities or require us or our collaborators or licensees to seek licenses to other parties' patents or proprietary rights. We or our collaborators or licensees may also be restricted or prevented from manufacturing or selling a drug or other product that we or they develop. Further, we or our future collaborators or licensees may not be able to obtain any necessary licenses on acceptable terms, if at all. If we are unable to develop non-infringing technology or license technology on a timely basis or on reasonable terms, our business could be harmed.

We may be unable to adequately protect or enforce our proprietary information, which may result in its unauthorized use, a loss of revenue under a collaboration agreement or loss of sales to generic versions of our products or otherwise reduce our ability to compete in developing and commercializing products.

Our business and competitive position depends in significant part upon our ability to protect our proprietary technology, including any drug products that we create. Despite our efforts to protect this information, unauthorized parties may attempt to obtain and use information that we regard as proprietary. For example, one of our collaborators may disclose proprietary information pertaining to our drug discovery efforts. In addition, while we have filed numerous patent applications with respect to ruxolitinib and our drug candidates in the United States and in foreign countries, our patent applications may fail to result in issued patents. In addition, because patent applications can take several years to issue as patents, there may be pending patent applications of others that may later issue as patents that cover some aspect of ruxolitinib and our drug candidates. Our existing patents and any future patents we may obtain may not be broad enough to protect our products or all of the potential uses of our products, or otherwise prevent others from developing competing products or technologies. In addition, our patents may be challenged and invalidated or may fail to provide us with any competitive advantages if, for example, others were first to invent or first to file a patent application for the technologies and products covered by our patents. As noted above under "—Risks Relating to Commercialization of Our Products—Competition for our products could potentially harm our business and result in a decrease in our revenue," a potential generic drug company competitor has challenged certain patents relating to JAKAFI.

Additionally, when we do not control the prosecution, maintenance and enforcement of certain important intellectual property, such as a drug candidate in-licensed to us or subject to a collaboration with a third-party, the protection of the intellectual property rights may not be in our hands. If we do not control the intellectual property rights in-licensed to us with respect to a drug candidate and the entity that controls the intellectual property rights does not adequately protect those rights, our rights may be impaired, which may impact our ability to develop, market and commercialize the in-licensed drug candidate.

Our means of protecting our proprietary rights may not be adequate, and our competitors may:

independently develop substantially equivalent proprietary information, products and techniques;

- otherwise gain access to our proprietary information; or
- design around patents issued to us or our other intellectual property.

We pursue a policy of having our employees, consultants and advisors execute proprietary information and invention agreements when they begin working for us. However, these agreements may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure. If we fail to maintain trade secret and patent protection, our potential future revenues may be decreased.

If the effective term of our patents is decreased due to changes in the United States patent laws or if we need to refile some of our patent applications, the value of our patent portfolio and the revenues we derive from it may be decreased.

The value of our patents depends, in part, on their duration. A shorter period of patent protection could lessen the value of our rights under any patents that we obtain and may decrease the revenues we derive from our patents. The United States patent laws were amended in 1995 to change the term of patent protection from 17 years from patent issuance to 20 years from the earliest effective filing date of the application. Because the time from filing to issuance of biotechnology applications may be more than three years depending on the subject matter, a 20-year patent term from the filing date may result in substantially shorter patent protection.

Additionally, United States patent laws were amended in 2011 with the enactment of the America Invents Act and third parties are now able to challenge the validity of issued U.S. patents through various review proceedings; thus rendering the validity of U.S. patents more uncertain. We may be obligated to participate in review proceedings to determine the validity of our U.S. patents. We cannot predict the ultimate outcome of these proceedings, the conduct of which could result in substantial costs and diversion of our efforts and resources. If we are unsuccessful in these proceedings some or all of our claims in the patents may be narrowed or invalidated and the patent protection for our products and drug candidates in the United States could be substantially shortened. Further, if all of the patents covering one of our products are invalidated, the FDA could approve requests to manufacture a generic version of that product prior to the expiration date of those patents.

Other changes in the United States patent laws or changes in the interpretation of patent laws could diminish the value of our patents or narrow the scope of our patent protection. For example, the Supreme Court of the United States recently ruled that isolated DNA sequences cannot be patented. Although we no longer receive significant revenues generated from our former information products business, the majority of our gene patent portfolio from that business consists of patents on isolated DNA sequences, and this ruling limits our ability to derive additional revenues from our gene patent portfolio. Additionally, the Supreme Court resolved a split among the circuit courts of appeals regarding antitrust challenges to settlements of patent infringement lawsuits under the Hatch-Waxman Act between brand-name drug companies and generic drug companies. The Court rejected the "scope of the patent" test and ruled that settlements involving "reverse payments" from brand-name drug companies to generic drug companies should be analyzed under the rule of reason. This ruling may create uncertainty and make it more difficult to settle patent litigation if a company seeking to manufacture a generic version of one of our products challenges the patents covering that product prior to the expiration date of those patents.

International patent protection is particularly uncertain and costly, and our involvement in opposition proceedings in foreign countries may result in the expenditure of substantial sums and management resources.

Biotechnology and pharmaceutical patent law outside the United States is even more uncertain and costly than in the United States and is currently undergoing review and revision in many countries. Further, the laws of some foreign countries may not protect our intellectual property rights to the same extent as United States laws. For example, certain countries do not grant patent claims that are directed to the treatment of humans. We have participated, and may in the future participate, in opposition proceedings to determine the validity of our foreign patents or our competitors' foreign patents, which could result in substantial costs and diversion of our efforts. For example, there is a patent opposition proceeding in India against our Indian patent that covers the composition of matter and use of certain Janus Kinase inhibitors, including ruxolitinib phosphate, for the treatment of myeloid proliferative disorders, cancer, immune-related diseases, skin disorders, and other diseases. Successful challenges to our patent or other intellectual property rights through

these proceedings could result in a loss of rights in the relevant jurisdiction and allow third parties to use our proprietary technologies without a license from us or our collaborators, which may also result in loss of future royalty payments. In addition, successful challenges may jeopardize or delay our ability to enter into new collaborations or commercialize potential products, which could harm our business and results of operations.

RISKS RELATING TO INFORMATION TECHNOLOGY AND DATA PRIVACY

Significant disruptions of information technology systems, breaches of data security, or unauthorized disclosures of sensitive data or personally identifiable information or individually identifiable health information could adversely affect our business, and could subject us to liability or reputational damage.

Our business is increasingly dependent on critical, complex, and interdependent information technology (IT) systems, including Internet-based systems, some of which are managed or hosted by third parties, to support business processes as well as internal and external communications. The size and complexity of our IT systems make us potentially vulnerable to IT system breakdowns, malicious intrusion, and computer viruses, which may result in the impairment of our ability to operate our business effectively.

We are continuously evaluating and, where appropriate, enhancing our IT systems to address our planned growth, including to support our planned manufacturing operations. There are inherent costs and risks associated with implementing the enhancements to our IT systems, including potential delays in access to, or errors in, critical business and financial information, substantial capital expenditures, additional administrative time and operating expenses, retention of sufficiently skilled personnel to implement and operate the enhanced systems, demands on management time, and costs of delays or difficulties in transitioning to the enhanced systems, any of which could harm our business and results of operations. In addition, the implementation of enhancements to our IT systems may not result in productivity improvements at a level that outweighs the costs of implementation, or at all. In addition, our systems and the systems of our third-party providers and collaborators are potentially vulnerable to data security breaches which may expose sensitive data to unauthorized persons or to the public. Such data security breaches could lead to the loss of confidential information, trade secrets or other intellectual property, could lead to the public exposure of personal information (including personally identifiable information or individually identifiable health information) of our employees, clinical trial patients, customers, business partners, and others, could lead to potential identity theft, or could lead to reputational harm. Data security breaches could also result in loss of clinical trial data or damage to the integrity of that data. In addition, the increased use of social media by our employees and contractors could result in inadvertent disclosure of sensitive data or personal information, including but not limited to, confidential information, trade secrets and other intellectual property.

Any such disruption or security breach, as well as any action by us or our employees or contractors that might be inconsistent with the rapidly evolving data privacy and security laws and regulations applicable within the United States and elsewhere where we conduct business, could result in enforcement actions by U.S. states, the U.S. Federal government or foreign governments, liability or sanctions under data privacy laws, including healthcare laws such as HIPAA, that protect certain types of sensitive information, regulatory penalties, other legal proceedings such as but not limited to private litigation, the incurrence of significant remediation costs, disruptions to our development programs, business operations and collaborations, diversion of management efforts and damage to our reputation, which could harm our business and operations. Because of the rapidly moving nature of technology and the increasing sophistication of cybersecurity threats, our measures to prevent, respond to and minimize such risks may be unsuccessful.

In addition, the European Parliament and the Council of the European Union adopted a comprehensive general data privacy regulation, known as the GDPR, which took effect in May 2018 and governs the collection and use of personal data in the European Union. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third party processors in connection with the processing of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States, provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the infringer, whichever is greater. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data,

including healthcare data or other personal information, may increase our costs of doing business, and the differing requirements of these laws and regulations can complicate our compliance efforts.

Increasing use of social media could give rise to liability, breaches of data security, or reputational damage.

We and our employees are increasingly utilizing social media tools as a means of communication both internally and externally. Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us or our employees to communicate about our products or business may cause us to be found in violation of applicable requirements. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our social media policy or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial patients, customers, and others. Furthermore, negative posts or comments about us or our products in social media could seriously damage our reputation, brand image, and goodwill.

Item 5. Other Information

Effective October 25, 2019, we amended and restated our employment agreement with Hervé Hoppenot, our President and Chief Executive Officer, to provide that, should Mr. Hoppenot remain employed by us through his retirement on a date after December 31, 2024 (as such date may be extended by mutual agreement), all outstanding unvested equity awards that are granted by us to Mr. Hoppenot after July 15, 2019 and before December 31, 2024 (or such later date after December 31, 2024 as may be mutually agreed upon) would continue to vest as if he continued to be employed by us following the date of his retirement. In addition, any outstanding stock option awards that are granted to Mr. Hoppenot after July 15, 2019 and before December 31, 2024 (or such later date after December 31, 2024 as may be mutually agreed upon) that either were vested at the date of his retirement or become vested due to the post-retirement continued vesting provisions will be exercisable during the remainder of their original term. The effectiveness of these provisions will be subject to Mr. Hoppenot's continued compliance with the non-solicitation/non-hiring and non-disparagement covenants set forth in the agreement, including during any period of post-retirement continued vesting provided by the amendments to the agreement.

The foregoing description is qualified in its entirety by reference to the full text of the amended and restated agreement, a copy of which is filed as Exhibit 10.3 to this report and incorporated herein by reference.

Item 6. Exhibits

Exhibit Number	Description of Document		
10.1†*	Collaboration and License Agreement entered into as of November 24, 2009, by and between the Comp		
	and Novartis International Pharmaceutical Ltd.		
10.1.1†*	Amendment, dated as of April 5, 2016, to Collaboration and License Agreement entered into as of November		
	24, 2009, by and between the Company and Novartis International Pharmaceutical Ltd.		
10.2†*	<u>License, Development and Commercialization Agreement, entered into as of December 18, 2009, by and between the Company and Eli Lilly and Company.</u>		
10.2.1†*	Amendment, dated June 22, 2010, to License, Development and Commercialization Agreement entered into as of December 18, 2009, by and between the Company and Eli Lilly and Company.		
10.2.2†*	Third Amendment, entered into effective March 31, 2016, to License, Development and Commercialization		
1	Agreement entered into as of December 18, 2009, by and between the Company and Eli Lilly and Company.		
10.3#*	Amended and Restated Employment Agreement between the Company and Hervé Hoppenot dated as of		
	October 25, 2019.		
31.1*	Rule 13a-14(a) Certification of Chief Executive Officer		
31.2*	Rule 13a-14(a) Certification of Chief Financial Officer		
32.1**	Statement of the Chief Executive Officer under Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350)		
32.2**	Statement of the Chief Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C.		
32.2	Section 1350)		
101	XBRL Instance - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document		
101.INS*	XBRL Instance Document		
101.SCH*	XBRL Taxonomy Extension Schema Document		
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document		
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document		
101.PRE*	XBRL Taxonomy Presentation Linkbase Document		
101.DEF*	XBRL Taxonomy Definition Linkbase Document		
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).		

^{*} Filed herewith.

^{**} In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 34-47986, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-Q and will not be deemed "filed" for purposes

of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act.

- † Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K and confidential treatment has been requested with respect to those portions.
- # Indicates management contract or compensatory plan or arrangement.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

INCYTE CORPORATION

Dated: October 29, 2019 By: /s/ HERVÉ HOPPENOT

Hervé Hoppenot

Chairman, President, and Chief Executive Officer

(Principal Executive Officer)

Dated: October 29, 2019 By: /s/ CHRISTIANA STAMOULIS

Christiana Stamoulis Chief Financial Officer (Principal Financial Officer) EXTENSION OF CONFIDENTIAL TREATMENT REQUESTED: Certain identified information, marked by [***], has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company, if publicly disclosed. An extension of confidential treatment for such information has been requested. An unredacted version of this document has been filed separately with the Securities and Exchange Commission (the "Commission").

COLLABORATION AND LICENSE AGREEMENT

by and between

Incyte Corporation

Experimental Station, Route 141 & Henry Clay Road Wilmington, Delaware

and

Novartis International Pharmaceutical Ltd.

131 Front Street Hamilton, Bermuda HM 12

TABLE OF CONTENTS

ARTICLE I Definitions		1
ARTICLE	II Licenses	18
2.1	Rights Granted by Incyte to Novartis	18
2.2	Rights Granted by Novartis to Incyte	18
2.3	Sublicense Rights	19
2.4	Section 365(n) of The Bankruptcy Code	19
2.5	Retained Rights	20
2.6	Non-Compete	21
ARTICLE	III Governance	23
3.1	Joint Steering Committee	23
3.2	Subcommittees	23
3.3	Committee Meetings	26
3.4	Authority	27
3.5	Decisions	27
3.6	Committee Membership	28
ARTICLE	IV Development; Regulatory Matters	29
4.1	Information Transfer	29
4.2	Conduct of Development Activities	30
4.3	Development Activity Proposals	33
4.4	c-MET Licensed Compound Co-Development Option	36
4.5	Potential JAK Back-Up Compounds	36
4.6	Development Reports	38
4.7	Regulatory Matters Related to Licensed Products	39
ARTICLE	V Clinical and Commercial Supply	40
5.1	Clinical Supply	40
5.2	Commercial Supply by Incyte	41
5.3	Supply by Novartis to Incyte	41
ARTICLE	VI Commercialization and Co-Detailing Option	42
6.1	Commercialization Diligence	42
6.2	Marketing Responsibilities For Licensed Products	42
6.3	Incyte Co-Detailing Option	42
6.4	Novartis Co-Detailing Option	43
6.5	Global Branding; Trademarks	44
ARTICLE	VII Intellectual Property Ownership, Protection and Related Matters	45
7.1	Inventorship; Ownership	45
7.2	Prosecution and Maintenance of Patent Rights	46
7.3	Third Party Infringement	48
7.4	Patent Marking	50

7.5	Third Party Licenses	50
ARTICLE	VIII Financial Provisions	51
8.1	License Fee	51
8.2	Milestone Payments	51
8.3	Royalties	56
8.4	Royalty Reports; Payments	58
8.5	Financial Records	58
8.6		58
8.7		59
	Currency Exchange	60
8.9	Late Payments	61
ARTICLE	IX Term and Termination	61
9.1	Agreement Term	61
9.2	Termination	61
9.3	Effects Of Termination	62
ARTICLE	X Indemnification; Limitation of Liability	65
	By Novartis	65
	By Incyte	66
	Limitation of Liability	67
	Insurance	67
	XI Representations and Warranties and Covenants	68
	Representation Of Authority; Consents	68
	No Conflict	68
	Additional Incyte Representations and Warranties	68
	Incyte Covenant	69
	Disclaimer of Warranty	69
11.6	Standstill	69
ARTICLE	XII Confidentiality	71
	Confidential Information	71
	Permitted Disclosure	72
	Publicity; Attribution; Terms of this Agreement; Non-Use of Names	72
	Publications	74
	Term	74
	Return of Confidential Information	74
ARTICI E	XIII Dispute Resolution	75
		75
	Dispute Resolution Process	75 75
13.2	2 Injunctive Relief	/3
	XIV Miscellaneous	75
	Governing Law	75
14.2	Consent to Jurisdiction	76

Assignment	76
· ·	77
	78
Notices	78
Force Majeure	79
Compliance With Laws	79
Use Of Names, Logos Or Symbols	79
Independent Contractors	79
Headings	80
No Implied Waivers; Rights Cumulative	80
Severability	80
Execution In Counterparts	80
No Third Party Beneficiaries	80
Exhibits	80
)	Force Majeure Compliance With Laws Use Of Names, Logos Or Symbols Independent Contractors Headings No Implied Waivers; Rights Cumulative Severability Execution In Counterparts No Third Party Beneficiaries

Exhibits

Exhibit A: Incyte Patent Rights

Exhibit A-1: c-MET Patent Rights Exhibit A-2: JAK Patent Rights

Exhibit B: Initial Information Transfer to Novartis

Exhibit C

Exhibit C-1 Out-of-Pocket Costs

Exhibit C-2 Clinical Supply Agreement

Exhibit D: Initial Development Plans

Exhibit D-1: c-MET Development Plan Exhibit D-2: JAK Development Plan

Exhibit E: c-MET Studies

Exhibit F: Study 351 and Study 352

Exhibit F-1: Out-of-Pocket Costs for Toxicology Studies

Exhibit F-2: Study 352 Out-of-Pocket Costs for EMEA Registration Study

Exhibit G: Press Release

Exhibit H: Replacement Provisions Exhibit I: Pharmacovigilance Agreement

Schedules

Schedule 1.14: c-MET Licensed Back-Up Compounds

Schedule 1.62: JAK Licensed Back-Up Compounds

Schedule 4.1: [***]

Schedule 4.1(c)(i): [***]

Schedule 11.3: Exceptions to Representations and Warranties

COLLABORATION AND LICENSE AGREEMENT

THIS COLLABORATION AND LICENSE AGREEMENT (the "<u>Agreement</u>") is entered into as of the 24th day of November, 2009 (the "<u>Effective Date</u>"), by and between Incyte Corporation, a Delaware corporation having an office at Experimental Station, Route 141 & Henry Clay Road, Wilmington, Delaware ("<u>Incyte</u>"), and Novartis International Pharmaceutical Ltd., a limited company organized under the laws of Bermuda having an office at 131 Front Street, Hamilton, Bermuda HM 12 ("<u>Novartis</u>").

WHEREAS, Incyte and Novartis are each in the business of discovering, developing and commercializing pharmaceutical products;

WHEREAS, Incyte has, pursuant to the c-MET Program (as defined below) and the JAK Program (as defined below), discovered and commenced Development of the Licensed Compounds (as defined below);

WHEREAS, Incyte and Novartis are interested in collaborating on activities relating to the c-MET Program and the JAK Program and Incyte has agreed to grant to Novartis the right to develop and commercialize the Licensed Compounds;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE I

DEFINITIONS

When used in this Agreement, each of the following terms shall have the meanings set forth in this ARTICLE I:

that (a) at any point in time prior to First Commercial Sale of a Licensed Product under such Program, no Good Faith Development activities have occurred during at least the preceding [***] and no significant constraints on such Development imposed by a Regulatory Authority or a Force Majeure Event have been in effect during such period and (b) at any point in time after First Commercial Sale of a Licensed Product under such Program, (i) Novartis does not promote a JAK Licensed Product in at least [***] EU Major Market Countries during the preceding [***] and during that period (w) Novartis has not reasonably determined that promotion in the remaining EU Major Market Countries is likely to reduce the overall commercial viability of the Program in the Novartis Territory, (x) no significant constraints on such promotion imposed by a Regulatory Authority have been in effect in the jurisdictions in which such promotion failed to occur, (y) no Force Majeure Event has been in effect in any jurisdictions in which such promotion failed to occur and (z) Novartis is not actively seeking pricing approval in at least [***] EU Major Market Countries, or (ii) Novartis does not promote a c-MET Licensed Product in at least [***] EU Major Market Countries and the United States during the preceding [***] months and during that period (w) Novartis

has not reasonably determined that promotion in the remaining EU Major Market Countries or the United States, as applicable, is likely to reduce the overall commercial viability of the Program in the Novartis Territory, (x) no significant constraints on such promotion imposed by a Regulatory Authority have been in effect in the jurisdictions in which such promotion failed to occur, (y) no Force Majeure Event has been in effect in any jurisdictions in which such promotion failed to occur and (z) Novartis is not actively seeking pricing approval in at least [***] EU Major Market Countries and the United States. For purposes of clarity, Novartis may be deemed to have Abandoned a Program irrespective of whether it has used Commercially Reasonable Efforts to Develop and Commercialize Licensed Product(s) for such Program.

- 1.2 "Accounting Standards" with respect to Incyte means that Incyte shall maintain records and books of accounts in accordance with (a) US GAAP (United States Generally Accepted Accounting Principles); or (b) if mandated by the SEC, IFRS (International Financial Reporting Standards); and with respect to Novartis shall mean that Novartis shall maintain records and books of accounts in accordance with IFRS. Notwithstanding the above, prior period restatements needed in conjunction with the IFRS adoption shall not impact royalty payments, milestone payments and Development Costs already paid prior to the IFRS adoption except for the fiscal year immediately prior to the fiscal year in which the change in accounting standards is implemented.
- 1.3 "Affiliate" means any Person that, directly or indirectly, controls, is controlled by or is under common control with a Party. For the purposes of this Section 1.3, the word "control" (including, with correlative meaning, the terms "controlled by" or "under common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such entity, whether by the ownership of [***] of the Voting Stock of such entity, by contract or otherwise. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than [***], and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity. Notwithstanding the foregoing, an entity shall not be deemed an Affiliate by virtue of ownership of greater than [***] of such entity if such ownership is coupled with limitations, contractual or otherwise, that prevent such owner from directing the management and policies of such entity [***].
- 1.4 "Annual Net Sales" means aggregate Net Sales of c-MET Licensed Products or JAK Licensed Products, as applicable, by Novartis or its Affiliates or sublicensees in any Calendar Year, or in the first and last years of the term of this Agreement, the portion of such Calendar Year during which this Agreement is in effect.

- 1.5 "Bankruptcy Event" means with respect to a Party, (i) the entry of an order for relief under the Bankruptcy Code (or any other bankruptcy, insolvency, reorganization or other similar act or law of any jurisdiction now or hereafter in effect) by such Party; (ii) the commencement of an involuntary proceeding under the Bankruptcy Code or any other bankruptcy, insolvency, reorganization or other similar act or law of any jurisdiction now or hereafter in effect against such Party, if not dismissed, bonded or stayed within [***] after such commencement; (iii) the making by such Party of a general assignment for the benefit of creditors; or (iv) the appointment of or taking possession by a receiver, liquidator, assignee, custodian, or trustee of all or substantially all of the business or property of such Party,
- 1.6 "<u>Business Day</u>" means a day other than a Saturday or Sunday or Federal holiday in Wilmington, Delaware, Basel, Switzerland or Hamilton, Bermuda.
- 1.7 "<u>Calendar Quarter</u>" means a calendar quarter ending on the last day of March, June, September or December.
- 1.8 "<u>Calendar Year</u>" means a period of time commencing on January 1 and ending on the following December 31.
 - 1.9 "Change of Control" of a Party means that any of the following has occurred:
- (a) any Person or group that is a [***] becomes the beneficial owner, directly or indirectly, of [***] or more of the outstanding Voting Stock or voting power over Voting Stock of (i) such Party or (ii) any one or more Persons that controls such Party (such Party, together with the Persons described in clause (ii), each hereinafter referred to, individually, as a "Group Company" and, collectively, as the "Group Companies"); or
- (b) the sale or disposition of all or substantially all of the assets of the Group Companies, on a consolidated basis; or
- (c) a merger, reorganization, consolidation or other similar transaction (or series of related transactions) of any Group Company with any Person or any Affiliate of such Person, in each case, that is a [***] (other than with any of the Group Company's wholly-owned subsidiaries) or with a group that contains a [***], that results in the shareholders of the applicable Group Company immediately before the occurrence of such transaction (or series of related transactions) beneficially owning immediately after such transaction [***] of the outstanding Voting Stock or voting power over Voting Stock of the surviving or newly-created entity in such transaction (or series of related transactions); or
- (d) a change in the board of directors of any Group Company in which the individuals who constituted the board of directors of such Group Company at the beginning of the [***] period immediately preceding such change (together with any other director whose election by the board of directors of such Group Company or whose nomination for election by the stockholders of such Group Company was approved by a vote of [***] the directors then in office either who were directors at the beginning of such period or whose election or nomination for election was previously so approved (either by a specific

vote or by approval of a proxy statement in which such individual is named as a nominee for election as a director)), cease for any reason to constitute a majority of the directors then in office.

For purposes of this definition of "Change of Control" only: (i) references to any Group Company shall be deemed to include all successors in any merger, consolidation, reorganization or similar transaction (or series of related transactions) preceding any transaction (or series of related transactions) described above; (ii) "beneficial ownership" (and other correlative terms) means beneficial ownership as defined in Rule 13d-3 under the Exchange Act; it being understood and agreed that "beneficial ownership" shall also include any securities that any Person or any of such Person's Affiliates has the right to acquire pursuant to any agreement, arrangement or understanding, or upon the exercise of conversion rights, exchange rights, rights, warrants or options, or otherwise; (iii) "group" means group as defined in the Exchange Act and the rules of the SEC thereunder as in effect on the date hereof; (iv) "control" (including, with correlative meaning, the term "controlled by") means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such entity, whether by the ownership of [***] of the Voting Stock of such entity, or by contract or otherwise; and (v) [***] shall mean at a given time, [***].

- 1.10 "<u>c-MET</u>" means human Met tyrosine kinase.
- 1.11 "c-MET Excluded Compound" means a [***].
- 1.12 "<u>c-MET Field</u>" means the treatment, control, management, mitigation, prevention, cure or diagnosis of any and all Indications in humans and animals.
 - 1.13 "c-MET Inhibitor Compound" means any compound [***].
- 1.14 "c-MET Licensed Compound" means (a) the c-MET Inhibitor Compound known as INCB28060 (the chemical structure of which has previously been disclosed to Novartis in a letter dated November 23, 2009); (b) the back-up c-MET Inhibitor Compounds set forth on Schedule 1.14 (the chemical structures of which have previously been disclosed to Novartis in a letter dated November 20, 2009) (each a "c-MET Licensed Back-Up Compound"); (c) all salts, prodrugs, esters, metabolites, solvates, stereoisomers and polymorphs of the foregoing; and (d) all derivatives of the foregoing containing one or more atoms substituted with a radio isotope (including without limitation derivatives containing deuterium).

- 1.15 "<u>c-MET Licensed Product</u>" means a product or product candidate that contains one or more c-MET Licensed Compounds as the active ingredient, including all formulations and dosages of such c-MET Licensed Compounds and all processes and delivery systems that incorporate such c-MET Licensed Compounds.
- 1.16 "c-MET Program" means a program conducted pursuant to this Agreement and directed to the research, Development and Commercialization of c-MET Licensed Compounds and c-MET Licensed Products in the c-MET Field.
- 1.17 "c-MET Program Term" means the period beginning on the Effective Date and continuing until the earlier of (a) the termination of this Agreement in its entirety or the c-MET Program in accordance with Section 9.2 or (b) following the First Commercial Sale of any c-MET Licensed Product, the expiration of the last-to-expire of all Royalty Terms with respect to all c-MET Licensed Compounds and c-MET Licensed Products.
- 1.18 "<u>Clinical Trial</u>" means a Phase I Study, a Phase II Study, a Phase III Study, a Phase IV Study or a combination of two (2) of any of the foregoing studies.
- 1.19 "<u>Commercialization</u>" or "<u>Commercialize</u>" means any activities directed to obtaining pricing and/or reimbursement approvals, marketing, promoting, distributing, importing, offering to sell, and/or selling a product (including establishing the price for such product).
- 1.20 "Commercially Reasonable Efforts" of a Party means the reasonable, diligent, good faith efforts of the type to accomplish such objective as such Party would normally use to accomplish a similar objective under similar circumstances, it being understood and agreed that, with respect to efforts to be expended in relation to a product, such efforts shall be substantially consistent with those efforts and resources commonly used by such Party for any other product owned by it or in relation to which it may have rights, which other product is at a similar stage in its Development or product life and is of similar market and economic potential as products expected to result from the Licensed Compounds at a similar stage in their Development or product life, and that any such other product owned by it or over which it has rights will not be given any preferential treatment when compared to the objectives to be carried out pursuant to this Agreement, provided that such efforts continue to be commercially reasonable in light of the scientific and economic outlook for the product, all as measured by the facts and circumstances at the time such efforts are due.
- 1.21 "<u>Confidential Information</u>" means (a) all confidential or proprietary information relating to Licensed Compounds, and (b) all other confidential or proprietary documents, technology, Know-How or other information (whether or not patentable) actually disclosed by one Party to the other pursuant to this Agreement or the Prior Confidentiality Agreements.
- 1.22 "Control" or "Controlled" means, with respect to any (a) material, document, item of information, method, data or other Know-How or (b) Patent Rights or other Intellectual Property Rights, the possession by a Party or its Affiliates, whether by ownership or license (other than by licenses granted under this Agreement), of the ability to grant to the other Party access, a license and/or a sublicense as provided herein without requiring the consent of a Third

Party or violating the terms of any agreement or other arrangement with any Third Party, in each case as of the Effective Date, or if any of the same are acquired or created after the Effective Date, at the date it is acquired or created by the relevant Party or its Affiliate.

- 1.23 "Cover", "Covering" or "Covered" with respect to a product, technology, process or method, means that, but for a license granted to a Person under a Valid Claim included in the Patent Rights under which such license is granted, the Development, manufacture, Commercialization and/or other use of such product or the practice of such technology, process or method, by such Person would infringe such Valid Claim (or, in the case of a Valid Claim that has not yet issued, would infringe such Valid Claim if it were to issue).
- 1.24 "<u>Detail</u>" means face-to-face discussions with physicians and other health care practitioners who are permitted under applicable Laws to prescribe a Licensed Product for the purpose of promoting a Licensed Product to such physicians or practitioners.
- 1.25 "Development" or "Develop" means, with respect to a compound, preclinical and clinical drug development activities, including, among other things: the conduct of Clinical Trials, test method development and stability testing, toxicology, formulation and delivery system development, process development, pre-clinical and clinical Drug Substance and Drug Product supply, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control procedure development and performance with respect to clinical materials, statistical analysis and report writing and clinical studies, regulatory affairs, and all other pre-Regulatory Approval activities. When used as a verb, "Develop" means to engage in Development. For the avoidance of doubt, "Development" shall include Phase IV Studies.
- 1.26 "Development Costs" means the costs and expenses incurred by or on behalf of a Party attributable to, or reasonably allocable to, the Development of Licensed Products and that are materially consistent, as applicable, with the Development Plan and Development Budget. Development Costs shall not include costs that are allocable to the costs of management, financial, legal or business development personnel. "Development Costs" shall include (a) the costs of Clinical Trials, the preparation, collation and/or validation of data from such Clinical Trials and the preparation of medical writing and publishing, (b) the FTE costs of the relevant Party or its Affiliates, (c) all Out-of-Pocket Costs incurred by the Parties or their Affiliates, including payments made to Third Parties with respect to any of the foregoing (except to the extent that such costs have been included in FTE costs), (d) Regulatory Expenses and (e) the cost of contract research organizations (CROs) and clinical supply, including: (i) costs of Drug Products, packaging of Drug Products and distribution of Drug Products used in Clinical Trials, (ii) expenses incurred to purchase and/or package comparator drugs, and (iii) costs and expenses of disposal of clinical samples.
- 1.27 "<u>Disclosing Party</u>" means, with respect to Confidential Information, Patent Rights or Know-How, the Party that Controls such Confidential Information, Patent Rights or Know-How.
 - 1.28 "Drug Product" means a finished dosage form that contains the Drug Substance.
 - 1.29 "<u>Drug Substance</u>" means the active pharmaceutical ingredient.

- 1.30 "EMEA" means the European Medicines Agency, or a successor agency thereto.
- 1.31 "EU Major Market Countries" means [***].
- 1.32 "Executive Officers" means the Chief Executive Officer of Incyte (or a senior executive officer of Incyte designated by Incyte's Chief Executive Officer) and the Chief Executive Officer of Novartis Oncology (or a senior executive officer of Novartis or its Affiliate as designated by the Chief Executive Officer of Novartis Oncology).
 - 1.33 "FDA" means the United States Food and Drug Administration, or a successor agency thereto.
 - 1.34 "Field" means the c-MET Field and the JAK Field.
- 1.35 "First Commercial Sale" means, with respect to a Licensed Product, the first shipment of such Licensed Product to a Third Party by, as applicable, Novartis or its Affiliates or sublicensees or Incyte or its Affiliates or sublicensees in a country following applicable Regulatory Approval (other than applicable governmental price and reimbursement approvals) of such Licensed Product in such country. Sales or transfers of reasonable quantities of Licensed Product for Clinical Trial purposes, or for compassionate or similar use, shall not be considered a First Commercial Sale.
- 1.36 "<u>Force Majeure Event</u>" means an event, act, occurrence, condition or state of facts, in each case outside the reasonable control of a Party, including acts of God; acts of any government; any rules, regulations or orders issued by any governmental authority or by any officer, department, agency or instrumentality thereof; fire; storm; flood; earthquake; accident; war; rebellion; insurrection; riot; terrorism and invasion, that interfere with the normal business operations of such Party.
- 1.37 "FPFV" means the first subject's first screening visit in a Clinical Trial that results in such subject signing an informed consent.
- 1.38 "FTE" means a full-time equivalent person year (consisting of a total of [***] hours per year) of scientific, technical or commercialization work undertaken by Incyte or Novartis employees, as applicable.
- 1.39 "FTE Rate" means the rate per FTE (which may be prorated on a daily basis as necessary) of [***] per annum, with respect to Development or Commercialization activities conducted pursuant to this Agreement, subject to annual adjustment by the rate of the Employment Cost Index for total compensation for the "management, professional and related" occupational group, as published by the United States Department of Labor, Bureau of Labor Statistics (or any similar index agreed upon by the Parties if such index ceases to be compiled and published).
- 1.40 "<u>Generic Competition</u>" means, with respect to a Licensed Product in any country in a given Calendar Quarter, if, during such Calendar Quarter and the immediately preceding Calendar Quarter, one or more Generic Products shall be commercially available in such country

and such Generic Products shall in the aggregate have a market share of [***] of the aggregate market share of such Licensed Product and Generic Products (based on data provided by IMS International or, if such data is not available, such other reliable data source as agreed by the Parties (such agreement not to be unreasonably withheld)) as measured by unit sales.

- 1.41 "Generic Product" means any pharmaceutical product that contains a Licensed Compound and that is sold under a marketing authorization granted by a Regulatory Authority to a Person other than a Party or its Affiliates, licensees or sublicensees.
- 1.42 "Good Faith Development" means Development conducted in good faith with the intention of advancing a Program toward registration (and not for the sole purpose of preserving rights hereunder).
- 1.43 "<u>Hematology Field</u>" means the treatment, control, mitigation, prevention, cure, or diagnosis of all hematologic Indications as defined as of the Effective Date in subsections 280 289 (Diseases of the blood and blood-forming organs) of the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM).
 - 1.44 "Incyte Group Member" means Incyte and any direct or indirect wholly owned subsidiary of Incyte.
 - 1.45 "Incyte IP" means Incyte Know-How and Incyte Patent Rights.
- 1.46 "<u>Incyte Know-How</u>" means all Know-How that (a) is Controlled by Incyte or any of its Affiliates as of the Effective Date or during the Term; and (b) is necessary or useful to Develop, manufacture or Commercialize any Licensed Products or Licensed Compounds; <u>provided</u>, <u>however</u>, that Incyte Know-How specifically excludes Joint IP.
- 1.47 "Incyte Patent Rights" means all Patent Rights that (a) are Controlled by Incyte or any of its Affiliates as of the Effective Date or during the Term; and (b) are necessary or useful to Develop, manufacture or Commercialize any of (x) c-MET Licensed Compounds and c-MET Licensed Products (the "c-MET Patent Rights"); and (y) JAK Licensed Compounds and JAK Licensed Products (the "JAK Patent Rights"); provided, however, that Incyte Patent Rights specifically exclude Joint IP. The c-MET Patent Rights that exist as of the Effective Date are set forth in Exhibit A-1 and the JAK Patent Rights that exist as of the Effective Date are set forth on Exhibit A-2.
- 1.48 "<u>Incyte Territory</u>" means, with respect to all JAK Licensed Products and JAK Patent Rights, the United States of America and its territories and possessions.
- 1.49 "IND" means an Investigational New Drug Application filed with the FDA under 21 C.F.R. Part 312 or similar non-United States application or submission in any country or group of countries for permission to conduct human clinical investigations.
- 1.50 "<u>Indication</u>" shall mean any disease, condition or syndrome, or sign or symptom of, or associated with, a disease or condition.

- 1.51 "Inflammatory Disease" means any inflammatory disease, including the following Indications: RA (and other arthritides including Juvenile RA, ankylosing spondylitis, Sero-negative spondyloarthropathies and psoriatic arthritis), IBD, Crohn's, Psoriasis, Asthma, chronic obstructive pulmonary disease, Multiple Sclerosis and Systemic Lupus Erythematosus. Notwithstanding the foregoing, Inflammatory Disease shall specifically exclude (a) any hematologic Indications as defined as of the Effective Date in subsections 280 289 (Diseases of the blood and blood-forming organs) of the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and (b) oncology Indications as defined as of the Effective Date in subsections 140 239 (Neoplasms) of the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), including all hematologic malignancies, solid tumors and myeloproliferative diseases (including Myelofibrosis, Polycythemia Vera and Essential Thrombocythemia).
- 1.52 "<u>Intellectual Property Rights</u>" means patents, trade secrets, copyrights and other forms of proprietary or industrial rights pertaining to inventions, Know-How, original works, and other forms of intellectual property.
- 1.53 "Inventions" means all patentable inventions, discoveries, improvements and other technology and any Patent Rights based thereon, that are discovered, made or conceived during and in connection with the research, Development, manufacture and Commercialization of Licensed Compounds or Licensed Products.
 - 1.54 "<u>JAK</u>" means human Jak Tyrosine Kinase.
 - 1.55 "JAK2" means Jak2 Tyrosine Kinase.
 - 1.56 "JAK3" means Jak3 Tyrosine Kinase.
 - 1.57 "JAK Excluded Compound" means a [***].
 - 1.58 "JAK2 Inhibitor Compound" means [***].
- 1.59 "JAK Field" means the Hematology Field and the Oncology Field, and includes all forms of administration except topical.
- 1.60 "JAK Licensed Compound" means (a) the JAK2 Inhibitor Compound known as INCB018424 (the chemical structure of which has previously been disclosed to Novartis in a letter dated November 23, 2009); (b) the back-up JAK2 Inhibitor Compounds set forth on Schedule 1.60 (the chemical structures of which have previously been disclosed to Novartis in a letter dated November 20, 2009) (each a "JAK Licensed Back-Up Compound"); (c) any Potential JAK Licensed Compound to the extent deemed a JAK Licensed Compound pursuant to Section 4.5; (d) all salts, prodrugs, esters, metabolites, solvates, stereoisomers and polymorphs of the foregoing; and (e) all derivatives of the foregoing containing one or more atoms substituted with a radio isotope (including without limitation derivatives containing deuterium).

- 1.61 "JAK Licensed Product" means a product or product candidate that contains one or more JAK Licensed Compounds as the active ingredient, including all formulations and dosages of such JAK Licensed Compounds and all processes and delivery systems that incorporate such JAK Licensed Compounds.
- 1.62 "JAK Program" means a program conducted pursuant to this Agreement and directed to the research, Development and Commercialization of JAK Licensed Compounds and JAK Licensed Products in the JAK Field.
- 1.63 "JAK Program Term" means the period beginning on the Effective Date and continuing until the earlier of (a) the termination of this Agreement in its entirety or the JAK Program in accordance with Section 9.2 or (b) following the First Commercial Sale of any JAK Licensed Product, the expiration of the last-to-expire of all Royalty Terms with respect to all JAK Licensed Compounds and JAK Licensed Products.
- 1.64 "<u>Know-How</u>" means any information, ideas, data, inventions, works of authorship, trade secrets, technology, or materials, including formulations, molecules, assays, reagents, compounds, compositions, human or animal tissue, samples or specimens, and combinations or components thereof, whether or not proprietary or patentable, or public or confidential, and whether stored or transmitted in oral, documentary, electronic or other form, including all Regulatory Documentation, but excluding any such information or materials publicly disclosed in Patent Rights.
- 1.65 "Law" means any law, statute, rule, regulation, ordinance or other pronouncement having the effect of law, of any federal, national, multinational, state, provincial, county, city or other political subdivision, including (a) good clinical practices and adverse event reporting requirements, guidance from the International Conference on Harmonization or other generally accepted conventions, and all other rules, regulations and requirements of the FDA and other applicable Regulatory Authorities, (b) the Foreign Corrupt Practices Act of 1977, as amended, or any comparable laws in any country, and (c) all export control laws.
- 1.66 "<u>Licensed Compounds</u>" means: (a) c-MET Licensed Compounds; and (b) JAK Licensed Compounds.
- 1.67 "<u>Licensed Patent Rights</u>" means with respect to the Patent Rights licensed to Novartis hereunder, the Incyte Patent Rights and with respect to the Patent Rights licensed to Incyte hereunder, the Novartis Patent Rights. In each case, Patent Rights forming part of the Joint IP shall be included, as applicable, in the Incyte Patent Rights and Novartis Patent Rights.
- 1.68 "<u>Licensed Product</u>" means a c-MET Licensed Product or a JAK Licensed Product. As used in this Agreement, except where not appropriate in context, the Licensed Product also includes the Licensed Compound contained in the Licensed Product.
 - 1.69 "[***]" means [***].
 - 1.70 "MHLW" means the Japanese Ministry of Health, Labor and Welfare, or a successor agency thereto.

- 1.71 "[***]" means [***].
- 1.72 "NDA" means (a) (i) a New Drug Application submitted to the FDA, or any successor application or procedure, as more fully defined in 21 C.F.R. § 314.50 et. seq., or (ii) any non-United States counterpart of such a New Drug Application, and (b) all supplements and amendments, including supplemental New Drug Applications (and any non-United States counterparts) that may be filed with respect to the foregoing.
- 1.73 "Net Sales" means, with respect to any Licensed Product, the net sales on behalf of a Royalty Paying Party or its Affiliates, licensees or sublicensees sold to Third Parties as determined in accordance with the Royalty Paying Party's usual and customary accounting methods, which are in accordance with Accounting Standards, as consistently applied by such Royalty Paying Party, including a deduction of a fixed percentage of [***] for distribution and warehousing expenses and any amounts credited for uncollectible amounts on previously sold Licensed Products.
- (a) In the case of any sale or other disposal of the Licensed Product between or among a Royalty Paying Party and its Affiliates, licensees and sublicensees for resale, Net Sales shall be deemed to occur and shall be calculated as above only on the first arm's-length sale thereafter to a Third Party.
- (b) In the case of any sale that is not invoiced or is delivered before invoice, Net Sales shall be calculated at the time all the revenue recognition criteria under the applicable Accounting Standards are met.
- (c) In the case of any sale or other disposal for value, such as barter or counter-trade, of Licensed Product, or part thereof, other than in an arm's length transaction exclusively for cash, Net Sales shall be calculated as above on the value of the non-cash consideration received or the fair market price (if higher) of the Licensed Product in the country of sale or disposal, as determined in accordance with the Accounting Standards.
- Product in combination with one or more other active ingredients (a "Combination Product"), the Net Sales of the Licensed Product, for the purposes of determining royalty payments, shall be determined by multiplying the Net Sales (as defined above in this Section) of the Combination Product by the fraction, A/(A+B) where A is the weighted (by sales volume) average sale price in a particular country of the Licensed Product in the prior Calendar Year when sold separately in finished form and B is the weighted average sale price in that country in the prior Calendar Year of the other product(s) sold separately in finished form. In the event that such average sale price cannot be determined for both the Licensed Product and the other product(s) in combination, Net Sales for purposes of determining royalty payments shall be

agreed by the Parties based on the relative value contributed by each component, such agreement shall not be unreasonably withheld.

- 1.74 "Novartis Group Member" means Novartis AG and any direct or indirect wholly owned subsidiary of Novartis.
- 1.75 "Novartis Improvements" means Novartis Patent Rights that (a) constitute an improvement to the Incyte IP that is made by or on behalf of Novartis or its Affiliates during the Term; (b) are necessary or useful to Develop, manufacture or Commercialize any JAK Licensed Compounds; and (c) relate to (i) uses of JAK Licensed Compounds or (ii) methods of manufacturing JAK Licensed Compounds.
 - 1.76 "Novartis IP" means, collectively, Novartis Know-How and Novartis Patent Rights.
- 1.77 "Novartis Know-How" means all Know-How that: (a) is Controlled by Novartis or any of its Affiliates as of the Effective Date or during the Term; and (b) is necessary or useful to Develop, manufacture or Commercialize any Licensed Compounds or Licensed Products; <u>provided</u>, <u>however</u>, that Novartis Know-How specifically excludes Joint IP.
 - 1.78 "Novartis Oncology" means the Novartis oncology business unit of Novartis.
- 1.79 "Novartis Patent Rights" means all Patent Rights that: (a) are Controlled by Novartis or its Affiliates as of the Effective Date or during the Term; and (b) are necessary or useful to Develop, manufacture or Commercialize all or any of the Licensed Compounds and Licensed Products; <u>provided, however</u>, that Novartis Patents Rights specifically excludes Joint IP.
- 1.80 "Novartis Sponsored Study" means any Clinical Trial sponsored by Novartis, its Affiliates or sublicensees, but specifically excludes any investigator initiated studies.
- 1.81 "Novartis Standard Exchange Rate Methodology" means, with respect to amounts invoiced in United States Dollars, all such amounts shall be expressed in United States Dollars. With respect to amounts invoiced in a currency other than United States Dollars, all such amounts shall be expressed both in the currency in which the amount was invoiced and in the United States Dollar equivalent. The United States Dollar equivalent shall be calculated using Novartis' then-current standard exchange rate methodology, which is in accordance with applicable Accounting Standards, applied in its external reporting (which is ultimately based on official rates such as those published by the European Central Bank) for the conversion of foreign currency sales into United States Dollars.
- 1.82 "Novartis Territory" means (a) with respect to c-MET Licensed Products and c-MET Patent Rights, the entire world; and (b) with respect to JAK Licensed Products and JAK Patent Rights, the entire world other than the Incyte Territory (the "Novartis JAK Territory").
- 1.83 "Oncology Field" means the treatment, control, mitigation, prevention, cure, or diagnosis of any oncology Indications as defined as of the Effective Date in subsections 140 239 (Neoplasms) of the International Classification of Diseases, Ninth Revision, Clinical

Modification (ICD-9-CM), including all hematologic malignancies, solid tumors and myeloproliferative diseases (including Myelofibrosis, Polycythemia Vera and Essential Thrombocythemia).

- 1.84 "Out-of-Pocket Costs" means, with respect to certain activities hereunder, direct expenses paid or payable by either Party or its Affiliates to Third Parties (other than employees of such Party or its Affiliates) that are specifically identifiable and incurred to conduct such activities for Licensed Products, have been recorded in accordance with the Accounting Standards, and for the avoidance of doubt, do not include pre-paid amounts or capital expenditures.
 - 1.85 "Party" means Novartis or Incyte. "Parties" means Novartis and Incyte.
- 1.86 "Patent Rights" means all patents and patent applications in any country in the world, including any continuations, continuations-in-part, divisions, provisionals or any substitute applications, any patent issued with respect to any such patent applications, any reissue, reexamination, renewal or extension (including any supplemental protection certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent, and all non-United States counterparts of any of the foregoing.
- 1.87 "<u>Patent Term Extension</u>" means any patent term extension, adjustment or restoration or supplemental protection certificates.
- 1.88 "Person" means any natural person, general or limited partnership, corporation, limited liability company, limited liability partnership, firm, association or organization or other legal entity.
- 1.89 "Phase I Study" means a study in humans which provides for the first introduction into humans of a product, conducted in healthy volunteers or patients to obtain information on product safety, tolerability, pharmacological activity or pharmacokinetics, as more fully defined in 21 C.F.R. § 312.21(a) (or the non-United States equivalent thereof).
- 1.90 "<u>Phase II Study</u>" means a study in humans of the safety, dose ranging and efficacy of a product, which is prospectively designed to generate sufficient data (if successful) to commence pivotal clinical trials, as further defined in 21 C.F.R. § 312.21(b) (or the non-United States equivalent thereof).
- 1.91 "<u>Phase III Study</u>" means a controlled study in humans of the efficacy and safety of a product, which is prospectively designed to demonstrate statistically whether such product is effective and safe for use in a particular Indication in a manner sufficient to file an NDA to obtain regulatory approval to market the product, as further defined in 21 C.F.R. § 312.21(c) (or the non-United States equivalent thereof).
- 1.92 "<u>Phase IV Study</u>" means a human clinical trial which is conducted on a product after Regulatory Approval of the product has been obtained from an appropriate Regulatory Authority, and includes (a) trials conducted voluntarily for enhancing marketing or scientific knowledge of an approved Indication or (b) trials conducted after Regulatory Approval due to

request or requirement of a Regulatory Authority or as a condition of a previously granted Regulatory Approval.

- 1.93 "<u>Primary Detail</u>" means a Detail in which [***] of the time spent during such sales presentation is spent on a Licensed Product and for which [***] of the sales representative's incentive compensation is tied to such Detail.
- 1.94 "<u>Prior Confidentiality Agreements</u>" means the Confidentiality Agreements between Incyte and Novartis Institutes for BioMedical Research, Inc., an Affiliate of Novartis, dated as of October 30, 2008 and between Incyte and Novartis Pharmaceuticals Corporation, an Affiliate of Novartis, dated as of December 11, 2008 and amended as of January 29, 2009.
- 1.95 "<u>Program</u>" means the JAK Program or the c-MET Program. "<u>Programs</u>" means the JAK Program and the c-MET Program.
- 1.96 "<u>Publication</u>" means any publication in a scientific journal, any abstract to be presented to any scientific audience, any presentation at any scientific conference, including slides and texts of oral or other public presentations, any other scientific presentation and any other oral, written or electronic disclosure directed to a scientific audience which pertains to the Licensed Compound, the Licensed Product or the use of the Licensed Product.
- 1.97 "<u>Randomized Clinical Trial</u>" means a Clinical Trial in human patients of the efficacy of a product that is designed with parallel groups comparing, as applicable, a c-MET Inhibitor Compound or Potential JAK Back-Up Compound to either a placebo or an active comparator.
- 1.98 "Regulatory Approval" means all approvals (including any applicable governmental price and reimbursement approvals), licenses, registrations, and authorizations of any federal, national, multinational, state, provincial or local Regulatory Authority, department, bureau and other governmental entity that are necessary and sufficient for the marketing and sale of a product in a country or group of countries.
- 1.99 "<u>Regulatory Authority</u>" means, with respect to a country, the regulatory authority or regulatory authorities of such country with authority over the testing, manufacture, use, storage, importation, promotion, marketing, pricing or sale of a pharmaceutical product in such country.
- 1.100 "Regulatory Documentation" means, with respect to the Licensed Compounds and Licensed Products, all INDs and other regulatory applications submitted to any Regulatory Authority, Regulatory Approvals, pre-clinical and clinical data and information, regulatory materials, drug dossiers, master files (including Drug Master Files, as defined in 21 C.F.R. 314.420 and any non-United States equivalents), and any other reports, records, regulatory correspondence and other materials relating to Development or Regulatory Approval of a Licensed Compound or Licensed Product, or required to manufacture, distribute or sell the Licensed Products, including any information that relates to pharmacology, toxicology, chemistry, manufacturing and controls data, batch records, safety and efficacy, and any safety database.

- 1.101 "<u>Regulatory Exclusivity</u>" means the ability to exclude Third Parties from Commercializing a Licensed Product in a country, either through data exclusivity rights, orphan drug designation, or such other rights conferred by a Regulatory Authority in such country, other than through Patent Rights.
- 1.102 "<u>Regulatory Expenses</u>" means, with respect to a Licensed Compound or Licensed Product, all Out-of-Pocket Costs incurred by or on behalf of a Party in connection with the preparation and filing of regulatory submissions for Licensed Product and obtaining of Regulatory Approvals.
- 1.103 "<u>Right of Reference or Use</u>" means a "Right of Reference or Use" as that term is defined in 21 C.F.R. §314.3(b), and any non-United States equivalents.
- 1.104 "Royalty Paying Party" means the Party required to pay royalties to the other Party with respect to a Licensed Product pursuant to Sections 2.6(a)(iii), 4.5(c), 8.3 and 9.3(a).
- 1.105 "Royalty Receiving Party" means the Party that is entitled to receive royalties from the other Party with respect to a Licensed Product pursuant to Sections 2.6(a)(iii), 4.5(c), 8.3 and 9.3(a).
 - 1.106 "SEC" means the United States Securities and Exchange Commission.
- 1.107 "Secondary JAK Patent Rights" means all JAK Patent Rights and Joint IP Covering the JAK Licensed Compounds and JAK Licensed Products ("Joint JAK IP") except for the Patent Rights that are designated as INCY0039 (the "INCY0039 Patent Rights"). The INCY0039 Patent Rights that exist as of the Effective Date are set forth as INCY0039 on Exhibit A-2.
- 1.108 "Software Source Code" means all Incyte Know-How that are computer programs and applications including implementation of algorithms, models and methodologies, in each case in source code form (unless Incyte does not Control the same in source code form and then in object code form), as well as compilations of data, descriptions, library functions, flow charts, architecture, database design, display screens and development tools and other information, work product or tools used to design, plan, organize or develop any of the foregoing that relate to the JAK Program or the c-MET Program or both.
- 1.109 "<u>Supply Agreement</u>" means a supply agreement entered into by Incyte and Novartis as described in ARTICLE V.
- 1.110 "<u>Terminated Program</u>" means (a) with respect to the termination of this Agreement with respect to a Program pursuant to Sections 9.2(a), 9.2(b) or 9.2(d), the Program subject to such termination; and (b) with respect to termination of this Agreement in its entirety, both Programs.
 - 1.111 "Third Party" means any Person other than a Party or any of its Affiliates.
- 1.112 "Valid Claim" means (a) a claim of an issued patent that has not expired or been abandoned, or been revoked, held invalid or unenforceable by a patent office, court or other

governmental agency of competent jurisdiction in a final and non-appealable judgment (or judgment from which no appeal was taken within the allowable time period) or (b) a claim within a patent application that has not been revoked, cancelled, withdrawn, held invalid or abandoned [***].

- 1.113 "<u>Viable Compound</u>" means a JAK Licensed Compound, Potential JAK Back-Up Compound or JAK Candidate that has not failed to meet predetermined efficacy or activity criteria established by unanimous agreement of the JSC and where the patentability and freedom to operate of the JAK Licensed Compound, Potential JAK Back-Up Compound or JAK Candidate appear favorable.
- 1.114 "<u>Voting Stock</u>" means securities of any class or series of a corporation, limited liability company, association or other entity, the holders of which are ordinarily, in the absence of contingencies, entitled to vote generally in matters put before the shareholders or members of such corporation, limited liability company, association or other entity.
- 1.115 <u>Additional Definitions</u>. Each of the following definitions is set forth in the section of this Agreement indicated below:

<u>DEFINITION</u>	<u>SECTION</u>
13D Group Agreement Auditee Audit Rights Holder Audit Team Bankruptcy Code Breaching Party Buy-In Party Clinical Supply Agreement c-MET JDC c-MET Licensed Back-Up Compound c-MET Patent Rights CoC Party Co-Detailing Right Combination Product	11.6(b) Preamble 8.6(f) 8.6(f) 8.6(a) 2.4 9.2(b) 4.3(c) 5.1(b) 3.2 1.14 1.47 Exhibit H 6.3(a) 1.73(d)
Controlling Party	7.2(d)
[***] Development Budget Development Plan Disclosing Party Effective Date Exchange Act [***] Global Branding Strategy Global Safety Database	[***] 4.3(a)(iii) 4.2(a)(ii) 12.1 Preamble 11.6 [***] 6.5(a) 4.7(c)

GMP	5.1(b)(ii)
Group Company	1.9(a)
INCY0039 Patent Rights	1.107
Incyte	Preamble
Incyte Indemnified Parties	10.1(a)
[***]	[***]
Initial Development Plan	4.2(a)(ii)
JAK Candidate	4.5(a)
JAK JDC	3.2
JAK Licensed Back-Up Compound	1.60
JAK Mark	6.5(b)(ii)
JAK Patent Rights	1.47
JCC	3.2
JIPC	3.2
Joint c-MET IP	7.2(b)
Joint Development Activity	4.3(a)(iii)
Joint IP	7.1(b)
Joint JAK IP	1.107
JPT	3.2
JSC	3.1(a)
[***]	[***]
[***]	[***]
Non-Breaching Party	9.2(b)
Non-CoC Party	Exhibit H
Non-Controlling Party	7.2(d)
Notice	14.6
Novartis	Preamble
Novartis Indemnified Parties	10.2(a)
Novartis Information Rights	4.1(c)(i)
Novartis JAK Territory	1.82
Payments	8.7
[***]	[***]
Pharmacovigilance Agreement	4.7(c)
Potential JAK Back-Up Compound	4.5(b)
Promotional Plan	6.3(a)
Receiving Party	12.1
Royalty Term	8.3(c)
Severed Clause	14.13
SOPs	3.2(a)(ii)
Term	9.1
Third-Party Infringement	7.3(a)
UCC	6.3(b)(iii)

- 1.116 <u>Construction</u>. In construing this Agreement, unless expressly specified otherwise:
- (a) references to Sections, Exhibits and Schedules are to sections of, and schedules and exhibits to, this Agreement;

- (b) except where the context otherwise requires, use of either gender includes the other gender, and use of the singular includes the plural and vice versa;
- (c) headings and titles are for convenience only and do not affect the interpretation of this Agreement;
- (d) any list or examples following the word "including" shall be interpreted without limitation to the generality of the preceding words;
 - (e) except where the context otherwise requires, the word "or" is used in the inclusive sense;
 - (f) all references to "dollars" or "\$" herein shall mean U.S. Dollars; and
- (g) each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof.

In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions.

ARTICLE II

LICENSES

2.1 Rights Granted by Incyte to Novartis.

- (a) <u>c-MET License Grant</u>. Subject to the terms of this Agreement, Incyte hereby grants Novartis, during the Term, an exclusive (even as to Incyte and its Affiliates), royalty-bearing, non-transferable (except in accordance with Section 14.3) license, with the right to sublicense (subject to Section 2.3), under Incyte IP and Incyte's and its Affiliates' interests in Joint IP, to research, Develop, Commercialize, make, have made, use, offer for sale, sell and import c-MET Licensed Compounds and c-MET Licensed Products in the Novartis Territory in the c-MET Field.
- (b) JAK License Grant. Subject to the terms of this Agreement, Incyte hereby grants Novartis, during the Term, an exclusive (even as to Incyte and its Affiliates), royalty-bearing, non-transferable (except in accordance with Section 14.3) license, with the right to sublicense (subject to Section 2.3), under Incyte IP and Incyte's and its Affiliates' interests in Joint IP, to (i) research, Develop, Commercialize, make, have made, use, offer for sale, sell and import JAK Licensed Compounds and JAK Licensed Products in the Novartis JAK Territory in the JAK Field and (ii) research, Develop, make and have made JAK Licensed Compounds and JAK Licensed Products in the Incyte Territory for the sole purpose of using, offering for sale and selling JAK Licensed Products in, and importing JAK Licensed Compounds and JAK Licensed Products into, the Novartis JAK Territory in the JAK Field; provided however, that Novartis may not, directly or indirectly, conduct Clinical Trials or other clinical studies, including any investigator initiated studies, in the Incyte Territory without the prior approval of the JSC.

2.2 <u>Rights Granted by Novartis to Incyte.</u>

- (a) Subject to the terms of this Agreement, Novartis hereby grants Incyte, during the Term, a non-exclusive non-transferable (except in accordance with Section 14.3) license, with the right to sublicense (subject to Section 2.3), under Novartis IP, to: (i) research, Develop, Commercialize, make, have made, use, offer for sale, sell and import JAK Licensed Compounds and JAK Licensed Products in the JAK Field in the Incyte Territory; and (ii) research, Develop, make and have made JAK Licensed Compounds and JAK Licensed Products in the Novartis JAK Territory for the sole purpose of using, offering for sale and selling JAK Licensed Products in, and importing JAK Licensed Compounds and JAK Licensed Products into, the Incyte Territory in the JAK Field; provided however, that Incyte may not, directly or indirectly, conduct Clinical Trials or other clinical studies, including any investigator initiated studies, in the Novartis Territory without the prior approval of the JSC.
- (b) Subject to the terms of this Agreement, Novartis hereby grants Incyte, during the Term, a non-exclusive non-transferable (except in accordance with Section 14.3) license, with the right to sublicense (subject to Section 2.3), under Novartis Improvements to research, Develop, make, have made, use, offer for sale, sell and import JAK Licensed Compounds (as such compounds exist as of the Effective Date) and JAK Licensed Products (as such compounds exist as of the Effective Date) in (i) topical formulations outside the JAK Field worldwide; and (ii) non-oral formulations for ophthalmic Indications worldwide.
- Sublicense Rights. Each Party shall have the right to grant sublicenses within the scope of the 2.3 licenses under Section 2.1 or 2.2, as applicable, solely to its Affiliates and to Third Parties that are conducting collaborative research, Development and/or Commercialization activities with such Party or its Affiliates with respect to Licensed Compounds and Licensed Products; provided that any sublicense granted to Third Party collaborators under this Agreement shall be pursuant to a written agreement that subjects such sublicensee to all relevant restrictions and limitations set forth in this Agreement, including the confidentiality provisions of ARTICLE XII. If either Party grants a sublicense to a Third Party as permitted by this Section 2.3, then such Party shall provide the other Party prompt written notice thereof and shall provide the other Party with an executed copy of any such sublicense (redacted as necessary to protect confidential or commercially sensitive information). Except as otherwise agreed by the Parties in writing, each Party shall be jointly and severally responsible with its sublicensees to the other Party for failure by its sublicensees to comply with this Agreement. In the event that (a) the sublicensee has failed to cure a material breach or take such steps as would be considered reasonable to effectively cure such breach under any such sublicense within [***] after notice of such breach and (b) such material breach also constitutes a breach of this Agreement, the sublicensor shall terminate the sublicense at the request of the Party that is not the sublicensor.
- 2.4 Section 365(n) of The Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement, including the licenses granted under this ARTICLE II and the rights granted under Section 4.3(d), are and will otherwise be deemed to be for purposes of Section 365(n) of the United States Bankruptcy Code (Title 11, U.S. Code), as amended (the "Bankruptcy Code"), licenses of rights to "intellectual property" as defined in Section 101(35A) of the Bankruptcy Code. The Parties will retain and may fully exercise all of their respective rights and elections under the Bankruptcy Code. Each Party agrees that the other Party, as licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the Bankruptcy Code or any other provisions of applicable Law outside the

United States that provide similar protection for "intellectual property." The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party under the Bankruptcy Code or analogous provisions of applicable Law outside the United States, the other Party will be entitled to a complete duplicate of (or complete access to, as the other (non-bankrupt) Party deems appropriate) such intellectual property and all embodiments of such intellectual property, which, if not already in such Party's possession, will be promptly delivered to it upon such Party's written request thereof. Any agreements supplemental hereto will be deemed to be "agreements supplementary to" this Agreement for purposes of Section 365(n) of the Bankruptcy Code.

2.5 Retained Rights.

- (a) No Implied Licenses or Rights. Except as expressly provided in Section 2.1, and subject to Section 2.6, all rights in and to the Incyte IP, Incyte's and its Affiliates' interests in Joint IP and any other Patent Rights or Know-How of Incyte and its Affiliates, are hereby retained by Incyte and its Affiliates. Except as expressly provided in Section 2.2, and subject to Section 2.6, all rights in and to the Novartis IP, and Novartis' and its Affiliates' interests in Joint IP and any other Patent Rights or Know-How of Novartis and its Affiliates, are hereby retained by Novartis and its Affiliates.
- (b) <u>Other Retained Rights</u>. Notwithstanding the exclusive licenses granted to Novartis pursuant to Section 2.1, Incyte retains the right to practice under the Incyte IP and Joint IP to:
- (i) perform (and to sublicense Third Parties to perform) its obligations under this Agreement and any Supply Agreement, including for the purpose of performing its activities in connection with the Clinical Trials and any related manufacture of Drug Product or Drug Substance; and
- (ii) make, have made, use, and test Licensed Compounds solely for internal research purposes. For purposes of clarity, the license granted to Novartis in Section 2.1 shall not require Incyte to remove any Licensed Compounds from Incyte's compound library.

(c) <u>JAK2 Inhibitor Compounds that are not JAK Licensed Compounds</u>.

- (i) For purposes of clarity, the Parties acknowledge that the license grant in Section 2.1 does not include any rights under Incyte IP and Joint IP to research, Develop, Commercialize, make, have made, use, offer for sale, sell and import JAK2 Inhibitor Compounds that are not JAK Licensed Compounds, including Incyte's compound INCB028050 and, subject to Section 2.6(b)(i), Incyte retains all rights to practice under the Incyte IP and Joint IP to research, Develop, Commercialize, make, have made, use, offer for sale, sell and import JAK2 Inhibitor Compounds that are not JAK Licensed Compounds (including Incyte's compound INCB028050) for all uses worldwide.
- (ii) Notwithstanding Sections 2.5(c)(i) and 4.5, Incyte shall not research, Develop, Commercialize, make, have made, use, offer for sale, sell and import, nor will

it allow its Affiliates or Third Party licensees to research, Develop, Commercialize, make, have made, use, offer for sale, sell and import, INCB028050 in the JAK Field.

2.6 Non-Compete.

(a) <u>c-MET Inhibitor Compounds and c-MET Licensed Compounds</u>.

- (i) During the c-MET Program Term, Incyte agrees not to, and shall cause its Affiliates not to, directly or indirectly, including through any ownership interest in any other entity (other than through an ownership interest of [***] or less of a public company), Develop or Commercialize any c-MET Inhibitor Compounds in any field in any country. Notwithstanding the foregoing, nothing in this Agreement shall prohibit Incyte or its Affiliates from Developing or Commercializing any c-MET Excluded Compound in any field anywhere in the world.
- (ii) During the c-MET Program Term, Novartis agrees not to, and shall cause its Affiliates not to, directly or indirectly, including through any ownership interest in any other entity (other than through an ownership interest of [***] or less of a public company), conduct any Randomized Clinical Trial with, or Commercialize, any c-MET Inhibitor Compound that is not a c-MET Licensed Compound. Notwithstanding the foregoing, nothing in this Agreement shall prohibit Novartis or its Affiliates from Developing or Commercializing any c-MET Excluded Compound in any field anywhere in the world.
- (iii) If no Licensed c-MET Inhibitor Compound has been Commercialized by Novartis under this Agreement and Novartis or its Affiliates commence a Randomized Clinical Trial of any c-MET Inhibitor Compound other than a c-MET Excluded Compound within [***] after the termination of Novartis' license under Section 2.1(a), then Novartis shall pay Incyte a [***] royalty on Net Sales of such c-MET Inhibitor Compound until the expiration of the relevant Patent Rights that Cover such c-MET Inhibitor Compound. For purposes of clarity, nothing in this Section 2.6(a)(iii) shall be construed to extend the license grants to Novartis under Section 2.1 to Cover such c-MET Inhibitor Compound.

(b) <u>JAK2 Inhibitor Compounds and JAK Licensed Compounds</u>.

- (i) During the JAK Program Term, Incyte agrees not to, and shall cause its Affiliates not to, directly or indirectly, including through any ownership interest in any other entity (other than through an ownership interest of [***] or less of a public company), Develop or Commercialize any JAK2 Inhibitor Compounds in the JAK Field anywhere in the world, other than as expressly permitted under this Agreement (including Section 4.5). Notwithstanding the foregoing, nothing in this Agreement shall prohibit Incyte or its Affiliates from Developing or Commercializing any JAK Excluded Compound in any field anywhere in the world.
- (ii) During the JAK Program Term, Novartis agrees not to, and shall cause its Affiliates not to, directly or indirectly, including through any ownership interest in any other entity (other than through an ownership interest of [***] or less of a public

company), Develop or Commercialize any JAK2 Inhibitor Compounds in the JAK Field anywhere in the world, other than as expressly permitted under this Agreement (including Section 4.5). Notwithstanding the foregoing, nothing in this Agreement shall prohibit Novartis or its Affiliates from Developing or Commercializing any JAK Excluded Compound in any field anywhere in the world.

- (iii) For the avoidance of doubt, neither Novartis nor its Affiliates will Develop or Commercialize any JAK Licensed Compounds anywhere in the world for the treatment of any Inflammatory Disease.
- (iv) Nothing herein shall limit Novartis' or its Affiliates' rights to Develop or Commercialize any product outside the JAK Field containing a compound whose primary activity is related to JAK3 as Developed or Commercialized by Novartis or its Affiliates or sublicensees [***].
- (v) During the JAK Program Term, Incyte may not Develop or Commercialize JAK Licensed Compounds outside the JAK Field except that Incyte may Develop and Commercialize JAK Licensed Compounds for use in (A) topical formulations outside the JAK Field worldwide, and (B) non-oral formulations for ophthalmic Indications anywhere in the world.
- JSC Designation as Excluded Compound. In the event that either Party identifies a c-MET Inhibitor Compound (that is not a c-MET Excluded Compound under Section 1.11(a)) or a JAK2 Inhibitor Compound (that is not a JAK Excluded Compound under Section 1.57(a)) that such Party reasonably believes would not compete with a Licensed Product, including because (i) such compound, when tested in vivo, is shown to have its pharmacological effect via a mechanism other than via c-MET or JAK2, respectively, or (ii) such compound would be reasonably expected to serve a different and distinct patient population compared to existing Licensed Products, then such Party may schedule a discussion on this topic for the next scheduled JSC meeting. At such JSC meeting, such Party shall present the data supporting its contention that such compound would reasonably be expected not to compete with existing Licensed Products and therefore formally request that such compound be designated either a c-MET Excluded Compound or a JAK Excluded Compound. The JSC shall, no later than the next scheduled JSC meeting, decide whether to approve such request, which decision shall be approved solely by unanimous agreement of the JSC, provided that the Parties shall consider such decisions in good faith on the merits of whether clause (i) or (ii) above have been satisfied. In the event that either Party identifies a c-MET Inhibitor Compound or a JAK2 Inhibitor Compound that such Party reasonably believes would serve a different and distinct patient population compared to the respective Licensed Product but also is expected to serve some portion of the patient population served by existing Licensed Products, then in addition to presenting the relevant data about that compound, the requesting Party shall also propose an appropriate royalty rate that would fairly compensate the other Party for the potential royalties that it would be expected to forego based on the likely use of such compound in lieu of the relevant Licensed Product.

ARTICLE III

GOVERNANCE

3.1 <u>Joint Steering Committee</u>.

- Establishment. The Parties shall establish a joint steering committee ("JSC") within thirty (a) (30) days after the Effective Date that will have the responsibility for the overall coordination and oversight of the Parties' activities under this Agreement. As soon as practicable following the Effective Date (but in no event more than thirty (30) days following the Effective Date), each Party shall designate its initial three (3) representatives on the JSC. Each Party's representatives and any substitute for a representative shall be bound by the obligations of confidentiality set forth in ARTICLE XII. A representative from Novartis shall act as the chairperson of the JSC. The chairperson shall not have any greater authority than any other representative on the JSC and shall conduct the following activities of the JSC: (i) calling meetings of the JSC; (ii) preparing and issuing minutes of each such meeting within thirty (30) days thereafter; (iii) ensuring that any decision-making delegated to the JSC is carried out in accordance with Section 3.5; and (iv) preparing and circulating an agenda for the upcoming meeting: provided that the chairperson shall include any agenda items proposed by Incyte. Each Party shall be free to change its representatives on notice to the other or to send a substitute representative to any JSC meeting; provided, however, that each Party shall ensure that at all times during the existence of the JSC, its representatives on the JSC are appropriate in terms of expertise and seniority (including at least one member of senior management) for the then-current stage of Development and Commercialization of the Licensed Products and have the authority to bind such Party with respect to matters within the purview of the JSC.
- (b) <u>Responsibilities</u>. The JSC shall have responsibility for: (i) the general oversight of the collaboration, including approval of Development Budgets; (ii) periodic review of the overall goals and strategy of the Programs; (iii) attempting to resolve any disputes and to consider any other issues brought to its attention by the Parties; (iv) establishing the efficacy and activity criteria for Viable Compounds in accordance with Section 1.113; and (v) performing such other functions as appropriate to further the purposes of this Agreement, as mutually agreed upon by the Parties in writing.
- 3.2 <u>Subcommittees</u>. The JSC may establish and disband such subcommittees as deemed necessary by the JSC. Each such subcommittee shall consist of the same number of representatives designated by each Party, which number shall be mutually agreed by the Parties. Each Party shall be free to change its representatives on notice to the other or to send a substitute representative to any subcommittee meeting; <u>provided</u>, <u>however</u>, <u>that</u> each Party shall ensure that at all times during the existence of any subcommittee, its representatives on such subcommittee are appropriate in terms of expertise and seniority for the then-current stage of Development and Commercialization of the Licensed Product in the Field in the Territory and have the authority to bind such Party with respect to matters within the purview of the relevant subcommittee. Each Party's representatives and any substitute for a representative shall be bound by the obligations of confidentiality set forth in ARTICLE XII. Except as expressly provided in this Agreement, no subcommittee shall have the authority to bind the Parties hereunder and each subcommittee shall report to, and any decisions shall be made by, the JSC. The initial subcommittees of the JSC will

be the Joint c-MET Development Committee ("<u>c-MET JDC</u>"), Joint JAK Development Committee ("<u>JAK JDC</u>"), Joint Program Team ("<u>JPT</u>"), the Joint Commercialization Committee ("<u>JCC</u>") and the Joint Intellectual Property Committee ("<u>JIPC</u>")

(a) <u>Joint c-MET Development Committee</u>.

- (i) The c-MET JDC will have the responsibility for the overall coordination and oversight of the c-MET Program in the c-MET Field in the Novartis Territory. As soon as practicable following the Effective Date (but in no event more than thirty (30) days following the Effective Date), each Party shall designate its initial three (3) representatives on the c-MET JDC. Novartis shall appoint a person from among its representatives on the c-MET JDC to serve as the chairperson of the c-MET JDC. The chairperson shall not have any greater authority than any other representative on the c-MET JDC and shall conduct the following activities of the c-MET JDC: (A) calling meetings of the c-MET JDC; (B) preparing and issuing minutes of each such meeting within thirty (30) days thereafter; (C) preparing and circulating an agenda for the upcoming meeting; provided that the chairperson shall include any agenda items proposed by Incyte; and (D) ensuring that any decision-making delegated to the c-MET JDC is carried out in accordance with Section 3.5.
- (ii) The c-MET JDC shall have responsibility for (A) overseeing the initial transfer of information and designated activities from Incyte to Novartis relating to the c-MET Program; (B) overseeing the subsequent flow and transfer of information between the Parties related to the c-MET Program pursuant to Section 4.1(b); (C) overseeing, reviewing and coordinating the c-MET Program; (D) subject to unanimous approval by the JSC, defining the exact assay conditions for c-MET testing activity and overseeing the exchange of standard operating procedures ("SOPs") in connection with the same; (E) approving c-MET Licensed Back-Up Compound(s) selected by Novartis for further Development; and (F) as applicable, overseeing, reviewing and coordinating the work being done under the Development Plans.

(b) <u>Joint JAK Development Committee</u>.

- (i) The JAK JDC will have the responsibility for the overall coordination and oversight of the JAK Program in the JAK Field worldwide. As soon as practicable following the Effective Date (but in no event more than thirty (30) days following the Effective Date), each Party shall designate its initial three (3) representatives on the JAK JDC. Novartis and Incyte shall each appoint a person from among its representatives on the JAK JDC to serve as the co-chairperson of the JAK JDC. The co-chairpersons shall not have any greater authority than any other representative on the JAK JDC and shall conduct the following activities of the JAK JDC: (A) calling meetings of the JAK JDC; (B) preparing and issuing minutes of each such meeting within thirty (30) days thereafter; (C) preparing and circulating an agenda for the upcoming meeting; and (D) ensuring that any decision-making delegated to the JAK JDC is carried out in accordance with Section 3.5.
- (ii) The JAK JDC shall have responsibility for (A) overseeing the initial transfer of information and designated activities from Incyte to Novartis relating to the JAK Program; (B) overseeing the subsequent flow and transfer of information between the Parties related to the JAK Program pursuant to Section 4.1(b); (C) overseeing, reviewing and

coordinating the JAK Program; (D) subject to unanimous approval by the JSC, defining the exact assay conditions for JAK testing activity and overseeing the exchange of SOPs in connection with the same; (E) approving the JAK Licensed Back-Up Compound(s) selected by the JPT for further Development; (F) as applicable, overseeing, reviewing and coordinating the work being done under the Development Plans; and (G) selecting Indications for Development for the JAK Program.

(c) <u>Joint Program Team</u>.

- (i) The JPT shall be the principal organization through which the Development of the JAK Program is planned, administered and evaluated. As soon as practicable following the Effective Date (but in no event more than thirty (30) days following the Effective Date), each Party shall designate its initial three (3) representatives on the JPT. The JPT shall be composed of representatives from Incyte's and Novartis's various functional groups involved in Development of the JAK Licensed Product, namely Clinical Development and Medical Affairs, Drug Regulatory Affairs, Exploratory Development, Marketing and Technical Research and Development. Novartis and Incyte shall each appoint a person from among its representatives on the JPT to serve as the co-chairperson of the JPT. The co-chairpersons shall not have any greater authority than any other representative on the JPT and shall conduct the following activities of the JPT: (A) calling meetings of the JPT; (B) preparing and issuing minutes of each such meeting within thirty (30) days thereafter; (C) preparing and circulating an agenda for the upcoming meeting; and (D) ensuring that any decision-making delegated to the JPT is carried out in accordance with Section 3.5.
- (ii) The JPT shall have responsibility for: (A) selecting the JAK Licensed Back-Up Compounds for approval by the JAK JDC; (B) reviewing the Development Plans prepared by Novartis pursuant to Section 4.2(a)(ii); (C) amending the Development Plan to include any Joint Development Activities in accordance with Section 4.3(a); and (D) overseeing the overall JAK Program.

(d) <u>Joint Commercialization Committee</u>.

- (i) The JCC shall oversee Commercialization of JAK Licensed Products in the Field worldwide. As soon as practicable following the Effective Date (but in no event more than thirty (30) days following the Effective Date), each Party shall designate its initial three (3) representatives on the JCC. The JCC shall be composed of appropriate and key executives of Novartis together with an equal number of appropriate and key executives from Incyte. Novartis and Incyte shall each appoint a person from among its representatives on the JCC to serve as the co-chairperson of the JCC. The co-chairpersons shall not have any greater authority than any other representative on the JCC and shall conduct the following activities of the JCC: (A) calling meetings of the JCC; (B) preparing and issuing minutes of each such meeting within thirty (30) days thereafter; (C) preparing and circulating an agenda for the upcoming meeting; and (D) ensuring that any decision-making delegated to the JCC is carried out in accordance with Section 3.5.
- (ii) The JCC shall be responsible for: (A) overseeing, reviewing and coordinating the Commercialization of JAK Licensed Products in the Field worldwide; (B)

developing and overseeing the Global Branding Strategy; (C) setting overall strategic objectives and plans related to Commercialization of JAK Licensed Products in the Field worldwide; (D) reviewing, commenting on and approving the Promotional Plan; (E) reviewing Commercialization issues for JAK Licensed Products in the Field in the Novartis Territory that will have an impact on Commercialization of JAK Licensed Products in the Field in the Incyte Territory that will have an impact on Commercialization of JAK Licensed Products in the Field in the Novartis Territory; (G) providing a forum for the Parties to discuss the Commercialization of JAK Licensed Products in the Field worldwide; and (H) such other responsibilities as may be assigned to the JCC pursuant to this Agreement or as may be mutually agreed upon by the Parties from time to time.

(e) <u>Joint Intellectual Property Committee</u>.

- (i) The JIPC shall have the responsibility for oversight relating to the filing, prosecution and maintenance of JAK Patent Rights under Section 7.2(c). As soon as practicable following the Effective Date (but in no event more than thirty (30) days following the Effective Date), each Party shall designate its two (2) representatives on the JIPC. A representative of Incyte shall act as the chairperson of the JIPC. The chairperson shall not have any greater authority than any other representative on the JIPC and shall conduct the following activities of the JIPC: (A) calling meetings of the JIPC at least every quarter; (B) preparing and issuing minutes of each such meeting within thirty (30) days thereafter; (C) preparing and circulating an agenda for the upcoming meeting, provided that the chairperson shall include any agenda items proposed by Novartis; and (D) ensuring that any decision-making delegated to the JIPC is carried out in accordance with Section 3.5.
- (ii) The JIPC shall have responsibility for the following with respect to JAK Patent Rights under Section 7.2(c): (A) on an application by-application basis, determining what claims will be prosecuted and what claims or applications will be abandoned; and (B) conducting periodic portfolio reviews to maximize the strength of the patent portfolio and cost effectiveness of the preparation, filing, prosecution and maintenance of JAK Patent Rights.
- (iii) Subject to JIPC discussions, Incyte shall promptly file any U.S. priority applications for patent rights covering the JAK Licensed Back-Up Compounds.

3.3 <u>Committee Meetings</u>.

(a) Commencing in the first Calendar Quarter of 2010, the JSC and each of the subcommittees shall each hold at least one (1) meeting per Calendar Quarter at such times during such Calendar Quarter as the chairperson elects to do so. Except where a Party fails to appoint a member or members to the JSC or its subcommittees or fails to participate in meetings of the JSC or its subcommittees pursuant to Section 3.6, meetings of the JSC and the subcommittees, respectively, shall be effective only if at least one (1) representative of each Party is present or participating. The JSC and its subcommittees may meet either (i) in person at either Party's facilities or at such locations as the Parties may otherwise agree or (ii) by audio or video teleconference; provided that no less than one (1) meeting during each Calendar Year shall be conducted in person. Other representatives of each Party involved with the Licensed Product

may attend meetings as non-voting participants, subject to the confidentiality provisions set forth in ARTICLE XII. Additional meetings of the JSC and its subcommittees may also be held with the consent of each Party, or as required under this Agreement, and neither Party shall unreasonably withhold its consent to hold such additional meetings. Each Party shall be responsible for all of its own expenses incurred in connection with participating in all such meetings.

- (b) At the first meeting of each of the JSC, c-MET JDC and JAK JDC, such committee shall establish, as applicable, the efficacy and activity criteria for Viable Compounds, the assay conditions for c-MET testing activity and the assay conditions for JAK testing activity.
- 3.4 <u>Authority</u>. The JSC and any subcommittee shall have only the powers assigned expressly to it in this ARTICLE III and elsewhere in this Agreement, and shall not have any power to amend, modify or waive compliance with this Agreement. In furtherance thereof, each Party shall retain the rights, powers and discretion granted to it under this Agreement and no such rights, powers or discretion shall be delegated or vested in the JSC or any subcommittee unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing.

3.5 Decisions.

- (a) <u>Initial Dispute Resolution Procedures</u>. Subject to the provisions of this Section 3.5, actions to be taken by the JSC and each of the subcommittees shall be taken only following a unanimous vote, with each Party having one (1) vote. If any subcommittee fails to reach unanimous agreement on a matter before it for decision for a period in excess of thirty (30) days, the matter shall be referred to the JSC.
- (b) <u>Final Decision-Making</u>. If the JSC fails to reach unanimous agreement on a matter before it for decision for a period in excess of thirty (30) days, the following provisions shall apply:
- matter involving (A) the Development or Commercialization of any c-MET Licensed Compound and c-MET Licensed Product (including selection of Indications); (B) the Development or Commercialization of any JAK Licensed Compound or JAK Licensed Product in the JAK Field (including selection of Indications) in the Novartis JAK Territory; (C) whether a Potential JAK Back-Up Compound is Developed in the JAK Field in the Novartis JAK Territory in a Randomized Clinical Trial and beyond in accordance with Section 4.5 and (D) any matter within the scope of responsibility of the JIPC pertaining to the Secondary JAK Patent Rights in the Novartis JAK Territory. Incyte shall have the right to appeal any such decision of the JSC to the Novartis Executive Officer or a designee of the Novartis Executive Officer with decision-making authority for resolution. In such case, the Novartis Executive Officer or designee shall have the final decision-making authority on such issue.
- (ii) The JSC representatives appointed by Incyte shall have the deciding vote on any matter involving (A) the Development or Commercialization of JAK Licensed Compound or JAK Licensed Product in the JAK Field (including selection of

Indications) in the Incyte Territory; (B) the Development activities described in Section 4.2(b) until such time as Novartis assumes responsibility for such activities; (C) whether a Potential JAK Back-Up Compound is Developed in the JAK Field in the Incyte Territory in a Randomized Clinical Trial and beyond in accordance with Section 4.5; and (D) any matter within the scope of responsibility of the JIPC pertaining to (x) the INCY0039 Patent Rights worldwide and (y) Secondary JAK Patent Rights in the Incyte Territory. Novartis shall have the right to appeal any such decision of the JSC to the Incyte Executive Officer or a designee of the Incyte Executive Officer with decision-making authority for resolution. In such case, the Incyte Executive Officer or designee shall have the final decision-making authority on such issue.

- (c) Exceptions. Notwithstanding the foregoing, neither Party shall exercise its right to finally resolve a dispute pursuant to Section 3.5(b): (i) in a manner that excuses such Party from any of its obligations specifically enumerated under this Agreement, (ii) in a manner that negates any consent rights or other rights specifically allocated to the other Party under this Agreement; (iii) to increase Development Costs for the other Party for a given Calendar Year by more than [***] above the then current Development Budget for the Calendar Year; (iv) to resolve any dispute regarding whether a Party may conduct Development or Commercialization activities in the other Party's territory; (v) to establish FTE Rates for any Development activities; (vi) to resolve any dispute regarding whether a milestone event set forth in Section 8.2 has been achieved; or (vii) in a manner that would require the other Party to perform any act that it reasonably believes to be inconsistent with any Law or any approval, order, policy or guidelines of a Regulatory Authority.
- (d) <u>Unanimous Agreement</u>. If the provisions of this Agreement (other than Section 3.5(a)) specify that unanimous agreement of the JSC or any subcommittee is required for any matter, then neither Party may exercise a deciding vote under the provisions of Section 3.5(b) with respect to such matter.

3.6 <u>Committee Membership.</u>

- (a) <u>Appointment is a Right</u>. The appointment of members of the JSC and any subcommittees of the JSC is a right of each Party and not an obligation and shall not be a "deliverable" as referenced in any existing authoritative accounting literature. Each Party shall be free to determine not to appoint members to the JSC or any subcommittee of the JSC.
- (b) <u>Consequence of Non-Appointment</u>. If a Party does not appoint members of the JSC or any subcommittee of the JSC, it shall not be a breach of this Agreement, nor shall any consideration be required to be returned, and unless and until such members are appointed, the Party that has made the requisite appointments may unilaterally discharge the roles of the JSC or any subcommittee thereof for which members were not appointed, <u>provided that</u> (i) neither Party shall unilaterally discharge the roles of the JSC or any subcommittee thereof as permitted under this Section 3.6(b) unless the other Party has not appointed any members within thirty (30) days after the first Party has completed its appointment of its members, and (ii) the responsibility of the JIPC shall be carried out through bilateral meetings of representatives of Incyte and Novartis, with any disputed matters resolved in accordance with Sections 3.5(b)(i)(D) and 3.5(b)(ii)(D).

ARTICLE IV

DEVELOPMENT; REGULATORY MATTERS

4.1 Information Transfer.

- (a) <u>Initial Information Transfer to Novartis</u>. (i) Within a reasonable period not to exceed [***] after the Effective Date, Incyte shall make available to Novartis, in a mutually-agreed upon format and without further financial consideration, the material clinical data and manufacturing Know-How included in the Incyte Know-How and that is described in <u>Exhibit B</u>, and (ii) from the Effective Date through [***], Incyte shall make its relevant scientific and technical personnel reasonably available to Novartis at Incyte's offices, at reasonable times during Incyte's normal business hours and upon reasonable prior notice, to answer any questions or provide instruction as reasonably requested by Novartis concerning the information delivered pursuant to this Section 4.1.
- (b) <u>Continuing Information Transfer</u>. On an ongoing basis during the JAK Program Term, on a [***] basis (or such more frequent basis as determined by the JAK JDC), each Party shall make available to the other Party, in a mutually agreed-upon format, (i) material clinical data, (ii) manufacturing Know-How included in the Incyte Know-How or Novartis Know-How, as applicable, (iii) software tools used by Incyte or Novartis, as applicable, to analyze data arising from the JAK Program, and (iv) such other aspects of the Incyte Know-How or Novartis Know-How, as applicable, as shall be reasonably requested by the other Party.

(c) <u>Access to Information Under Incyte Clinical and Supply Agreements.</u>

- (i) As promptly as practicable following the Effective Date, Incyte [***], "Novartis Information Rights"). Without limiting the foregoing, Incyte [***] the Novartis Information Rights. Incyte shall [***]. If [***] the Novartis Information Rights [***], Novartis shall [***]. Incyte shall [***] to the extent [***] the Novartis Information Rights [***].
- (ii) Subject to the exception set forth in subsection (iv) and unless and to the extent that Novartis previously agrees in writing, Incyte shall not enter into a [***],

in each case [***], unless such [***]. As used above, the term [***].

- (iii) Novartis shall exercise the Novartis Information Rights only under circumstances in which specified Incyte Know-How that would be encompassed within the Novartis Information Rights (including information that would be obtained through any audit, inspection, collection and retention of physical samples, interview of personnel and attendance and participation at meetings) has not been provided by Incyte pursuant to Section 4.1(b) and Novartis has requested such information in writing but has been unable to obtain such information promptly through exercise of its other rights hereunder. In the event that Novartis obtains Incyte Know-How through the exercise of Novartis Information Rights, Novartis shall limit its use of such Incyte Know-How to the JAK Program in the JAK Field and in the Novartis JAK Territory.
- (iv) The provisions of subsection (ii) shall not apply to any Incyte Know-How arising out of agreements with Third Parties to the extent relating to a Clinical Trial or other Development activities that are the subject of a proposal by Incyte under Section 4.3(a) on which Novartis elects not to collaborate with Incyte, unless and until Novartis exercises its buy-in rights with respect to such Clinical Trial or Development activity under Section 4.3(c).
- (d) <u>Software Source Code.</u> Following the Effective Date, Incyte shall upon request by Novartis and in any event no less frequently than every [***] transfer to Novartis any Software Source Code that has not previously been provided to Novartis, including updates and bug fixes to previously provided Software Source Code.
- (e) <u>Right of Reference or Use</u>. Incyte hereby grants to Novartis, solely for the purposes set forth in this Agreement, a Right of Reference or Use to any and all Regulatory Documentation Controlled by Incyte relating to Licensed Products and existing as of the Effective Date or generated from any Clinical Trial commenced by Incyte prior to the Effective Date, and agrees to sign, and cause its Affiliates to sign, any instruments reasonably requested by Novartis in order to effect such grant. Notwithstanding the foregoing, nothing in this Section 4.1 is intended to imply the existence of any particular data, information, drug master file or other Regulatory Documentation.
- (f) <u>Applicability of Bankruptcy Code</u>. For the avoidance of doubt, rights granted under this ARTICLE IV shall be deemed to be license of rights to "intellectual property" as defined in Section 101 (35A) of the Bankruptcy Code and shall otherwise be subject to Section 2.4.
 - 4.2 <u>Conduct of Development Activities</u>.

(a) <u>Generally</u>.

- (i) From and after the Effective Date, (A) Novartis will, subject to the terms of this Agreement, be responsible, at its expense, for the Development of (1) the c-MET Licensed Products in the c-MET Field in the Novartis Territory and (2) the JAK Licensed Products in the JAK Field in the Novartis JAK Territory; and (B) Incyte will remain responsible, at its expense, for the Development of the JAK Licensed Products in the JAK Field in the Incyte Territory. While the Parties may choose, at their sole discretion, to work together on particular projects, except as otherwise provided in this Agreement, the Parties will operate independently in their activities for their respective Development and Commercialization of the Licensed Products, but will provide access to certain information related to the Development of c-MET Licensed Products to the c-MET JDC, the JSC and to each other as expressly described in this Agreement and certain information related to the Development and Commercialization of JAK Licensed Products to the JAK JDC, the JPT, the JCC, the JSC and to each other as expressly described in this Agreement.
- (ii) The Development of Licensed Products shall be governed by Development plans that describe the proposed overall program of Development for c-MET Licensed Products and JAK Licensed Products (the "Development Plans"). The initial Development Plans are attached hereto as Exhibits D-1 and D-2 respectively (collectively, the "Initial Development Plan"). Novartis shall have the sole right and responsibility for preparing the Development Plan for each Licensed Product in the Field in the Novartis Territory. Except as otherwise provided in this Agreement (including as provided in Sections 4.2(b) and 4.3), with respect to Licensed Product in the Field in the Novartis Territory, all decisions with respect to the creation, modification and implementation of the Initial Development Plan, all other Development Plans and all Development activities shall be made by Novartis in its sole discretion; provided that Novartis will present a draft Development Plan for each Licensed Product and any material changes to the Initial Development Plan to, as applicable, the c-MET JDC or the JAK JDC and will give due consideration to any comments of Incyte thereto.
- (iii) Notwithstanding the foregoing, prior to commencing any Clinical Trial or other clinical study as part of the JAK Program, the Party that proposes to conduct such Clinical Trial or other clinical study shall first submit to the JPT the proposed protocol for such proposed Clinical Trial or clinical study and a written summary, in a form mutually agreed by the Parties, of such Clinical Trial or clinical study for review by the JPT; provided that neither Party may proceed with such Clinical Trial or clinical study if the other Party reasonably determines that the Clinical Trial or clinical study is reasonably likely to have a material adverse impact on the Development and/or Commercialization of JAK Licensed Products in its territory. Notwithstanding the foregoing, any disputes regarding whether an activity is reasonably likely to have a material adverse impact on the Development and/or Commercialization of JAK Licensed Products in a Party's territory shall be resolved in accordance with Section 3.5.
- (iv) Novartis shall use Commercially Reasonable Efforts to (A) conduct the studies and Development activities described in Exhibit D; and (B) Develop Licensed Compounds and Licensed Products in accordance with the applicable Development Plan.

- (v) Incyte shall use Commercially Reasonable Efforts to conduct study 351 in accordance with the protocol existing on the Effective Date.
- (b) <u>Specific Incyte c-MET Licensed Compound Development Responsibilities</u>. Notwithstanding anything to the contrary above, Incyte will be responsible and shall bear all costs for the conduct of the studies described in <u>Exhibit E</u>. For the avoidance of doubt, Novartis shall be responsible for conducting and shall bear all costs for all c-MET Development activities other than the studies described in <u>Exhibit E</u> and as provided in Section 4.4.

(c) <u>Studies 352 and 351</u>.

- The Parties acknowledge that (A) Incyte shall be responsible for conducting and shall (i) bear the Out-of-Pocket Costs for the toxicology studies as described in Exhibit F-1; (B) Novartis shall bear the Out-of-Pocket Costs for the toxicology studies as described in Exhibit F-1; and (C) Novartis shall be responsible for conducting and shall bear all Out-of-Pocket Costs for the Clinical Trial as described in Exhibit F-2, in addition to all Development Costs incurred by Novartis with respect to study 352 after the Effective Date of the Agreement. A Party seeking reimbursement of Out-of-Pocket Costs hereunder shall submit an itemized invoice together with reasonable back-up documentation, and the other Party shall pay such invoice within [***] of receipt. Each Party shall have the right to possess, retain and use all clinical data and related Regulatory Documentation Controlled by either Party and generated in the course of studies 352 and 351 (which studies are described in Exhibit D and for which the costs are described in Exhibit F) in order to Develop, obtain Regulatory Approval for and Commercialize Licensed Product in the Field in such Party's territory, in accordance with the terms of this Agreement. Each Party shall disclose to the other Party on a quarterly basis (and without further financial consideration) all clinical data (including the data from interim reviews), internal and external reports, and related Regulatory Documentation Controlled by such Party and generated in the course of such Clinical Trials and hereby grants to the other Party a Right of Reference or Use to any and all such clinical data, reports and Regulatory Documentation, and agrees to sign, and cause its Affiliates to sign, any instruments reasonably requested by such other Party in order to effect such grant.
- (ii) Incyte shall make available to Novartis, at Novartis' expense, all material clinical data generated in the course of study 351 as required by Novartis to support Novartis' registration of INCB018424 for the Indication of Myelofibrosis as well as for any subsequent needs related to the Development of JAK Licensed Compounds, including safety updates, and responses to requests from Regulatory Authorities, and Novartis shall make available to Incyte, at Incyte's expense, all material clinical data generated in the course of study 352 as required by Incyte to support Incyte's registration of INCB018424 for the Indication of Myelofibrosis as well as for any subsequent needs related to the Development of JAK Licensed Compounds, including safety updates, and responses to requests from Regulatory Authorities. [***]. Incyte shall provide Novartis

with at least [***] prior notice from the date of data cut-off. Novartis shall provide such data set within [***] following the date of data cut-off and shall also provide Incyte with [***]. At its own discretion, Novartis may also choose to provide by this same date, the Tables, Listings and Figures for such study, provided that all analyses defined in the protocol have been performed as defined in such study's Statistical Analysis Plan. The Statistical Analysis Plan for study 352 shall be the responsibility of Novartis, but may be reviewed upon request by Incyte. The Statistical Analysis Plan for study 351 shall be the responsibility of Incyte, but may be reviewed upon request by Novartis. Unless otherwise agreed by both Parties, Incyte shall provide to Novartis a final clinical study report of Study 351 within [***] of the last patient's last visit to be included in the database for the clinical study report and unless otherwise agreed by both Parties, Novartis shall provide to Incyte a final clinical study report of Study 352 within [***] of the last patient's last visit to be included in the database for the clinical study report. Following submission to Regulatory Authorities, if the Regulatory Authority requests a safety update, the Party providing such data set shall provide an electronic data set to the requesting Party at the requesting Party's cost and expense not more than [***] days after receipt of a written request from the requesting Party.

4.3 <u>Development Activity Proposals</u>.

(a) <u>Joint Development Activities</u>.

- (i) Either Party may at any time submit to the JPT a proposal to collaborate with the other Party to conduct Clinical Trials or other Development activities in connection with the Development of a JAK Licensed Product; provided that such proposal is submitted in writing as far in advance as reasonably practicable and in any event not later than three (3) months before the planned FPFV. Such proposal shall contain, at a minimum, information supporting the rationale for the proposed activity related to the JAK Licensed Product from a scientific, regulatory and commercial standpoint, as well as an estimated developmental critical path and an estimate of the cost of such Development.
- (ii) At any time during the period between when the proposal has been presented to the JPT and the JPT has approved the Clinical Trial or Development activity, and prior to six (6) months after such proposal is received by the JPT, the other Party may elect to participate in such Clinical Trial or other Development activity.
- (iii) In the event (A) the JPT determines that such Clinical Trial or Development activity may support the worldwide Development of JAK Licensed Products; (B) the JPT approves such proposal; and (C) the Parties agree to collaborate to conduct such Clinical Trial or other Development activity with respect to JAK Licensed Products (the "Joint Development Activity"), then the Parties shall, through the JPT, amend the Development Plan for JAK Licensed Products to include a detailed description of the Joint Development Activity to be undertaken by the Parties and develop a detailed annual budget for all Development Costs for such activities to be included in the applicable Development Plan (the "Development Budget"). Each Party shall use Commercially Reasonable Efforts to perform the obligations allocated to such Party under a Development Plan for a Joint Development Activity. [***] Development Costs

set forth in the applicable Development Budget [***] set forth in the applicable Development Budget). At the time such Development Plan and Development Budget is created by the JPT and approved by the JSC, the Parties shall agree upon a quarterly reporting and payment structure to implement the cost sharing set forth in the preceding sentence. In the event either Party fails to timely make an undisputed payment under the agreed upon payment plan, the payment amount shall be reflected as a credit against the monies due by the other Party under ARTICLE VIII, or, if no such credit is available as no such monies are due, shall be paid within [***] after invoice.

(b) Right to Proceed with Development Activity. If the other Party declines or does not elect to participate in such proposed Development activity prior to the planned FPFV (so long as such FPFV does not occur less than three (3) months after receipt by the JPT of a written proposal in accordance with Section 4.3(a)(i)), the submitting Party may proceed with such Clinical Trial or Development activity for its territory; provided that neither Party may proceed with such Clinical Trial or Development activity if a Party reasonably determines that the activity is reasonably likely to have a material adverse impact on the Development and/or Commercialization of JAK Licensed Products in its territory. Any disputes regarding whether an activity is reasonably likely to have a material adverse impact on the Development and/or Commercialization of JAK Licensed Products in a Party's territory shall be resolved in accordance with Section 3.5.

(c) <u>Buy-In Right</u>.

- (i) If a Party fails to elect to participate in a Clinical Trial or Development activity pursued by the other Party pursuant to Section 4.3(b) within the [***] period following receipt by the JPT of a written proposal in accordance with Section 4.3(a)(i) relating thereto, such Party (the "Buy-In Party") may obtain access to and use of the clinical data generated pursuant to the relevant Clinical Trial or Development activity in accordance with the following procedure: At least on a [***] basis, the Party participating in a Clinical Trial or Development activity pursuant to Section 4.3(b) shall update the Buy-In Party on the status of such Clinical Trial or Development activity, including a summary of relevant data. At any time, the Buy-In Party may provide the other Party with notice of its election to participate in such Clinical Trial or Development activity, and promptly thereafter the other Party shall provide the Buy-In Party with an invoice for [***] of the Development Costs incurred by the other Party in the generation of such clinical data as of the date of the Buy-In Party's written request, which invoice the Buy-In Party shall pay within [***] after receipt. Thereafter, to the extent the Development activity has not been completed, the Buy-In Party shall be responsible for [***] of the Development Costs incurred by the other Party. Such payment shall entitle the Buy-In Party to use only the data so paid for. The other Party shall, as applicable, provide copies of, and/or a Right of Reference or Use of, the requested clinical data to the Buy-In Party promptly after receipt of the invoiced amount.
- (ii) In the event Novartis is the Buy-In Party and has exercised the buy-in right with respect to a Clinical Trial that would qualify for a milestone set forth in Section

- 8.2, then in addition to the Development Costs set forth in Section 4.3(a)(i) above, Incyte shall invoice Novartis for the applicable milestone payment(s) set forth in Section 8.2 and Novartis shall pay such milestone payment(s) in accordance with Section 8.2(i).
- (iii) For the avoidance of doubt, the buy-in right pursuant to this Section 4.3(c) does not include the right to operational participation in the conduct of the Clinical Trial or Development activity unless, at the sole discretion of the Party that initiated the Clinical Trial or Development activity, such Party grants operational participation to the Buy-In Party.
- (iv) In the event the Buy-In Party fails to meet any payment obligation pursuant to this Section 4.3(c), and such failure continues for [***] after the original due date of the payment, until such delinquency is cured, the data generated pursuant to the Clinical Trial or Development activity shall not be shared with the Buy-In Party. In the event such delinquency is not cured within [***], the Buy-In Party's notice of election to participate shall be considered void.
 - (d) Rights to Data and Documentation. With respect to any Joint Development Activities:
- (i) Subject to Section 4.3(c), each Party shall have the right to possess, retain and use all clinical and non-clinical data and related Regulatory Documentation Controlled by either Party and generated in the course of such Development activities in order to Develop, obtain Regulatory Approval for and Commercialize JAK Licensed Products in the JAK Field in such Party's territory in accordance with the terms of this Agreement. For the avoidance of doubt, Novartis' right to possess, retain and use pre-clinical and clinical data related to JAK Licensed Compounds and JAK Licensed Products and Controlled by Incyte that exist as of the Effective Date or that are generated from Study INCB018424-256 for all Polycythemia Vera filings to a Regulatory Authority for JAK Licensed Compounds and JAK Licensed Products, shall not be subject to Section 4.3(c);
- (ii) each Party hereby grants to the other Party a Right of Reference or Use to any and all such Regulatory Documentation, and agrees to sign, and cause its Affiliates to sign, from time to time, promptly upon request, any instruments reasonably requested by such other Party in order to effect such grant;
- (iii) each Party shall maintain complete and accurate records of all results, data, Development Costs and developments made pursuant to its efforts under the Development Plan. Such records shall appropriately reflect all work done and results achieved in the performance of Development activities in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes; and
- (iv) in any agreement between either Party and a clinical research organization related to a Joint Development Activity, the contracting Party shall use reasonable efforts to name the other Party as a third party beneficiary for the purpose of receiving data derived from Clinical Trials related to such Joint Development Activity from such clinical research organization in the event of a Bankruptcy Event of such Party.

4.4 <u>c-MET Licensed Compound Co-Development Option</u>.

- (a) Within [***] prior to the anticipated initiation of a Phase III Study for the c-MET Licensed Compound INCB28060, Novartis shall notify Incyte of such anticipated initiation and shall provide Incyte with the following information: all material pre-clinical and clinical data and related analysis and regulatory information submitted to any Regulatory Authorities prior to the applicable time-period mentioned above, and Novartis' then current Development plans and budgets with respect to such c-MET Licensed Compound. Incyte shall have the option, exercisable by (A) providing Novartis written notice within [***] after receipt of such information and (B) co-funding [***] of Novartis' global Development Costs for such c-MET Licensed Compound incurred after the date of such notice.
- (b) If Incyte timely delivers such notice, within [***] following the end of each Calendar Quarter after Incyte has delivered such notice, Novartis shall prepare and deliver to Incyte a quarterly report detailing its Development Costs incurred during such period with respect to such c-MET Licensed Compound. Novartis shall submit any supporting information reasonably requested by Incyte related to such Development Costs included in its report within [***] after its receipt of such request. Novartis shall issue an invoice to Incyte for [***] of the Development Costs identified in such report. Incyte shall pay all amounts payable under any such invoice within [***] after its receipt of such invoice. Incyte shall have the right to audit the records of Novartis with respect to any purported Development Costs included in such reports, in accordance with Section 8.6.
- (c) If Incyte pays all Development Costs invoiced for such c-MET Licensed Compound as described above, the royalty rates set forth in Section 8.3(a) payable on any c-MET Licensed Product that contains INCB28060 shall [***] will be [***]. For purposes of clarity, the royalty rate shall not be changed unless and until payment of all such Development Costs have been received in cash by Novartis.

4.5 <u>Potential JAK Back-Up Compounds</u>.

- (a) Either Party or its Affiliates may Develop a JAK2 Inhibitor Compound (that is not a JAK Excluded Compound or Incyte's compound INCB028050) in the JAK Field up to the point of, but not including, a Randomized Clinical Trial. The Party or its Affiliates Developing such JAK2 Inhibitor Compound shall be solely responsible for the cost of Development to such point. A Party shall provide written notice to the other if such Party or its Affiliates Develops a JAK2 Inhibitor Compound (that is not a JAK Excluded Compound or Incyte's compound INCB028050) prior to proceeding to the first clinical use of such compound in a human (a "JAK Candidate").
- (b) If a Party elects to propose to the JSC that a JAK Candidate proceed to a Randomized Clinical Trial, such Party shall provide written notice to the JSC identifying such JAK Candidate (a "<u>Potential JAK Back-Up Compound</u>"). The submitting Party shall include

with such written notice information supporting the rationale for proceeding to a Randomized Clinical Trial with respect to such Potential JAK Back-Up Licensed Compound from a scientific, regulatory and commercial standpoint, as well as an estimated developmental critical path and an estimate of the cost of such Development. Such Potential JAK Back-Up Compound may be further Developed either if:

- (i) the JSC determines that the Development of INCB018424 has failed, whether due to unacceptable safety or tolerability, failure to meet the primary efficacy endpoint, or an adverse Regulatory Authority action; or
- (ii) the JSC determines to conduct such Development for life cycle management purposes with respect to INCB018424 following receipt of Regulatory Approval for the first JAK Licensed Product that contains INCB018424; or
- (iii) the Parties otherwise explicitly agree to the Development of such Potential JAK Back-Up Compound.
- (c) If a Potential JAK Back-Up Compound is further Developed in accordance with Section 4.5(b), the following provisions shall apply, as applicable:
- (i) if both Parties agree to participate in the Development of such Potential JAK Back-Up Compound prior to FPFV of a Randomized Clinical Trial, such Potential JAK Back-Up Compound will be deemed to be a JAK Licensed Compound for all purposes under this Agreement, including with respect to ARTICLE II and ARTICLE VIII (including Novartis' obligations thereunder to pay development milestones, regulatory milestones, sales milestones and royalties [***]), except as set forth in subsection (iii) below.
- (ii) if either Party declines to participate in the Development of such Potential Back-Up Compound prior to FPFV of a Randomized Clinical Trial, then the following provisions shall apply, as applicable:
- A. If Incyte has declined to participate in such Development, then Novartis may proceed with such Development and the Commercialization in the JAK Field in the Novartis JAK Territory of any such Potential JAK Back-Up Compound proposed to the JSC by Novartis, to the extent that Novartis has the right to do so absent a license from Incyte under the Incyte IP. At Novartis' request, Incyte may, in its sole discretion, extend the license grant under the Incyte IP and Incyte's and its Affiliates' interests in Joint IP set forth in Section 2.1(b) (subject to Incyte's retained rights set forth in Section 2.5) to include such Potential JAK Back-Up Compound, and such Potential JAK Back-Up Compound shall be deemed a JAK Licensed Compound for the purposes of ARTICLE II and ARTICLE VIII, in which event Novartis shall pay to Incyte the development milestones, regulatory milestones, sales milestones and royalties payable by Novartis pursuant to ARTICLE VIII;

- B. If Novartis has declined to participate in such Development, then Incyte may proceed with such Development and the Commercialization in the JAK Field in the Incyte Territory of any such Potential JAK Back-Up Compound proposed to the JSC by Incyte, to the extent that Incyte has the right to do so absent a license from Novartis under the Novartis IP. At Incyte's request, Novartis may, in its sole discretion, extend the license grant under the Novartis IP set forth in Section 2.2 to include such Potential JAK Back-Up Compound, and such Potential JAK Back-Up Compound shall be deemed a JAK Licensed Compound for the purposes of ARTICLE II and ARTICLE VIII, [***]; and
- C. At any time after a Party declines to participate in such Development, then the non-participating Party may elect to obtain rights to such Potential JAK Back-Up Compound by buying-in to such Development in accordance with the procedure set forth in Section 4.3(c) as if such Development were a Joint Development Activity. In the event a Party exercises such option, such Potential JAK Back-Up Compound will be deemed to be a JAK Licensed Compound for all purposes under this Agreement, including with respect to ARTICLE II and ARTICLE VIII (including Novartis' obligations thereunder to pay development milestones, regulatory milestones, sales milestones and royalties [***]), except as set forth in subsection (iii) below.
- (iii) If, pursuant to Section 4.5(c)(i) or Section 4.5(c)(ii)(C), both Parties participate in the Development of a Potential JAK Back-Up Compound and both of the following are applicable:
- A. There are no JAK Licensed Compounds, Potential JAK Back-Up Compounds or JAK Candidates Controlled by Incyte that are Viable Compounds; and
- B. The Development, manufacture, Commercialization and/or other use of such Potential JAK Back-Up Compound is not Covered by a Valid Claim of Patent Rights Controlled by Incyte;

then certain of the payments under ARTICLE VIII with respect to such Potential JAK Back-Up Compound will be modified as follows: [***], it being understood that, except for the specific modifications set forth in subsections (1) and (2) above, all other payment obligations in ARTICLE VIII shall remain in effect.

4.6 <u>Development Reports</u>.

(a) Novartis shall provide, as applicable, the c-MET JDC and the JAK JDC with a written report at least quarterly summarizing in reasonable detail Novartis' and its Affiliates' activities and progress related to the Development of Licensed Products in the Field in the Novartis Territory, including information concerning the conduct of non-clinical activities and Clinical Trials, applications for and securing of Regulatory Approvals, First Commercial Sale of the Licensed Product on a country-by-country basis and any future planned Development

activities; <u>provided that</u> a presentation before the JSC, accompanied with written documentation such as slides, may substitute for such written report.

(b) Incyte shall provide, as applicable, the c-MET JDC and the JAK JDC with a written report at least quarterly summarizing in reasonable detail Incyte's and its Affiliates' activities and progress related to the Development of c-MET Licensed Products in accordance with Section 4.2(b) and the Development of JAK Licensed Products in the JAK Field in the Incyte Territory, including information concerning the conduct of non-clinical activities and Clinical Trials, applications for and securing of Regulatory Approvals, First Commercial Sale of JAK Licensed Product in the JAK Field in the Incyte Territory and any future planned Development activities; provided that a presentation before the JSC, accompanied with written documentation such as slides, may substitute for such written report.

4.7 <u>Regulatory Matters Related to Licensed Products.</u>

Regulatory Submissions. Incyte shall oversee, monitor and coordinate all regulatory actions, (a) communications and filings with, and submissions to, the FDA with respect to JAK Licensed Products in the JAK Field in the Incyte Territory. Novartis shall oversee, monitor and coordinate all regulatory actions, communications and filings with, and submissions to: (i) the EMEA, MHLW and other Regulatory Authorities in the Novartis JAK Territory with respect to the JAK Licensed Products in the JAK Field and (ii) all Regulatory Authorities with respect to the c-MET Licensed Products in the c-MET Field in the Novartis Territory. Each Party shall keep the JAK JDC reasonably informed in connection with the preparation of all Regulatory Documentation, Regulatory Authority review of Regulatory Documentation, and Regulatory Approvals, annual reports, annual re-assessments, and variations and labeling, in each case with respect to the JAK Licensed Product in the Field; provided that the providing Party shall have the right to redact any information to the extent not related to JAK Licensed Product in the Field. Each Party shall respond within a reasonable time frame to all reasonable inquiries by the other Party with respect to any information provided pursuant to this Section 4.7(a). Unless already the Confidential Information of a Party, any information disclosed pursuant to this Section 4.7(a) shall be the Confidential Information of the disclosing Party. For the purposes of this Section 4.7(a), each Party grants the other Party a royalty-free license to use, copy and distribute any articles, clinical study summaries or other materials that it has prepared solely for the purposes of preparing and pursuing its regulatory submissions and filings and communication with the Regulatory Authorities. The Parties shall use Commercially Reasonable Efforts to promptly take the actions described in this Section 4.7(a)

(b) <u>Regulatory Meetings and Correspondence.</u>

(i) Incyte shall be responsible for interfacing, corresponding and meeting with the FDA with respect to JAK Licensed Products in the JAK Field in the Incyte Territory. Novartis shall be responsible for interfacing, corresponding and meeting with: (i) the EMEA, MHLW and other Regulatory Authorities with respect to the JAK Licensed Products in the JAK Field in the Novartis JAK Territory and (ii) FDA, EMEA, MHLW and other Regulatory Authorities with respect to the c-MET Licensed Products in the c-MET Field in the Novartis Territory.

- (ii) The Party not responsible for interfacing, corresponding and meeting with the applicable Regulatory Authorities in a country with respect to the JAK Licensed Products in the JAK Field shall have the right to have a senior, experienced employee reasonably acceptable to the responsible Party, participate as an observer in material or scheduled face-to-face meetings, video conferences and any teleconferences, involving participation of personnel beyond regulatory experts, with the FDA, EMEA, and MHLW, and shall be provided with advance access to the responsible Party's material documentation prepared for such meetings. Prior to submission of material correspondence to the applicable Regulatory Authority, the responsible Party shall, sufficiently in advance for the other Party to review and comment, provide the other Party any material correspondence with the FDA, EMEA and MHLW related to such meetings. The responsible Party shall also provide the other Party with copies of any material correspondence with the FDA, EMEA, and MHLW relating to Development of, or the process of obtaining Regulatory Approval for, JAK Licensed Products in the JAK Field, and respond within a reasonable time frame to all reasonable inquiries by the other Party with respect thereto.
- (c) <u>Global Safety Database; Pharmacovigilance Agreement</u>. Contemporaneous with Novartis' assumption of responsibility for study 352, Novartis shall establish, hold and maintain the global safety databases for each Licensed Product (the "<u>Global Safety Database</u>") into which it shall enter information on all adverse events concerning the Licensed Product occurring anywhere in the world and reported to either of the Parties in accordance with a pharmacovigilance agreement for each Licensed Product in substantially the same form as the draft agreements attached in Exhibit I (each, "<u>Pharmacovigilance Agreement</u>"), which the Parties shall execute on the Effective Date. Pursuant to the terms of the Pharmacovigilance Agreement, such database shall comply in all material respects with all Laws reasonably applicable to pharmacovigilance anywhere where the Licensed Products are being or have been Developed or Commercialized. The Pharmacovigilance Agreement shall, among other things, govern cooperation between the Parties that will enable each of them to comply with its respective obligations under applicable Laws with regard to adverse event data collection, analysis and reporting and to enable each Party to satisfy its duty of care, and to govern the Global Safety Database.

ARTICLE V

CLINICAL AND COMMERCIAL SUPPLY

5.1 <u>Clinical Supply</u>.

(a) <u>Manufacture and Supply of JAK Licensed Product for Study 352</u>. Except as specifically provided in that letter agreement dated November 13, 2009, Incyte shall remain responsible for the supply of preclinical and clinical material of JAK Licensed Product for use in the conduct of study 352, until such time as the JAK JDC determines that Novartis should assume responsibility for study 352. Within [***] after the Effective Date, Novartis shall reimburse Incyte the Out-of-Pocket Costs for the supply of Drug Substance and Drug Product for JAK Licensed Compounds and JAK Licensed Products as described in <u>Exhibit C-1</u> and that have been incurred as of the Effective Date.

- (b) <u>On-Going Clinical Supply by Incyte</u>. In the event that Novartis determines that Incyte should provide the supply of Drug Substance and Drug Product for Licensed Product for Novartis Development activities, the Parties shall enter into a clinical supply agreement in the form attached as Exhibit C-2 (the "<u>Clinical Supply Agreement</u>"), under which Incyte shall:
- (i) use Commercially Reasonable Efforts to supply Novartis with such Drug Substance or Drug Product as requested in writing from Novartis, including API, Formulation, CMC and blister formulation work. Novartis shall reimburse Incyte's Out-of-Pocket Costs, subject to an agreed upon budget and payment schedule by the Parties;
- (ii) use Commercially Reasonable Efforts to manufacture, handle and supply, and shall use Commercially Reasonable Efforts to cause its Third Party supplier(s), as applicable, to manufacture, handle and supply, all such Drug Substance or Drug Product for Licensed Compound and Licensed Product supplied by Incyte or its Affiliate to Novartis pursuant to the Clinical Supply Agreement (A) in accordance with then-current Good Manufacturing Practices, as defined in any applicable Regulatory Authority's rules and regulations, as the same may be amended from time to time ("GMP"); (B) in compliance with all applicable Laws; (C) in conformance with all specifications for such Drug Substance or Drug Product as determined by the Parties and as required by Regulatory Authorities, including specifications pertaining to manufacturing methods, testing, materials, facilities, release, labeling, packaging, storage, shipment, and shelf-life.
- (iii) provide Novartis with access to all suppliers in Incyte's supply chain, as permitted under Incyte's agreement(s) with such parties, for the purposes of auditing and ensuring compliance with GMPs and HSE issues; and
- (iv) at Novartis' request, Incyte shall use reasonable efforts to facilitate negotiations between Novartis and Incyte's Third Party manufacturer(s) that manufacture such Drug Product or Drug Substance to enable Novartis to discuss with such Third Party manufacturer(s) the direct supply of Drug Product or Drug Substance to Novartis.
- 5.2 <u>Commercial Supply by Incyte</u>. If requested by Novartis and agreed to by Incyte, Incyte shall provide commercial supply of Drug Product for Licensed Product to Novartis under the terms of a commercial quality and supply agreement. The Parties shall commence negotiations on the terms of such agreement [***] prior to the anticipated filing date and shall make a good faith effort to have an executable agreement no later than [***] prior to the anticipated date of first supply.
- 5.3 <u>Supply by Novartis to Incyte</u>. If requested by Incyte and agreed to by Novartis, Novartis shall supply bulk Drug Product to Incyte under the terms of a clinical supply agreement or under a commercial quality and supply agreement. The Parties shall commence negotiations on the terms of such agreement [***] prior to the anticipated filing date and shall make a good faith effort to have an executable agreement no later than [***] of prior to the anticipated date of first supply.

ARTICLE VI

COMMERCIALIZATION AND CO-DETAILING OPTION

6.1 <u>Commercialization Diligence</u>. Novartis shall use Commercially Reasonable Efforts, at its expense, to Commercialize Licensed Products in the Field in the Novartis Territory after receipt of Regulatory Approval therefor.

6.2 <u>Marketing Responsibilities For Licensed Products</u>.

- c-MET Licensed Products. Subject to the provisions of Section 6.1, all business decisions regarding Commercialization of c-MET Licensed Products in the c-MET Field in the Novartis Territory, including the design, sale, pricing, and promotion of c-MET Licensed Products in the c-MET Field in the Novartis Territory under this Agreement, shall be within the sole discretion of Novartis and its Affiliates. All materials used in the promotion of all c-MET Licensed Products in the c-MET Field in the Novartis Territory, including product packaging, materials used in detailing doctors, product messaging and content used in the promotion of such c-MET Licensed Products, shall be approved solely by Novartis.
- (b) JAK Licensed Products. All business decisions regarding Commercialization of JAK Licensed Products in the JAK Field, including the design, sale, pricing, and promotion of JAK Licensed Products in the JAK Field under this Agreement, shall be within Incyte's discretion in the Incyte Territory and within Novartis' discretion in the Novartis Territory, both subject to JCC oversight pursuant to Section 3.2(d); provided that, to the extent commercially reasonable, Novartis and its Affiliates shall maintain separate sales forces for the Commercialization of any product that directly competes on the same Indications with the JAK Licensed Product in the EU Major Market Countries and Japan. All materials used in the promotion of all JAK Licensed Products in the JAK Field, including product packaging, materials used in detailing doctors, product messaging and content used in the promotion of such JAK Licensed Products, shall be within Incyte's discretion in the Incyte Territory and within Novartis' discretion in the Novartis Territory, both subject to JCC oversight pursuant to Section 3.2(d).

6.3 <u>Incyte Co-Detailing Option</u>.

(a) <u>Co-Detailing Right</u>. Incyte shall have a non-exclusive right to Detail the first c-MET Licensed Product in the first Indication which is marketed in the United States on the terms and conditions set forth in this Section 6.3 ("<u>Co-Detailing Right</u>"). Novartis shall notify Incyte at least [***] prior to the anticipated launch of the first c-MET Licensed Product in the United States and shall provide Incyte with the following information: Novartis' then-current Commercialization plans ("<u>Promotional Plan</u>") with respect to such c-MET Licensed Product. Incyte's Co-Detailing Right is limited to specialists outlined in the Promotional Plan. Incyte may exercise its Co-Detailing Right by providing Novartis written notice at any time not later than [***] or earlier than [***] prior to the initial anticipated launch of such c-MET Licensed Product in the United States.

(b) <u>Effects of Exercise of Co-Detailing Right</u>. If Incyte exercises its Co-Detailing Right:

- (i) The Parties shall, no later than four (4) months prior to the initial anticipated launch of such c-MET Licensed Product in the United States, set out the number of FTE sales representatives Primary Detailing such c-MET Licensed Product in the United States. In no event shall Incyte be responsible for a number of FTE sales representatives Primary Detailing such c-MET Licensed Product which exceeds [***] of Novartis' total FTEs for such c-MET Licensed Product in the United States.
- (ii) Incyte shall be responsible for its costs in conducting co-Detailing activities as well as all incremental training and meeting costs in accordance with Section 6.3(b)(iv); provided that Novartis shall reimburse Incyte at [***] of the FTE Rate for each Incyte sale representative conducting the co-Detailing. Incyte shall provide an invoice to Novartis for such expense on a quarterly basis, and Novartis shall pay such invoice within [***] after receipt.
- (iii) The Parties shall establish a joint U.S. Commercialization Committee ("<u>UCC</u>") to oversee the Detailing of the relevant c-MET Licensed Product in the U.S. Incyte shall be entitled to have one (1) representative sit on the UCC or any group carrying out the UCC's function after the Effective Date but prior to the UCC's establishment. The UCC shall have responsibility for general oversight of all promotion and Detailing activities with respect to such c-MET Licensed Product in the United States. The UCC (or any group carrying out the UCC's function after the exercise of the Co-Detailing Right but prior to the UCC's establishment) will meet quarterly or more frequently as agreed by the JSC. The term of the UCC will be determined by the JSC.
- (iv) Incyte's sales representatives will be included in training programs with respect to the applicable c-MET Licensed Product that Novartis provides to its own sales representatives Detailing such c-MET Licensed Product. Such training shall be provided by Novartis to Incyte free of charge, provided that Incyte shall be responsible for meeting and training costs incremental to that provided to Novartis' sales representatives, including any travel, lodging or other similar expenses that may be incurred by Incyte in connection with the training.
- (v) Incyte's sales representatives shall be provided, at Novartis' expense, with the same promotional materials, including literature and samples, as Novartis provides to its own similarly-situated representatives.
- (vi) Novartis shall approve all training and promotional materials for such c-MET Licensed Product (including messaging) and shall present this information to the UCC. Incyte shall promote such c-MET Licensed Product in accordance with the standards reasonably established by Novartis for such c-MET Licensed Product; provided that if the standards Incyte normally uses are more stringent that the standards established by Novartis, Incyte may use its own standards, subject to Novartis' approval.
 - 6.4 Novartis Co-Detailing Option.

- (a) If at any time during the Term, Incyte, or any of its Affiliates, desires to commence negotiations with one or more Third Parties (other than a contract sales organization) to co-detail or co-promote JAK Licensed Products in the United States, Incyte shall promptly notify Novartis of its intent to commence negotiations and shall provide Novartis a summary of the proposed terms.
- (b) Within [***] after receipt of such notification, Novartis shall notify Incyte in writing either that (i) Novartis is interested in negotiating an agreement with Incyte with respect to such transaction or (ii) Novartis has no interest and therefore waives such right of first offer. If Novartis notifies Incyte within such [***] period that Novartis desires to negotiate an agreement with respect to such transaction, then Incyte shall in good faith negotiate exclusively with Novartis for up to [***] from the date of such notification from Novartis, or such longer period as agreed between the Parties, regarding the terms pursuant to which the Parties would enter into such transaction.
- (c) Failure by Novartis to give notice of its interest or lack of interest in negotiating for such agreement within [***] after receipt of written notice from Incyte as described in the first sentence of this Section 6.4 shall be deemed to constitute a waiver by Novartis of its right of first offer with respect to such transaction. In addition, failure of the Parties to agree within such [***] negotiation period (or such longer period as agreed between the Parties) shall result in the termination of such right of first offer.
- (d) If Novartis waives its right of first offer or such right of first offer terminates with respect to any such transaction, then Incyte shall be free to enter into a transaction for such JAK Licensed Product with a Third Party; provided that if Novartis has notified Incyte in writing of its interest in negotiating an agreement but the Parties have failed to reach agreement, then for a period of [***]; provided further that if, [***].
- (e) Should Novartis exercise the co-detailing option under this Section 6.4, and the Parties reach agreement on terms for such transaction, the terms of such transaction shall be reflected in a separate U.S. commercialization agreement entered into by the Parties or their Affiliates.

6.5 Global Branding; Trademarks.

(a) <u>Global Branding Strategy</u>. The JCC shall have the right, from time to time during the Term, to implement (and thereafter modify and update) a global branding strategy, including global positioning, for JAK Licensed Products for use in the Field throughout the world (the "<u>Global Branding Strategy</u>"). To the extent the JCC determines to utilize such Global

Branding Strategy, each Party shall adhere to the Global Branding Strategy in its Commercialization of the Licensed Product in its territory.

(b) <u>Trademarks</u>.

- (i) Novartis and its Affiliates shall select their own trademarks under which they will market Licensed Products (provided that no such trademark shall contain the word "Incyte") and shall own such trademarks. Incyte and its Affiliates shall select their own trademarks under which they will market Licensed Products (provided that no such trademark shall contain the word "Novartis") and shall own such trademarks.
- (ii) Notwithstanding Section 6.5(b)(i), consistent with the Global Branding Strategy, each Party shall, to the extent permitted by applicable regulatory and legal authorities, utilize the trademark or trademarks selected by the JCC in connection with the marketing and sale of the JAK Licensed Products in such Party's territory (each, a "JAK Mark" and collectively, the "JAK Marks"). Incyte shall own and shall be responsible for registering and maintaining the JAK Marks in the Incyte Territory. Novartis shall own and shall be responsible for registering and maintaining the JAK Marks in the Novartis Territory. As the owner of the JAK Marks in the Incyte Territory, Incyte shall be solely responsible for determining what, if any, action to take in response to any alleged infringement of such trademarks by Third Parties in the Incyte Territory. As the owner of the JAK Marks in the Novartis JAK Territory, Novartis shall be solely responsible for determining what, if any, action to take in response to any alleged infringement of such trademarks by Third Parties in the Novartis JAK Territory.
- (c) Novartis shall use, in connection with all packaging, literature, labels and other printed matters, to the extent permitted by Law, and where reasonably practicable in light of space limitations, an expression to the effect that the Licensed Products were developed under license from Incyte, together with the Incyte logo. The provisions of this Section 6.5 shall not apply to primary packaging of the Licensed Products. Primary packaging shall mean packaging that is in direct contact with the Licensed Products or the Licensed Products themselves, including but not limited to vials, blister packs, tablets and capsules.

ARTICLE VII

INTELLECTUAL PROPERTY OWNERSHIP, PROTECTION AND RELATED MATTERS

7.1 <u>Inventorship</u>; <u>Ownership</u>.

(a) <u>Inventorship</u>. Inventorship of Inventions conceived or reduced to practice during the course of the performance of activities pursuant to this Agreement shall be determined in accordance with the patent Laws of the United States; <u>provided however</u>, that in the event that determining inventorship in accordance with such Laws would render any Patent Right that Covers such Invention invalid, inventorship shall be determined in accordance with the Laws of the jurisdiction where such Patent Right is filed.

Ownership. As between the Parties, all Inventions made or information created, by a Party's or any of its Affiliates' employees, independent contractors or consultants, in the course of conducting activities under this Agreement, together with all Intellectual Property Rights therein, shall be owned by such Party. All inventions or discoveries made, or information created, jointly by each Party's (or any of its Affiliates') employees, independent contractors or consultants, in the course of conducting activities under this Agreement, together with all Intellectual Property Rights therein, shall be jointly owned by the Parties and are "Joint IP". Joint IP shall be owned jointly by Incyte and Novartis on the basis of an undivided interest without a duty to account to the other Party and shall be deemed to be Controlled by each Party. Notwithstanding anything to the contrary herein, each Party shall have the right to use such Joint IP, or license such Joint IP to its Affiliates or any Third Party, or sell or otherwise transfer its interest in such Joint IP to its Affiliates or a Third Party, in each case without the consent of the other Party, so long as such use, sale, license or transfer is subject to the licenses granted pursuant to this Agreement and is otherwise consistent with this Agreement. The Parties, through the JSC and in accordance with Section 7.2, shall determine which Party shall be responsible for the filing, prosecution and maintenance of Joint IP on a case-by-case basis. Each Party hereby authorizes and grants the other Party its permission and consent to assume, directly or through its authorized agents, attorneys, or representatives, the responsibilities set forth in Section 7.2.

7.2 <u>Prosecution and Maintenance of Patent Rights</u>.

- (a) <u>Novartis Patent Rights</u>. At Novartis' expense, Novartis shall have the sole right to file, prosecute and maintain Novartis Patent Rights.
- (b) <u>c-MET Patent Rights</u>. [***] shall have the initial right to file, prosecute and maintain c-MET Patent Rights and Joint IP that Covers c-MET Licensed Compounds or c-MET Licensed Products (the "<u>Joint c-MET IP</u>"), at [***] expense. If [***] declines to file, prosecute or maintain any c-MET Patent Rights or Joint c-MET IP in any country of the world, or desires to allow any c-MET Patent Rights or Joint c-MET IP to lapse in any country of the world, or desires to abandon any c-MET Patent Rights or Joint c-MET IP in any country of the world before all appeals within the respective jurisdiction have been exhausted, then:
- (i) [***] shall provide [***] with reasonable written notice of such decision so as to permit [***] to decide whether to file, prosecute or maintain such c-MET Patent Rights or Joint c-MET IP and to take any necessary action.
- (ii) Following notice from [***] pursuant to subclause (i), [***] may, by providing prompt written notice thereof to [***], assume control of the filing, prosecution and/or maintenance of such c-MET Patent Rights or Joint c-MET IP in the name of the owner(s) of such c-MET Patent Rights or Joint c-MET IP, at [***] expense. Any such c-MET Patent Rights in such country shall no longer be exclusively licensed to [***] and its Affiliates under Section 2.1 and instead shall be licensed on a non-exclusive basis, but otherwise shall remain [***] Patent Right hereunder for all purposes.
 - (c) JAK Patent Rights.

- (i) [***] shall have the initial right to file, prosecute and maintain, at [***] expense, the (x) Secondary Patent Rights in the [***] and (y) the INCY0039 Patent Rights worldwide; provided that [***] shall use a Third Party law firm selected by [***] and reasonably acceptable to [***] to conduct such filing, prosecution and maintenance; and provided further, that [***] shall act promptly with respect to decisions [***] on the filing and prosecution of priority applications. If [***] determines to change the Third Party law firm initially selected to conduct such filing, prosecution and maintenance, [***] shall select a replacement Third Party law firm reasonably acceptable to [***]. If [***] declines to file, prosecute or maintain any INCY0039 Patent Rights in [***], desires to allow to lapse any INCY0039 Patent Rights in [***] before all appeals within the respective jurisdiction have been exhausted, then:
- A. [***] shall provide [***] with reasonable written notice of such decision so as to permit [***] to decide whether to file, prosecute or maintain such INCY0039 Patent Rights in [***] and to take any necessary action.
- B. Following notice from [***] pursuant to clause (A), [***] may, by providing prompt written notice thereof to [***], assume control of the filing, prosecution and/or maintenance of such INCY0039 Patent Rights in [***] in the name of the owner(s) of such INCY0039 Patent Rights, at [***] expense.
- (ii) [***] shall have the initial right to file, prosecute and maintain, at [***] expense, the Secondary JAK Patent Rights in the [***]. If [***] declines to file, prosecute or maintain any Secondary JAK Patent Rights in [***], desires to allow any Secondary JAK Patent Rights to lapse in [***], or desires to abandon any Secondary JAK Patent Rights in [***] before all appeals within the respective jurisdiction have been exhausted, then:
- A. [***] shall provide [***] with reasonable written notice of such decision so as to permit [***] to decide whether to file, prosecute or maintain such Secondary JAK Patent Right in [***] and to take any necessary action.
- B. Following notice from [***] pursuant to clause (A), [***] may, by providing prompt written notice thereof to [***], assume control of the filing, prosecution and/or maintenance of such Secondary JAK Patent Right in [***], at [***] expense.
- (d) <u>Cooperation</u>. Solely with respect to the rights and obligations described in Section 7.2(c), an individual Party responsible for the filing, prosecution and maintenance of a Patent Right will be referred to as the "<u>Controlling Party</u>" and the other Party will be referred to as the "<u>Non-Controlling Party</u>".
- (i) The Non-Controlling Party shall, at the Controlling Party's expense and reasonable request, assist and cooperate in the filing, prosecution and maintenance

of or any related necessary action for, as applicable, the Novartis Patent Rights or Incyte Patent Rights.

- (ii) The Controlling Party shall provide the Non-Controlling Party sufficiently in advance, where reasonable, for the Non-Controlling Party to comment, with copies of all patent applications and other material submissions and communications (including oral communications) with any patent counsel or patent authorities pertaining to the Incyte Patent Rights and, within the Incyte Territory, the Novartis Patent Rights.
- (iii) Upon a request by the Non-Controlling Party, the Parties will discuss and consider in good faith filing separate Patent Rights for claims that Cover Licensed Products (e.g., methods of manufacturing and uses of such Licensed Product) specifically or generically and claims that Cover only other compounds and methods of making and using such other compounds.
- (iv) The Controlling Party shall give due consideration to the Non-Controlling Party's comments, but shall have the final say in determining whether or not to incorporate such comments.
- (v) Each Party shall provide the other with copies of all material communications received from any patent counsel or patent authorities pertaining to such Incyte Patent Rights.
- (vi) "<u>Material</u>" for the purposes of this Section 7.2(d) means that the submission or communication could affect the patentability or scope of the patents Covering the Licensed Compounds or Products.
- (e) <u>Patent Term Extensions</u>. [***] may select which, if any, c-MET Patent Rights for which a Patent Term Extension is to be sought or obtained. [***] may, in consultation with [***], select which, if any, JAK Patent Rights for which a Patent Term Extension is to be sought or obtained with respect to JAK Licensed Products in the [***]. Except as set forth in the preceding sentence, [***] may select which, if any, JAK Patent Rights for which a Patent Term Extension is to be sought or obtained.

7.3 <u>Third Party Infringement.</u>

(a) <u>Notice</u>. Each Party shall promptly provide the other Party with written notice reasonably detailing any known or alleged infringement by a Third Party of Joint IP, Incyte IP or any Novartis IP, including any "patent certification" filed in the United States under 21 U.S.C. §355(b)(2) or 21 U.S.C. §355(j)(2) or similar provisions in other jurisdictions, and of any declaratory judgment, opposition, or similar action alleging the invalidity, unenforceability or non-infringement of any such Intellectual Property Rights (collectively "<u>Third-Party Infringement</u>"). Within [***] after receipt of such notice, the Parties shall consult via the JSC to determine the response to any Third Party Infringement.

(b) <u>Enforcement</u>.

- If within [***] after receipt of the notice set forth in Section 7.3(a) the JSC fails to (i) agree on a joint course of action with respect to a Third Party Infringement, [***] will have the initial right to determine and control a course of action designed to curtail such Third Party Infringement, whether legal or commercial in the [***] in connection with the Third Party Infringement against a Third Party which is infringing the relevant Intellectual Property Rights by making, using or selling a product that competes with a Licensed Product in the Field in the [***], at its own expense as it reasonably determines appropriate. In the event such course of action includes litigation, [***] may choose, at its own expense, to be represented in such action by counsel of its own choice; provided, however, that if [***] is required as a necessary party to such action, [***] shall pay [***] reasonable expenses associated therewith. [***] shall keep [***] reasonably informed as to any legal or commercial courses of action it pursues pursuant to this subsection (i). At the request and expense of [***], [***] shall provide reasonable assistance to [***] in connection therewith, including by executing reasonably appropriate documents, cooperating in discovery and joining as a party to the action. In connection with any such proceeding, [***] shall not enter into any settlement admitting the invalidity of, or otherwise impairing [***] rights in, [***] or Joint IP without the prior written consent of [***]. Any recoveries resulting from such an action relating to a claim of Third Party Infringement shall be applied as follows:
- A. First, to reimburse each Party for all Out-of-Pocket Costs in connection with such proceeding (on a pro rata basis, based on each Party's respective litigation costs, to the extent the recovery was less than all such litigation costs); and

B. Second, [***].

If within [***] after [***] receipt of a notice of a Third Party Infringement with respect to Joint IP or [***], [***] does not take any action as described in Section 7.3(b)(i) and permitted hereunder against a Third Party who is infringing such Intellectual Property Rights by making, using or selling a product that competes with a Licensed Product in the [***], [***] may, subject to the following sentence, in its sole discretion, bring and control any legal action in connection therewith at its sole expense. If [***] intends to bring any such legal action, it shall first notify [***] in writing of such intent and the reasons therefor and provide [***] with an opportunity to indicate to [***] its reasons for not bringing such legal action; and if [***] provides either a reasonable (x) legal basis for [***] not bringing such legal action, or (y) explanation of how [***] is taking commercial steps to curtail the Third Party Infringement, [***] shall not bring such legal action. [***] shall keep [***] reasonably informed as to any legal or commercial courses of action it pursues pursuant to this subsection (ii). At the request and expense of [***], [***] shall provide reasonable assistance to [***] in connection therewith, including by executing reasonably appropriate documents, and cooperating in discovery; provided, however, that nothing herein shall require [***] to join as a party or otherwise participate in such legal action, if in [***] reasonable opinion such participation will damage any of [***] commercial relationships. [***] may choose, at its own expense, to be represented in any such action by counsel of its own choice; provided, however, that if [***] is required as a necessary party to such action, [***] shall pay [***] reasonable expenses associated

therewith. In connection with any such proceeding, [***] shall not enter into any settlement admitting the invalidity of or otherwise impairing [***] rights under the Joint IP or such [***] without the prior written consent of [***]. Any recoveries resulting from such an action relating to a claim of Third Party Infringement (after payment of each Party's costs and expenses) will be retained by [***].

- (iii) In the event of a Third Party Infringement of JAK Patent Rights that occurs only in the [***], [***], at its own expense, will have the right to bring and control any legal action in the [***] in connection with such Third Party Infringement.
- 7.4 Patent Marking. If permitted and to the extent that Novartis does so with respect to its other products in the same geographic market, Novartis shall, and shall cause its Affiliates, distributors and licensees, to (a) mark the Licensed Products with the number of each issued patent under the Incyte Patent Rights that apply to the Licensed Product and (b) comply with the patent marking statutes in each country in which the Licensed Product is manufactured by or on behalf of Novartis or its Affiliates.

7.5 Third Party Licenses.

- If [***] in good faith believes that it is necessary to obtain a license under any Patent Rights of a Third Party that would be infringed by the making, using, selling, offering for sale or importing by [***] of a Licensed Compound in the Field in any country in the [***], then prior to commencing negotiations or entering into an agreement with respect to any such Third Party Patent Rights, [***] shall promptly notify [***]. The Parties shall thereafter conduct good faith discussions regarding whether such Third Party Patent Rights are necessary to make, use, sell, offer for sale or import Licensed Compound in the Field in any country in the [***]. If the Parties agree that such Third Party Patent Rights are necessary to make, use, sell, offer for sale or import Licensed Compound in the Field in any country in the [***], the Parties shall meet to discuss and determine which Party will be primarily responsible for the negotiation and execution of the corresponding license agreement; provided, however, that [***] shall have the first right to obtain a license and negotiate and execute a license agreement, in connection with the manufacture of Licensed Compounds and Licensed Products or with respect to any intellectual property applicable to the Licensed Compounds and Licensed Product. In the event the Parties agree that [***] shall have the right to negotiate and execute such a license agreement, at the request of [***], any such license from a Third Party shall include a license to [***] and its sublicensees with respect to the Licensed Compound in the [***] in and/or outside the Field. Notwithstanding the foregoing, neither Party shall enter into a definitive license agreement with regard to such rights in the other Party's territory without the other Party's written consent. In the event that the Parties cannot agree on whether a license from a Third Party is necessary, [***] shall make the final decision with respect to licenses covering all or part of the [***].
- (b) To the extent the Parties have agreed or [***] has determined in accordance with Section 7.5(a) that a license under such Third Party Patent Rights is necessary to avoid infringement based on the making, using, selling, offering for sale or importing of JAK Licensed Compound in the Field and such license agreement relates to worldwide rights for JAK

Licensed Compounds or JAK Licensed Products, [***] of any up-front license fee or other acquisition cost and milestones based on the principle that such rights in the Incyte Territory constitute [***] of such cost and such rights in the Novartis JAK Territory constitute [***] of such cost. If such Third Party license rights are available only in one Party's territory, such Party shall be responsible for one hundred percent (100%) of such costs subject to the deductions permitted under Section 7.5(c) and (d).

- Regardless of which Party licenses such rights, (i) each Party shall pay to the applicable Third Party licensor (or as applicable, to the licensing Party for delivery to such Third Party) all royalties payable in respect of sales of products by such Party, its Affiliates, or sublicensees and (ii) to the extent the Parties agree or [***] has determined in accordance with Section 7.5(a) that such in-licensed rights are necessary to make, use, sell, offer for sale or import Licensed Compound in the Field in any country in the [***] without infringing such Third Party Patent Rights, [***] shall be entitled to deduct up to [***] of the royalties paid or payable to such Third Party (pursuant to a license under such Third Party's issued Valid Claim(s) that Cover the making, using, selling, offering for sale or importing of the applicable Licensed Compound in the Field in such country in the [***]) with respect to sales of a Licensed Product that contains such Licensed Compound in such country in the [***] from the royalties payable by [***] to [***] hereunder with respect to Net Sales of such Licensed Product in such country; provided, however, that in no event shall the royalties payable under Section 8.3(a) be reduced in the aggregate pursuant to this Section 7.5(c) by more than [***] of the amounts set forth in Section 8.3(a).
- (d) Notwithstanding the foregoing, solely with respect to patent application no. [***], Novartis shall be entitled to deduct up to [***] of the royalties paid or payable to such Third Party (pursuant to a license under such Third Party's issued Valid Claim(s) that Cover the making, using, selling, offering for sale or importing by Novartis of the applicable c-MET Licensed Compound in the Field in any country in the Novartis Territory) with respect to sales of a c-MET Licensed Product that contains such c-MET Licensed Compound in such country in the Novartis Territory from the royalties payable by Novartis to Incyte hereunder with respect to Net Sales of such c-MET Licensed Product in such country; provided, however, that in no event shall the royalties payable under Section 8.3(a) be reduced in the aggregate pursuant to this Section 7.5(d) by more than [***] of the amounts set forth in Section 8.3(a).

ARTICLE VIII

FINANCIAL PROVISIONS

- 8.1 <u>License Fee.</u> Within [***] after the Effective Date, Incyte shall submit an invoice to Novartis for a one-time, non-creditable, non-refundable license fee of One Hundred Fifty Million U.S. Dollars (US\$150,000,000), which Novartis shall pay within [***] after receipt.
- 8.2 <u>Milestone Payments</u>. Novartis shall pay Incyte the following amounts after the first achievement by Novartis, its Affiliates or its sublicensees of the corresponding milestone events set forth below:

(a) <u>c-MET Development Milestones</u>.

c-MET Development	[***]	[***]	[***]
Milestones			
(i) [***] Phase 1*	US\$15,000,000	[***]	[***]
(ii) FPFV in a Phase II			
Study that is a Novartis	US\$25,000,000	US\$7,000,000	US\$5,000,000
Sponsored Study			
[***]	[***]	[***]	[***]

^{*} For purposes of clarity, a study conducted by Incyte pursuant to this Agreement shall qualify for the milestone set forth in this Section 8.2(a)(i) with respect to the [***] for a c-MET Licensed Product.

(b) <u>c-MET Regulatory Milestones</u>.

c-MET Regulatory Milestones	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
	[***]	[***]	[***]
[***]	[***]	[***]	[***]

(c) <u>JAK Development Milestones</u>.

JAK Development Milestones	[***]	[***]	[***]
(i) FPFV in a [***] Study that is a Novartis Sponsored Study	[***]	US\$20,000,000	[***]
(ii) FPFV in a Phase III Study that is a Novartis Sponsored Study *	US\$60,000,000	US\$30,000,000	[***]

^{*} For purposes of clarity, Study 352 as described in Exhibit F-1 shall qualify for the milestone set forth in this Section 8.2(c)(ii) with respect to the [***] for a JAK Licensed Product.

(d) <u>JAK Regulatory Milestones</u>.

JAK Regulatory Milestones	[***]	[***]	[***]
[***] Receipt of Regulatory Approval from the FDA	US\$10,000,000	[***]	[***]
ii) EU [***]			
[***]Receipt of [***] EMEA [***] Regulatory Approval [***] reimbursement [***] EU [***]	US\$40,000,000	US\$25,000,000	[***]
	US\$60,000,000	US\$40,000,000	[***]
[***] Receipt of Regulatory Approval from the MHLW	US\$25,000,000	US\$15,000,000	[***]

(e) <u>Sales Milestones</u>.

(i) <u>c-MET Licensed Product Sales Milestones</u>. Novartis shall make the non-refundable, non-creditable, one-time payments to Incyte of as set forth below upon the first achievement of aggregate Annual Net Sales of c-MET Licensed Products that meet or exceed the thresholds set forth below.

c-MET Licensed Product Annual Net Sales Threshold	Milestone Payment
(A) Annual Net Sales of c-MET Licensed Products equal to or greater than [***]	[***]
(B) Annual Net Sales of c-MET Licensed Products equal to or greater than [***]	[***]
(C) Annual Net Sales of c-MET Licensed Products equal to or greater than [***]	[***]
(D) Annual Net Sales of c-MET Licensed Products equal to or greater than [***]	[***]
(E) Annual Net Sales of c-MET Licensed Products equal to or greater than [***]	[***]

(ii) <u>JAK Licensed Product Sales Milestones</u>. Novartis shall make the non-refundable, non-creditable, one-time payments to Incyte of as set forth below upon the first achievement of aggregate Annual Net Sales of JAK Licensed Products in the Novartis JAK Territory that meet or exceed the thresholds set forth below.

JAK Licensed Product Annual Net Sales Threshold	Milestone Payment
(A) Annual Net Sales of JAK Licensed Products equal to or greater than US\$300,000,000	US\$20,000,000
(B) Annual Net Sales of JAK Licensed Products equal to or greater than US\$600,000,000	US\$40,000,000
(C) Annual Net Sales of JAK Licensed Products equal to or greater than US\$900,000,000	US\$60,000,000
(D) Annual Net Sales of JAK Licensed Products equal to or greater than [***]	[***]

- (iii) Achievement of the milestone events above in this Section 8.2(e) shall be determined based on Annual Net Sales of the Licensed Products made by Novartis and its Affiliates and sublicensees throughout the Novartis Territory. More than one of the sales milestone payments may be earned concurrently based on the same Annual Net Sales of the Licensed Products. By way of example, if in the first Calendar Year following the First Commercial Sale of a JAK Licensed Product, the Annual Net Sales for JAK Licensed Products is equal to or exceeds [***], then Novartis shall pay Incyte the milestone payments set forth in both Sections 8.2(e) (ii)(A) and (B) (total [***]).
- (f) Except as otherwise specified, none of the payments listed in this Section 8.2 shall be payable more than once, and each shall be payable at the first achievement of a milestone event for a Licensed Product and shall not be payable again if subsequently another Licensed Product achieves the same milestone event. [***].
- (g) If a foreseen Development activity described in Section 8.2(a)(i), (a)(ii) or (c)(i) is not conducted in the course of accelerating the Development activities for an Indication, then, effective upon achievement of the later milestone with respect to the same Indication set forth in Section 8.2(a)(ii), (a)(iii) or (c)(ii) as the case may be, the previously unpaid payments that would be due for the preceding milestones shall also become due and payable even though the missing milestone has not been achieved.
- (h) For purposes of clarity, the milestone payment set forth in Sections 8.2(b)(ii)(B) and 8.2(d) (ii)(B) shall be in addition to the milestone payment set forth in Sections 8.2(b)(ii)(A) and 8.2(d)(ii)(A).
- (i) Novartis shall provide Incyte written notice of the achievement of each milestone event: (A) within [***] after achievement of the milestone event set forth in Section 8.2(a), (b), (c) or (d); and (B) within [***] after the end of any Calendar Quarter in which a milestone set forth in Section 8.2(e) is achieved. Incyte shall provide Novartis written notice of the achievement of the milestone event set forth in Section 8.2(d)(i) within [***] after the achievement of such milestone. Novartis shall pay to Incyte, by wire transfer to an account designated by Incyte, the applicable non-refundable, non-creditable milestone payment listed above: (1) with respect to milestone events set forth in Section 8.2(a), (b), (c) or (d), within [***] after Novartis' receipt of invoice and (2) with respect to all milestone events set forth in Section 8.2(e), within [***] after the end of the applicable Calendar Quarter; provided that Incyte has issued the relevant invoice for such sales milestones within [***] after Incyte's receipt of notice from Novartis of the achievement of such sales milestones. In the event Incyte fails to issue an invoice within such [***] period as described above, Novartis's obligation to pay such amount within [***] after the end of the applicable Calendar Quarter shall be extended by the

number of days that lapse between the date Incyte should have invoiced Novartis and the date Incyte actually invoices Novartis.

8.3 Royalties.

- (a) <u>Novartis Royalties to Incyte</u>. Novartis shall pay to Incyte royalties on aggregate Net Sales of each Licensed Product, on a Licensed Product-by-Licensed Product basis, at the following rates:
- (i) <u>c-MET Licensed Products</u>. Subject to Section 4.4(c), on a c-MET Licensed Product-by-c-MET Licensed Product basis, Novartis shall pay to Incyte royalties on Net Sales of each c-MET Licensed Product in the Novartis Territory as follows:

Annual Net Sales of c-MET Licensed Product	Royalty Rate
On Annual Net Sales less than or equal to [***]	12%
On Annual Net Sales greater than [***] and less than or equal to [***]	[***]%
On Annual Net Sales greater than [***]	14%

(ii) <u>JAK Licensed Products</u>. On a JAK Licensed Product-by-JAK Licensed Product basis, Novartis shall pay to Incyte royalties on Net Sales of each JAK Licensed Product in the JAK Field in the Novartis JAK Territory as follows:

Annual Net Sales of such JAK Licensed Product	Royalty Rate
On Annual Net Sales less than or equal to [***]	[***]%
On Annual Net Sales greater than [***] and less than or equal to [***]	[***]%
On Annual Net Sales greater than [***] and less than or equal to [***]	[***]%
On Annual Net Sales greater than [***]	[***]%

- (b) Incyte Royalties to Novartis.
- (i) Incyte shall pay to Novartis a royalty, on a JAK Licensed Product-by-JAK Licensed Product basis, on annual Net Sales of such JAK Licensed Product in the JAK Field in the Incyte Territory at the following rates (the "Incyte Reverse Royalty Rates"); provided that royalties shall only be payable to Novartis on Net Sales of JAK Licensed Products in the JAK Field in the Incyte Territory made after Novartis has received reimbursement [***] EU [***].

Annual Net Sales of JAK Licensed Product	Royalty Rate
On Annual Net Sales less than or equal to [***]	[***]%
On Annual Net Sales greater than [***] and less than or equal to [***]	[***]%
On Annual Net Sales greater than [***]	[***]%

- (ii) [***].
- Product-by-Licensed Product and country-by-country basis from the date of First Commercial Sale of each Licensed Product with respect to which royalty payments are due for a period which is the longer of: (i) the last to expire of any Valid Claim of Licensed Patent Rights Covering such Licensed Product in such country; (ii) [***] following the date of First Commercial Sale in such country; and (iii) the expiration of Regulatory Exclusivity for such Licensed Product in such country (each such term with respect to a Licensed Product and a country, a "Royalty Term"). Notwithstanding the foregoing, in the event that either (A) the Royalty Term continues solely due to clause (ii) (i.e. in a specific country the Licensed Product is neither Covered by a Valid Claim of Licensed Patent Rights nor is such Licensed Product subject to Regulatory Exclusivity) or (B) Generic Competition exists with respect to a Licensed Product in a country with respect to a royalty-reporting period, then the royalty rates in such country for such Licensed Product (for such royalty-reporting period, if applicable) will be [***] the applicable rate in Section 8.3(a) [***], based on the weighted average annual royalty rate in the Novartis Territory or the Incyte Territory, as the case may be, beginning on January 1st of the Calendar Year following the first Calendar Year in which there exists a situation described in (A) or (B) of this sentence in the applicable country.
- (d) Upon the expiration of the Royalty Term with respect to a Licensed Product in a country, (i) the licenses granted by Incyte to Novartis pursuant to Section 2.1 shall be deemed to be fully paid-up, irrevocable and perpetual with respect to such Licensed Product

in such country; and (ii) the licenses granted by Novartis to Incyte pursuant to Section 2.2 shall be deemed to be fully paid-up, irrevocable and perpetual with respect to such JAK Licensed Product in such country.

- Royalty Reports; Payments. Within [***] after the end of any Calendar Quarter, the Royalty Paying Party shall provide the Royalty Receiving Party with a report stating the sales in units and in value of the Licensed Product made by the Royalty Paying Party, its Affiliates, licensees and sublicensees, as applicable, in the Royalty Paying Party's territory, on a country-by-country basis, together with the calculation of the royalties due to the Royalty Receiving Party, including the method used to calculate the royalties and the exchange rates used. Royalty payments shall be made by the Royalty Paying Party to the bank account indicated by the Royalty Receiving Party within [***] after the end of the applicable Calendar Quarter; provided that the Royalty Receiving Party has issued the relevant invoice for royalty payment within [***] after the Royalty Receiving Party's receipt of the royalty report from the Royalty Paying Party. In the event the Royalty Receiving Party fails to issue an invoice within such [***] period as described above, the Royalty Paying Party's obligation to pay such amounts within [***] after the end of the applicable Calendar Quarter shall be extended by the number of days that lapse between the date the Royalty Receiving Party should have invoiced the Royalty Paying Party and the date the Royalty Receiving Party actually invoices the Royalty Paying Party.
- 8.5 <u>Financial Records</u>. The Parties shall keep complete and accurate books and records in accordance with the defined Accounting Standards. The parties will keep such books and records for at least [***] following the end of the Calendar Year to which they pertain. Such books of accounts shall be kept at the principal place of business of the financial personnel with responsibility for preparing and maintaining such records. With respect to royalties, such records shall be in sufficient detail to support calculations of royalties due to either Party. Novartis and Incyte shall also keep complete and accurate records and books of accounts containing all data reasonably required for the calculation and verification of Development Costs, including internal FTEs utilized by either Party in jointly funded Clinical Trials or other Development activities and any amounts that are subject to reimbursement pursuant to Section 6.3(b)(ii).

8.6 Audits.

- (a) Each Party may, upon request and at its expense (except as provided for herein), cause an internationally-recognized independent accounting firm selected by it (except one to whom the Auditee has a reasonable objection), (the "Audit Team") to audit during ordinary business hours the books and records of the other Party and the correctness of any payment made or required to be made to or by such Party, and any report underlying such payment (or lack thereof), pursuant to the terms of this Agreement. Prior to commencing its work pursuant to this agreement, the Audit Team shall enter into an appropriate confidentiality agreement with the Auditee.
- (b) In respect of each audit of the Auditee's books and records: (i) the Auditee may be audited only [***], (ii) no records for any given year for an Auditee may be audited more than [***]; provided that the Auditee's records shall still be made available if such

records impact another financial year which is being audited, (iii) the Audit Rights Holder shall only be entitled to audit books and records of an Auditee from the [***] prior to the Calendar Year in which the audit request is made.

- (c) In order to initiate an audit for a particular Calendar Year, the Audit Right Holder must provide written notice to the Auditee. The Audit Rights Holder exercising its audit rights shall provide the Auditee with notice of one or more proposed dates of the audit not less than [***] prior to the first proposed date. The Auditee will reasonably accommodate the scheduling of such audit. The Auditee shall provide such Audit Team(s) with full and complete access to the applicable books and records and otherwise reasonably cooperate with such audit.
- (d) The audit report and basis for any determination by an Audit Team shall be made available first for review and comment by the Auditee, and the Auditee shall have the right, at its expense, to request a further determination by such Audit Team as to matters which the Auditee disputes (to be completed no more than [***] after the first determination is provided to such Auditee and to be limited to the disputed matters). If the Parties disagree as to such further determination, the Audit Right Holder and the Auditee shall mutually select an internationally-recognized independent accounting firm that shall make a final determination as to the remaining matters in dispute that shall be binding upon the Parties. Such accountants shall not disclose to the Audit Rights Holder any information relating to the business of the Auditee except that which should properly have been contained in any report required hereunder or otherwise required to be disclosed to such Party to the extent necessary to verify the payments required to be made pursuant to the terms of this Agreement.
- (e) If the audit shows any under-reporting or underpayment, or overcharging by any Party, that under-reporting, underpayment or overcharging shall be reported to the Audit Rights Holder and the underpaying or overcharging Party shall remit such underpayment or reimburse such overcompensation (together with interest at the annual interest rate of [***] as published in the [***] or its successor on the last business day of the applicable calendar quarter prior to the audit) to the underpaid or overcharged Party within [***] after receiving the audit report. Further, if the audit for an annual period shows an under-reporting or underpayment or an overcharge by any Party for that period in excess of [***] of the amounts properly determined, the underpaying or overcharging Party, as the case may be, shall reimburse the applicable underpaid or overcharged Audit Rights Holder conducting the audit, for its respective audit fees and reasonable Out-of-Pocket Costs in connection with said audit, which reimbursement shall be made within [***] after receiving appropriate invoices and other support for such audit-related costs.
- (f) For the purposes of the audit rights described herein, an individual Party subject to an audit in any given year will be referred to as the "Auditee" and the other Party who has certain and respective rights to audit the books and records of the Auditee will be referred to as the "Audit Rights Holder".
- 8.7 <u>Tax Matters</u>. The royalties, milestones and other amounts payable by Novartis to Incyte pursuant to this Agreement ("<u>Payments</u>") shall not be reduced on account of any taxes

unless required by Law. Incyte alone shall be responsible for paying any and all taxes (other than withholding taxes required by Law to be deducted and paid on Incyte's behalf by Novartis) levied on account of, or measured in whole or in part by reference to, any Payments it receives. The Parties will cooperate in good faith to obtain the benefit of any relevant tax treaties to minimize as far as reasonably possible any taxes which may be levied on any Payments. Novartis shall deduct or withhold from the Payments any taxes that it is required by Law to deduct or withhold. Notwithstanding the foregoing, if Incyte is entitled under any applicable tax treaty to a reduction of the rate of, or the elimination of, applicable withholding tax, it may deliver to Novartis or the appropriate governmental authority (with the assistance of Novartis to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve Novartis of its obligation to withhold tax, and Novartis shall apply the reduced rate of withholding tax, or dispense with withholding tax, as the case may be, provided that Novartis has received evidence of Incyte's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) [***] prior to the time that the Payment is due. If, in accordance with the foregoing, Novartis withholds any amount, it shall make timely payment to the proper taxing authority of the withheld amount, and send to Incyte proof of such payment within [***] following that latter payment. Notwithstanding the foregoing, Novartis represents that the payments to be paid by Novartis to Incyte pursuant to Sections 8.1, 8.2 and 8.3 hereof shall not be subject to withholding tax under conditions less favorable to Incyte than those applicable to treaty-eligible residents under the income tax treaty between the United States and Switzerland in force at the point of time such payments are paid.

8.8 <u>Currency Exchange</u>.

- (a) <u>Sales and Royalty Calculations</u>. The currency exchange method set out in this Section 8.8(a) shall be applied for calculations of amounts for sales and royalties. With respect to amounts invoiced in United States Dollars, all such amounts shall be expressed in United States Dollars. With respect to amounts invoiced in a currency other than United States Dollars, all such amounts shall be expressed both in the currency in which the amount was invoiced and in the United States Dollar equivalent. The United States Dollar equivalent shall be calculated using the Novartis Standard Exchange Rate Methodology for the conversion of foreign currency sales into United States Dollars.
- (b) Development Cost Calculations. The currency exchange method set out in this Section 8.8(b) shall be applied for calculations of amounts for Development Costs. For purposes of any Development cost sharing between the Parties under this Agreement, such costs shall be calculated on a quarterly basis. With respect to amounts invoiced in United States Dollars, all such amounts shall be expressed in United States Dollars. With respect to amounts invoiced in a currency other than United States Dollars, all such amounts shall be expressed both in the currency in which the amount was invoiced and in the United States Dollar equivalent. The United States Dollar equivalent shall be calculated using the average of the last (bid) U.S. dollar/foreign currency rates for the last Business Day of each month in the calendar quarter for which Development Costs are being reported, as reported by The Wall Street Journal, for the conversion of foreign currency sales into United States Dollars.

8.9 <u>Late Payments</u>. The paying Party shall pay interest to the receiving Party on the aggregate amount of any payments that are not paid on or before the date such payments are due under this Agreement at a rate per annum equal to the lesser of the [***], as reported by <u>The Wall Street Journal</u>, [***] or the highest rate permitted by applicable Law, calculated on the number of days such payments are paid after the date such payments are due; <u>provided</u>, <u>that</u> with respect to any disputed payments, no interest payment shall be due until such dispute is resolved and the interest which shall be payable thereon shall be based on the finally-resolved amount of such payment, calculated from the original date on which the disputed payment was due through the date on which payment is actually made.

ARTICLE IX

TERM AND TERMINATION

9.1 <u>Agreement Term.</u> The term of this Agreement shall commence on the Effective Date and shall continue on a Program-by-Program basis until the earlier of (i) the termination of this Agreement or any program in accordance with Section 9.2; or (ii) following the First Commercial Sale of any Licensed Product, the expiration of the last-to-expire of all Royalty Terms with respect to all Licensed Compounds and Licensed Products within such Program (the "<u>Term</u>"). Notwithstanding the above, if there are any ongoing disputes at the end of the Term as set forth above, this Agreement shall remain in full force and effect until all such disputes are resolved.

9.2 <u>Termination</u>.

- (a) <u>Termination for Convenience</u>. Novartis shall have the right to terminate this Agreement, in its entirety or on a Program-by-Program basis, for convenience upon [***] prior written notice to Incyte.
- (b) Termination for Material Breach. If either Party (the "Non-Breaching Party") believes that the other Party (the "Breaching Party") is in material breach of this Agreement, then the Non-Breaching Party may deliver notice of such breach to the Breaching Party. If the Breaching Party fails to cure such breach, or take such steps as would be considered reasonable to effectively cure such breach, within the [***] period after delivery of such notice, the Non-Breaching Party may terminate this Agreement upon written notice to the Breaching Party, which termination shall apply (x) solely with respect to a Program (and all Licensed Compounds and Licensed Products for such Program) if such breach is related solely to such Program, or (y) either on a Program-by-Program basis or to the Agreement in its entirety at the discretion of the Non-Breaching Party if such breach is not related solely to a Program.
- (c) <u>Termination if Novartis Challenges Incyte IP</u>. If Novartis or any of its Affiliates, directly or indirectly, (i) initiates or requests an interference or opposition proceeding with respect to any Incyte Patent Right, (ii) makes, files or maintains any claim, demand, lawsuit, or cause of action to challenge the validity or enforceability of any Incyte Patent Right in a tribunal or forum, or (iii) opposes any extension of, or the grant of a supplementary protection certificate with respect to, any Incyte Patent Right, Incyte shall have the right to terminate this

Agreement upon [***] written notice to Novartis. Any such termination shall only become effective if Novartis or its Affiliate, as applicable, has not withdrawn such action before the end of the above notice period.

- either the JAK Program or the c-MET Program, Incyte may deliver written notice to Novartis setting out in reasonable detail the basis for Incyte's belief. Novartis shall have [***] from receipt of such notice to take such steps as would be considered reasonably likely to result in Novartis not being deemed to have Abandoned such Program within a reasonable period following such actions. If Novartis fails to take such action and fails to dispute the facts giving rise to such notice within such [***] period, then Incyte may within [***] following the expiration of such [***] period elect to terminate such Program by providing Novartis written notice of such termination, such termination to be effective immediately and otherwise effected in accordance with Section 9.3(a).
- (e) <u>Termination Disputes</u>. If a Party gives notice of termination under this Section 9.2(b) or 9.2(d), and the other Party disputes whether such notice was proper, then the issue of whether or not this Agreement was properly terminated shall be resolved in accordance with ARTICLE XIII, and the Agreement shall remain in full force and effect until such dispute is resolved. If as a result of such dispute resolution process it is determined that the notice of termination was proper, then such termination shall be deemed to be effective on the date on which such notice was first provided. On the other hand, if as a result of the dispute resolution process it is determined that the notice of termination was improper, then no termination shall have occurred and this Agreement shall remain in full force and effect.

9.3 Effects Of Termination.

- (a) Upon termination of this Agreement in whole or with respect to a Terminated Program in accordance with Section 9.2(a) or by Incyte under 9.2(b), 9.2(c) or 9.2(d):
- (i) all licenses granted by Incyte to Novartis hereunder with respect to such Terminated Program(s) shall terminate and Novartis shall not have any rights to use or exercise any rights under the Incyte IP;
- (ii) Novartis shall be released from its Development and Commercialization obligations with respect to such Terminated Program(s);
- (iii) Novartis shall provide to Incyte a fair and accurate summary report of the status of the Development and Commercialization of the Licensed Products in such Terminated Program(s) in each country in the Novartis Territory through the effective date of termination within [***] after such termination;
- (iv) Incyte shall have no further obligation to [***] if the Terminated Program is the JAK Program or if the Agreement is terminated in its entirety;

- (v) if Incyte elects to continue such license, (A) the license granted to Incyte pursuant to Section 2.2(a) shall remain in effect and automatically be expanded to include, with respect to the Terminated Program(s) the right to research, Develop, make, have made, use, offer for sale, sell and import all applicable Licensed Products that formed a part of the Terminated Program(s) in the Novartis Territory, [***], and (B) the license granted to Incyte pursuant to Section 2.2(b) shall remain in effect [***];
- (vi) in the event that Incyte terminates a Program pursuant to Section 9.2(d), then, irrespective of whether Incyte elects to continue the license granted to Incyte pursuant to Section 2.2(a), [***], and [***]; provided that if subclause (v) and this subclause (vi) both apply, then [***] either subclause (v) or this (vi) [***];
- (vii) Novartis shall promptly transfer and assign to Incyte all of Novartis' and its Affiliates' rights, title and interests in and to the product trademark(s) (but not any Novartis house marks) owned by Novartis and used for the Licensed Products in the Terminated Program(s) in the Novartis Territory, in exchange for a payment to Novartis in an amount equal to reimbursement of Novartis' reasonable accumulated costs related to the development, clearance, registration, enforcement and maintenance of the applicable trademark throughout the Novartis Territory;
- (viii) Novartis shall as soon as reasonably practicable transfer and assign to Incyte all Regulatory Documentation, the data comprising the Global Safety Database and other documented technical and other information or materials Controlled by Novartis' which are necessary or useful for the Development, manufacture and Commercialization of the Licensed Compounds or Licensed Products in Terminated Program(s) in the Novartis Territory; provided that Novartis may retain a single copy of such items for its records. Within [***] after Incyte's receipt of an invoice therefor, Incyte shall reimburse Novartis for Novartis' and its Affiliates' reasonable Out-of-Pocket Costs incurred in connection with such transfers and assignment (but not the generation, creation or development of such information and materials);
- (ix) Incyte shall have the option, exercisable within [***] following the effective date of such termination, to obtain Novartis inventory of Licensed Products manufactured by a Third Party with respect to such Terminated Program(s) [***]

for such inventory of Licensed Product. Incyte may exercise such option by written notice to Novartis during such [***] period; provided that in the event Incyte exercises such right to purchase such inventory, Novartis shall grant, and hereby does grant, a royalty-free right and license to any trademarks, names and logos of Novartis contained therein [***] to permit the orderly sale of such inventory;

- (x) the provisions of ARTICLE VII (other than Section 7.1 and Section 7.2(a))shall be terminated with respect to such Terminated Program, provided that Novartis shall provide reasonable assistance to Incyte and cooperation in connection with the transition of prosecution, maintenance and enforcement responsibilities to Incyte, including execution of such documents as may be necessary to effect such transition; and
- (xi) to the extent that Novartis is responsible for manufacturing a Licensed Product prior to termination of this Agreement for a Terminated Program, Novartis shall:
- A. in accordance with the terms of the Supply Agreement, and in exchange for a payment equal to [***] of Novartis' costs, including allocated overhead for the supply of product, and if Regulatory Approval has been obtained for such Licensed Product, use Commercially Reasonable Efforts to supply Incyte and its Affiliates with comparable quantities of the applicable Licensed Products in the dosage strength, formulation and presentation as were being Commercialized as of the effective date of termination until the earlier of [***] after the effective date of the termination or establishment by Incyte of an alternative supply for such Licensed Product; provided that Incyte shall use its Commercially Reasonable Efforts to establish an alternative supply as promptly as reasonably practicable;
- B. cooperate with Incyte in reasonable respects to transfer manufacturing documents and materials which are used (at the time of the termination) by Novartis in the Manufacture of the applicable Licensed Products; and
- C. cooperate with Incyte in reasonable respects to transfer to Incyte, or Incyte's designated contract manufacturer, the manufacturing technologies (including all relevant Know-How) that are used and necessary (at the time of the termination) and Controlled by Novartis in the manufacture of the applicable Licensed Products, provided that Incyte shall reimburse Novartis for Novartis's reasonable Out-of-Pocket Costs to provide such requested assistance.
- (b) Upon termination of this Agreement by Novartis in whole or with respect to a Terminated Program in accordance with Section 9.2(b):
- (i) all licenses granted by Novartis to Incyte hereunder with respect to such Terminated Program(s) shall terminate and Incyte shall not have any rights to use or exercise any rights under the Novartis IP;

- (ii) Novartis shall be released from its Development and Commercialization obligations with respect to such Terminated Program(s) and any exclusivity and non-compete obligations pertaining solely to such Terminated Program(s);
- (iii) Incyte shall provide to Novartis a fair and accurate summary report of the status of the Development and Commercialization of the Licensed Products in such Terminated Program(s) in the Incyte Territory through the effective date of termination within [***] after such termination;
 - (iv) [***];
- (v) with respect to the Terminated Program(s), the license granted to Novartis pursuant to Section 2.1 shall remain in effect and all payment obligations under ARTICLE VIII shall remain in effect; provided that with respect to royalties arising after the effective date of termination, Novartis [***] payable under Section 8.3(a) as they become due;
- (vi) Novartis' rights and Incyte's obligations pursuant to Sections 7.2 and 7.3 shall survive; and
- (vii) the provisions of Section 3.2(e) (Joint Intellectual Property Committee) shall remain in effect solely with respect to the INCY0039 Patent Rights; provided that if the JIPC fails to reach unanimous agreement on a matter before it for decision for a period in excess of thirty (30) days, the JIPC representatives appointed by Incyte shall have the deciding vote on such matter.
- (c) ARTICLES I (Definitions), IX (Term and Termination), X (Indemnification and Limitation of Liability), XII (Confidentiality), XIII (Dispute Resolution) and XIV (Miscellaneous) and Sections 2.6(a)(iii), 7.1 (Inventorship; Ownership), 8.5 (Financial Records), 8.6 (Audits), 11.5) (Disclaimer of Warranty) and 11.6 (Standstill) shall survive termination or expiration (in accordance with Section 9.1 (Agreement Term) of this Agreement).
- (d) Termination of this Agreement shall be in addition to, and shall not prejudice, the Parties' remedies at law or in equity, including the Parties' ability to receive legal damages and/or equitable relief with respect to any breach of this Agreement (including a breach of a representation or warranty set forth in ARTICLE XI), regardless of whether or not such breach was the reason for the termination.

ARTICLE X

INDEMNIFICATION; LIMITATION OF LIABILITY

10.1 By Novartis.

(a) Novartis agrees, at Novartis's cost and expense, to defend, indemnify and hold harmless Incyte and its Affiliates and their respective directors, officers, employees and

agents (the "<u>Incyte Indemnified Parties</u>") from and against any losses, costs, damages, fees or expenses arising out of any Third Party claim relating to (a) any breach by Novartis of any of its representations, warranties or obligations pursuant to this Agreement, (b) the gross negligence or willful misconduct of Novartis, and (c) the Development, manufacture, Commercialization, use, sale or other disposition by Novartis, its Affiliates or sublicensees of any Licensed Compound or Licensed Product; [***].

- (b) In the event of any such claim against the Incyte Indemnified Parties by any Third Party, Incyte shall promptly, [***], notify Novartis in writing of the claim. Novartis shall have the right, exercisable by notice to Incyte within [***] after receipt of notice from Incyte of the claim, to assume direction and control of the defense, litigation, settlement, appeal or other disposition of the claim (including the right to settle the claim solely for monetary consideration) with counsel selected by Novartis and reasonably acceptable to Incyte; [***]. The Incyte Indemnified Parties shall cooperate with Novartis and may, at their option and expense, be separately represented in any such action or proceeding. Novartis shall not be liable for any litigation costs or expenses incurred by the Incyte Indemnified Parties without Novartis's prior written authorization. In addition, Novartis shall not be responsible for the indemnification or defense of any Incyte Indemnified Party to the extent arising from any negligent or intentional acts by any Incyte Indemnified Party or the breach by Incyte of any obligation or warranty under this Agreement, or any claims compromised or settled without its prior written consent.
- (c) Notwithstanding anything to the contrary above, in the event of any such claim against the Incyte Indemnified Parties by a governmental or criminal action seeking an injunction against Incyte, Incyte shall have the right to control the defense, litigation, settlement, appeal or other disposition of the claim at Novartis' expense.

10.2 By Incyte.

(a) Incyte agrees, at Incyte's cost and expense, to defend, indemnify and hold harmless Novartis and its Affiliates and their respective directors, officers, employees and agents (the "Novartis Indemnified Parties") from and against any losses, costs, damages, fees or expenses arising out of any Third Party claim relating to (a) any breach by Incyte of any of its representations, warranties or obligations pursuant to this Agreement, or (b) the gross negligence or willful misconduct of Incyte, and (c) the Development, manufacture, Commercialization, use, sale or other disposition by Incyte, its Affiliates or sublicensees of any JAK Licensed Compound, JAK Licensed Product, c-MET Licensed Compound or c-MET Licensed Product; provided, however, that Incyte shall not defend, indemnify nor hold harmless Novartis Indemnified Parties from and against any losses, costs, damages, fees or expenses arising out of any Third Party claims pertaining directly to the Novartis IP.

- In the event of any such claim against the Novartis Indemnified Parties by any Third (b) Party, Novartis shall promptly, and in any event within [***], notify Incyte in writing of the claim. Incyte shall have the right, exercisable by notice to Novartis within [***] after receipt of notice from Novartis of the claim, to assume direction and control of the defense, litigation, settlement, appeal or other disposition of the claim (including the right to settle the claim solely for monetary consideration) with counsel selected by Incyte and reasonably acceptable to Novartis; provided that the failure to provide timely notice of a claim by a Third Party shall not limit a Novartis Indemnified Party's right for indemnification hereunder except to the extent such failure results in actual prejudice to Incyte; and provided further that before entering into a settlement, Incyte shall provide Novartis with a bond, or other evidence reasonably satisfactory to Novartis that Incyte has readily available funds, in either case in an amount sufficient to indemnify Novartis in full promptly thereafter. The Novartis Indemnified Parties shall cooperate with Incyte and may, at their option and expense, be separately represented in any such action or proceeding. Incyte shall not be liable for any litigation costs or expenses incurred by the Novartis Indemnified Parties without Incyte's prior written authorization. In addition, Incyte shall not be responsible for the indemnification or defense of any Novartis Indemnified Party to the extent arising from any negligent or intentional acts by any Novartis Indemnified Party, or the breach by Novartis of any representation, obligation or warranty under this Agreement, or any claims compromised or settled without its prior written consent.
- (c) Notwithstanding anything to the contrary above: (i) in the event of any such claim against the Novartis Indemnified Parties by a governmental or criminal action seeking an injunction against Novartis, or (ii) if at the time that a claim for which indemnification may be sought under this Section 10.2, or at any time thereafter prior to the final resolution of such claim, a Bankruptcy Event of Incyte has occurred, Novartis shall have the right to control the defense, litigation, settlement, appeal or other disposition of the claim at Incyte's expense.
- 10.3 <u>Limitation of Liability</u>. EXCEPT WITH RESPECT TO A BREACH OF ARTICLE XII OR A PARTY'S LIABILITY PURSUANT TO ARTICLE X, NEITHER PARTY SHALL BE LIABLE FOR SPECIAL, CONSEQUENTIAL, EXEMPLARY, PUNITIVE OR OTHER INDIRECT OR REMOTE DAMAGES, OR, EXCEPT WITH RESPECT TO A BREACH OF ARTICLE II OR SECTION 4.1(A) OR (B), FOR LOSS OF PROFITS, LOSS OF DATA OR LOSS OF USE DAMAGES, IN EACH CASE ARISING IN ANY WAY OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, WHETHER BASED UPON WARRANTY, CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OR LOSS.
- 10.4 <u>Insurance</u>. Each Party shall use all commercially reasonable efforts to maintain Third Party insurance and/or self-insurance, as applicable, including product liability insurance, with respect to its activities hereunder in amounts customary to such insurance and sufficient to meet its obligations under this Agreement, and shall claim upon such insurance policy according to such policy's relevant terms and conditions before relying upon indemnification from the other Party.

ARTICLE XI

REPRESENTATIONS AND WARRANTIES AND COVENANTS

- 11.1 <u>Representation Of Authority; Consents</u>. Incyte and Novartis each represents and warrants to the other Party that:
 - (a) as of the Effective Date, it has full right, power and authority to enter into this Agreement;
- (b) as of the Effective Date, this Agreement has been duly executed by such Party and constitutes a legal, valid and binding obligation of such Party, enforceable in accordance with its terms, except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other Laws relating to or affecting creditors' rights generally and by general equitable principles and public policy constraints (including those pertaining to limitations and/or exclusions of liability, competition Laws, penalties and jurisdictional issues including conflicts of Laws); and
- (c) as of the Effective Date, all necessary consents, approvals and authorizations of all government authorities and other persons required to be obtained by such Party in connection with the execution, delivery and performance of this Agreement have been and shall be obtained.
- 11.2 No Conflict. Each Party represents and warrants to the other Party that the execution and delivery of this Agreement and the performance of such Party's obligations hereunder (a) do not conflict with or violate such Party's corporate charter and bylaws or any requirement of applicable Laws and (b) do not and shall not conflict with, violate or breach or constitute a default or require any consent under, any oral or written contractual obligation of such Party. Each Party agrees that it shall not during the term of this Agreement grant any right, license, consent or privilege to any Third Party or otherwise undertake any action, either directly or indirectly, that would conflict with the rights granted to the other Party or interfere with any obligations of such Party set forth in this Agreement.
- 11.3 <u>Additional Incyte Representations and Warranties</u>. Incyte represents and warrants that, as of the Effective Date, except as disclosed in <u>Schedule 11.3</u>:
- (a) Neither it nor any of its Affiliates or any of its or their sublicensees has received written notice of any claim or litigation which alleges any Intellectual Property Rights of a Third Party are infringed by a Licensed Compound or the Development or Commercialization of any Licensed Compound; to the knowledge of Incyte and its Affiliates, none of Incyte or any of its Affiliates has in the past infringed or is currently infringing any Third Party Intellectual Property Rights through activities related to the Licensed Compounds; and to the knowledge of Incyte and its Affiliates, the Development and Commercialization activities contemplated by Incyte under this Agreement, will not infringe the Intellectual Property Rights of any Third Party;
- (b) there are no claims, judgments or settlements against or owed by Incyte or any of its Affiliates, nor, to the knowledge of Incyte or any of its Affiliates, any pending reissue,

reexamination, interference, opposition or similar proceedings, with respect to any Licensed Compounds or Incyte IP, and Incyte has not received written notice of any threatened claims or litigation or any reissue, reexamination, interference, opposition or similar proceedings seeking to invalidate or otherwise challenge any Incyte IP;

- (c) to the knowledge of Incyte and its Affiliates, no Third Party is infringing any Incyte Patent Rights;
- (d) (i) Incyte is the legal and beneficial owner or has the right to grant to Novartis the rights granted herein, to all Incyte IP, (ii) no Third Party has any right, interest or claim in or to such rights that would limit the rights granted to Novartis under this Agreement and (iii) all assignments to Incyte of inventorship rights relating to the Incyte Patent Rights Controlled by Incyte are valid and enforceable;
- (e) all fees due to date that are required to maintain the Incyte IP have been paid in full and to Incyte's knowledge, the Incyte IP is valid and enforceable;
- (f) Incyte has not granted to any Third Party rights that are inconsistent with Novartis' rights hereunder, including a grant of rights that removed Incyte IP from Incyte's Control and limited the rights granted to Novartis under this Agreement, and there are no agreements or arrangements to which Incyte or any of its Affiliates is a party relating to Licensed Compounds or Incyte IP that would limit the rights granted to Novartis under this Agreement; and
- (g) Incyte has disclosed to Novartis all material information known to it and its Affiliates with respect to the safety and efficacy of each of the Licensed Compounds.
- 11.4 <u>Incyte Covenant</u>. Incyte shall not grant to any Third Party rights that would be inconsistent with Novartis' rights hereunder, including a grant of rights that would remove Incyte IP from Incyte's Control and limit the rights granted to Novartis under this Agreement.
- 11.5 <u>Disclaimer of Warranty.</u> Nothing in this Agreement shall be construed as a representation made or warranty given by either Party that either Party will be successful in obtaining any Patent Rights, that any patents will issue based on pending applications or that any such pending applications or patents issued thereon will be valid. ALL INCYTE IP TRANSFERRED PURSUANT TO THIS AGREEMENT SHALL BE PROVIDED ON AN "AS IS" BASIS. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, EACH PARTY EXPRESSLY DISCLAIMS, WAIVES, RELEASES AND RENOUNCES ANY WARRANTY, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT.
- 11.6 <u>Standstill</u>. Novartis agrees that, for a period commencing on the Effective Date and ending [***] after the Effective Date, unless specifically invited in writing to do so by Incyte, Novartis and each of its Affiliates (as that term is defined in Rule 12b-2 under the Securities Exchange Act of 1934 (the "<u>Exchange Act</u>") will not in any manner, directly or indirectly:

- (a) effect, or seek, offer or propose to effect (whether publicly or otherwise) or cause or participate in, (i) any acquisition of (A) any Voting Stock of Incyte, (B) direct or indirect rights or options to acquire any Voting Stock of Incyte, or (C) assets or securities of Incyte or any of its subsidiaries, (ii) any merger, consolidation, tender or exchange offer, or other business combination involving Incyte or any Affiliate thereof, (iii) any restructuring, recapitalization, liquidation, dissolution or similar transaction with respect to Incyte or any Affiliate thereof, or (iv) any "solicitation" of "proxies" (as such terms are defined or used in Regulation 14A under the Exchange Act) or consents with respect to any Voting Stock of Incyte, any "election contest" (as such term is defined or used in Rule 14a-11 of the Exchange Act) with respect to Incyte, or any demand for a copy of Incyte's stock ledger, list of its stockholders, or other books and records;
- (b) form, join, participate in or encourage the formation of any "group" (within the meaning of Section 13(d)(3) of the Exchange Act) ("13D Group") with respect to any Voting Stock of Incyte;
- (c) otherwise act (other than as contemplated under this Agreement), alone or in concert with others (including by providing financing for another party), to seek or offer to control or influence, in any manner, the management, Board of Directors or policies of Incyte;
- (d) take any action that might force Incyte to make a public announcement regarding any of the types of matters set forth in Section 11.6(a) above;
- (e) make (publicly or to Incyte, or its directors, officers, employees, agents or security holders, directly or indirectly) any request or proposal to amend, waive or terminate any provision of this Agreement or any inquiry or statement relating thereto; or
- (f) instigate, encourage or assist any Third Party to do any of the foregoing; <u>provided that</u> Novartis and its Affiliates may acquire, hold or sell, through their respective treasury departments, an aggregate amount not to exceed [***] of the voting power represented by Incyte's Voting Stock solely for the purposes of investment in the ordinary course of business (so long as any decision to make such acquisition or sale is in compliance with United States securities law), [***] and <u>provided further</u> that the restrictions set forth in this Section 11.6 shall terminate immediately if: (i) a Person or 13D Group not including Novartis or its Affiliates [***], either (x) Incyte publicly announces its

willingness to consider such proposal or alternative proposals for a transaction described in clause (ii)(A) or (B) below, or (y) the Board of Directors of Incyte determines to engage in negotiations with such Person or 13D Group or any other party other than Novartis or its Affiliates with respect to a transaction described in clause (ii)(A) or (B) below [***], (ii) Incyte or its Affiliates enters in to a letter of intent or definitive agreement with any party other than Novartis or its Affiliates (A) [***]; or (B) which would result in all or substantially all of Incyte's assets being sold to any Person or 13D Group not including Novartis or its Affiliates; (iii) Incyte announces its determination to pursue (w) a transaction described in clause (ii)(A) or (B) above, (x) [***] that represents more than [***] of the voting power of the outstanding Voting Stock of Incyte, (y) the sale, transfer or disposition of all or substantially all of Incyte's assets or [***] with any party other than Novartis or its Affiliates; [***]; or (vi) the sale, transfer or disposition to [***]; provided, however, that any termination pursuant to clause (i)(B) above shall not permit Novartis or its Affiliates to take any action described in Section 11.6(a)(iv), Section 11.6(b) or Section 11.6(f). In the event that the transactions contemplated by clauses (i), (ii) and/or (iii) shall have been terminated or abandoned, and such termination or abandonment is demonstrable by a press release issued by Incyte (or, in the case of clause [***]), then this Section 11.6 shall again be applicable for the remainder of the period specified herein.

Further, nothing in this Section 11.6 shall obligate Novartis or its Affiliates to cause Novartis' or its Affiliates' advisors (including financial advisors, attorneys, accountants and consultants) to comply with the terms of this Section 11.6 when acting on their own behalf or on behalf of Third Parties.

ARTICLE XII

CONFIDENTIALITY

12.1 <u>Confidential Information</u>. All Confidential Information of a Party ("<u>Disclosing Party</u>") shall not be used by the other Party (the "<u>Receiving Party</u>") except in performing its obligations or exercising rights explicitly granted under this Agreement and shall be maintained

in confidence by the Receiving Party and shall not otherwise be disclosed by the Receiving Party to any Third Party, without the prior written consent of the Disclosing Party with respect to such Confidential Information, except to the extent that the Confidential Information:

- (a) was known by the Receiving Party or its Affiliates prior to its date of disclosure to the Receiving Party; or
- (b) is lawfully disclosed to the Receiving Party or its Affiliates by sources other than the Disclosing Party rightfully in possession of the Confidential Information; or
- (c) becomes published or generally known to the public through no fault or omission on the part of the Receiving Party, its Affiliates or its sublicensees; or
- (d) is independently developed by or for the Receiving Party or its Affiliates without reference to or reliance upon such Confidential Information, as established by written records.

Specific information shall not be deemed to be within any of the foregoing exclusions merely because it is embraced by more general information falling within those exclusions.

- 12.2 <u>Permitted Disclosure</u>. The <u>Receiving Party</u> may provide the <u>Disclosing Party</u>'s Confidential Information:
- (a) to the Receiving Party's respective employees, consultants and advisors, and to the employees, consultants and advisors of such Party's Affiliates, who have a need to know such information and materials for performing obligations or exercising rights expressly granted under this Agreement and have an obligation to treat such information and materials as confidential;
- (b) to patent offices in order to seek or obtain Patent Rights or to Regulatory Authorities in order to seek or obtain approval to conduct Clinical Trials or to gain Regulatory Approval with respect to the Licensed Product as contemplated by this Agreement; <u>provided</u>, that such disclosure may be made only following reasonable notice to the Disclosing Party and to the extent reasonably necessary to seek or obtain such Patent Rights or approvals; or
- (c) if such disclosure is required by Law or to defend or prosecute litigation or arbitration; <u>provided</u>, that prior to such disclosure, to the extent permitted by Law, the Receiving Party promptly notifies the Disclosing Party of such requirement and furnishes only that portion of the Disclosing Party's Confidential Information that the Receiving Party is legally required to furnish.
 - 12.3 <u>Publicity; Attribution; Terms of this Agreement; Non-Use of Names.</u>
- (a) Except as required by judicial order or applicable Law or as set forth below, neither Party shall make any public announcement concerning this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed. The Party preparing any such public announcement shall provide the other Party with a draft thereof at least [***] prior to the date on which such Party would like

to make the public announcement. Notwithstanding the foregoing, the Parties shall each issue a separate press release, in the forms attached as <u>Exhibit G</u>, within one (1) Business Day after the Effective Date to announce the execution of this Agreement and describe the material financial and operational terms of this Agreement. Neither Party shall use the name, trademark, trade name or logo of the other Party or its employees in any publicity or news release relating to this Agreement or its subject matter, without the prior express written permission of the other Party.

- (b) Notwithstanding the terms of this ARTICLE XII,
- (i) either Party shall be permitted to disclose the existence and terms of this Agreement to the extent required, in the reasonable opinion of such Party's legal counsel, to comply with applicable Laws, including the rules and regulations promulgated by the SEC or any other governmental authority. Notwithstanding the foregoing, before disclosing this Agreement or any of the terms hereof pursuant to this Section 12.3(b), the Parties will coordinate in advance with each other in connection with the redaction of certain provisions of this Agreement with respect to any filings with the SEC, London Stock Exchange, the UK Listing Authority, NYSE, the NASDAQ Stock Market or any other stock exchange on which securities issued by a Party or a Party's Affiliate are traded, and each Party will use Commercially Reasonable Efforts to seek confidential treatment for such terms as may be reasonably requested by the other Party; provided that each Party will ultimately retain control over what information that Party discloses to their relevant exchange, and provided further that the Parties will use their Commercially Reasonable Efforts to file redacted versions with any governing bodies which are consistent with redacted versions previously filed with any other governing bodies. Other than such obligation, neither Party (nor its Affiliates) will be obligated to consult with or obtain approval from the other Party with respect to any filings to the SEC, London Stock Exchange, the UK Listing Authority, NYSE, the NASDAQ Stock Market or any other stock exchange
- (ii) Either Party may disclose the existence and terms of this Agreement in confidence to its attorneys and advisors, and to potential acquirers (and their respective professional attorneys and advisors), in connection with a potential merger, acquisition or reorganization and to existing and potential investors or lenders of such Party, as a part of their due diligence investigations, or to existing and potential licensees or sublicensees or to permitted assignees, in each case under an agreement to keep the terms of confidentiality and non-use substantially no less rigorous than the terms contained in this Agreement and to use such information solely for the purpose permitted pursuant to this Section 12.3(b).
- (iii) Either Party may issue a press release or make a public disclosure relating to this Agreement or the Supply Agreement or the Parties' activities under this Agreement to the extent that such disclosure describes the commencement and/or "top-line" results of Clinical Trials of the Licensed Product, the achievement of any Development events with respect to the Licensed Product or the filing for or receipt of Regulatory Approval with respect to the Licensed Product, amounts paid to either Party in respect of the achievement of any milestone events, or the termination of this Agreement. Prior to making any such disclosure, the Party making the disclosure shall provide the other Party with a draft of such proposed disclosure at least [***] (or, to the extent timely disclosure of a material event is required by Law or stock exchange or stock market rules, such period of time sufficiently in advance of the disclosure so that the other Party will have the opportunity to comment upon the

disclosure) prior to making any such disclosure, for the other Party's review and comment, which shall be considered in good faith by the disclosing Party.

- (c) For purposes of clarity, either Party may issue a press release or public announcement or make such other disclosure relating to this Agreement if the contents of such press release, public announcement or disclosure (i) has previously been made public other than through a breach of this Agreement by the issuing Party or its Affiliates or (ii) is contained in such Party's financial statements prepared in accordance with Accounting Standards.
- Publications. Each Party and its Affiliates shall have the right to make disclosures pertaining to 12.4 Licensed Compound or Licensed Product to Third Parties in Publications in accordance with the following procedure: The publishing Party shall provide the non-publishing Party with an advance copy of the proposed Publication, and each Party shall then have [***] prior to submission for any Publication in which to recommend any changes it reasonably believes are necessary to preserve any Patent Rights or Know-How belonging in whole or in part to the non-publishing Party. If the non-publishing Party informs the publishing Party that such Publication, in the non-publishing Party's reasonable judgment, could be expected to have a material adverse effect on any patentable invention owned by or licensed, in whole or in part, to the non-publishing Party (other than pursuant to a license granted under this Agreement), or on any Know-How which is Confidential Information of the nonpublishing Party, the publishing Party shall delay or prevent such Publication as follows: (i) with respect to a patentable invention, such Publication shall be delayed sufficiently long (not to exceed [***]) to permit the timely preparation and filing of a patent application; and (ii) with respect to Know-How which is Confidential Information of such non-publishing Party, such Know-How shall be deleted from the Publication. Each Party shall have the right to present its Publications, which Publications shall be subject to the requirements in this Section 12.4, at scientific conferences, including at any conferences in any country in the world.
- 12.5 <u>Term.</u> All obligations under this ARTICLE XII shall expire (i) [***] following expiration of this Agreement pursuant to Section 9.1, (ii) [***] following termination of this Agreement pursuant to Section 9.2(b), or (iii) [***] following termination of this Agreement pursuant to Section 9.2(c).
- Receiving Party shall return to the Disclosing Party all Confidential Information received by the Receiving Party from the Disclosing Party (and all copies and reproductions thereof). In addition, the Receiving Party shall destroy: (a) any notes, reports or other documents prepared by the Receiving Party which contain Confidential Information of the Disclosing Party; and (b) any Confidential Information of the Disclosing Party (and all copies and reproductions thereof) which is in electronic form or cannot otherwise be returned to the Disclosing Party. Alternatively, upon written request of the Disclosing Party, the Receiving Party shall destroy all Confidential Information received by the Receiving Party from the Disclosing Party (and all copies and reproductions thereof) and any notes, reports or other documents prepared by the Receiving Party which contain Confidential Information of the Disclosing Party. Nothing in this Section 12.6 shall require the alteration, modification, deletion or destruction of archival tapes or other electronic back-up media made in the ordinary course of business; provided that the Receiving Party shall continue to be bound by its obligations of

confidentiality and other obligations under this ARTICLE XII with respect to any Confidential Information contained in such archival tapes or other electronic back-up media. Any requested destruction of Confidential Information shall be certified in writing to the Disclosing Party by an authorized officer of the Receiving Party supervising such destruction. Notwithstanding the foregoing, (i) the Receiving Party's legal counsel may retain one copy of the Disclosing Party's Confidential Information solely for the purpose of determining the Receiving Party's continuing obligations under this ARTICLE XII and (ii) the Receiving Party may retain the Disclosing Party's Confidential Information and its own notes, reports and other documents (A) to the extent reasonably required (i) to exercise the rights and licenses of the Receiving Party expressly surviving expiration or termination of this Agreement; (ii) to perform the obligations of the Receiving Party expressly surviving expiration or termination of this Agreement; or (B) to the extent it is impracticable to do so without incurring disproportionate cost. Notwithstanding the return or destruction of the Disclosing Party's Confidential Information, the Receiving Party shall continue to be bound by its obligations of confidentiality and other obligations under this ARTICLE XII.

ARTICLE XIII

DISPUTE RESOLUTION

- Dispute Resolution Process. Matters before the JSC and subcommittees shall be governed by the process specified in Section 3.5. Any controversy, claim or dispute arising out of or relating to this Agreement that is not subject to Section 3.5, shall be settled, if possible, through good faith negotiations between the Parties. If the Parties are unable to settle such dispute within [***], and a Party wishes to pursue the matter, the matter may be referred by either Party to the Executive Officers, who shall meet to attempt to resolve the dispute in good faith. Such resolution, if any, of a referred issue shall be final and binding on the Parties. All negotiations pursuant to this Section 13.1 are confidential and shall be treated as compromise and settlement negotiations for purposes of applicable rules of evidence. If the Executive Officers are unable to settle the dispute within [***] after referral thereto pursuant to Section 13.1, then each Party reserves its right to any and all remedies available under law or equity with respect to the dispute, subject to Section 13.2.
- 13.2 <u>Injunctive Relief.</u> Notwithstanding anything to the contrary in this ARTICLE XIII, any Party may seek immediate injunctive or other interim relief from any court of competent jurisdiction as necessary to enforce the provisions of Section 11.6 or ARTICLE XII and to enforce and prevent infringement or misappropriation of the Patent Rights, Know-How or Confidential Information Controlled by such Party.

ARTICLE XIV

MISCELLANEOUS

14.1 <u>Governing Law</u>. This Agreement (and any claims or disputes arising out of or related thereto or to the transactions contemplated thereby or to the inducement of any party to enter therein, whether for breach of contract, tortious conduct, or otherwise and whether predicated on common law, statute or otherwise) shall in all respects be governed by and

construed in accordance with the laws of the State of New York, including all matters of construction, validity and performance, in each case without reference to any conflict of law rules that might lead to the application of the laws of any other jurisdiction.

States District Court for the Southern District of New York or the United States District Court for the District of Delaware, for the purposes of any suit, action or other proceeding arising out of the Transaction. Each Party agrees to commence any such action, suit or proceeding either in the United States District Court for the Southern District of New York or the United States District Court for the District of Delaware or if such suit, action or other proceeding may not be brought in such court for jurisdictional reasons, in the Supreme Court of the State of New York, New York County. Each Party further agrees that service of any process, summons, notice or document by U.S. registered mail to such Party's respective address set forth in Section 14.6 shall be effective service of process for any action, suit or proceeding in New York or Delaware with respect to any matters to which it has submitted to jurisdiction in this Section 14.2. Each Party irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of this Agreement in (i) the United States District Court for the Southern District of New York or (ii) the United States District Court for the District of Delaware, and hereby and thereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

14.3 Assignment.

- (a) Neither Party may assign its rights and obligations under this Agreement without the prior written consent of the other Party, except that without prior written consent of the other Party (A) Novartis may make such assignment to a Novartis Group Member, (B) Incyte may make such assignment to an Incyte Group Member, and (C) either Party may make such assignment to a Third Party to whom a Party is required to, or reasonably believes that it will be required to, divest any Novartis IP or Incyte IP, as the case may be, to the extent necessary to comply with Law or the order of any governmental authority as a result of such transaction (so long as in each such case such Party shall remain jointly and severally liable with such assignee with respect to all obligations so assigned). Any request for consent to assignment shall not be unreasonably withheld or delayed. Any purported assignment in contravention of this Section 14.3 shall, at the option of the non-assigning Party, be null and void and of no effect. No assignment shall release either Party from responsibility for the performance of any accrued obligation of such Party hereunder. This Agreement shall be binding upon and enforceable against the successor to or any permitted assignee from either of the Parties.
 - (b) Each Party agrees that, notwithstanding any provisions of this Agreement to the contrary:
- (i) either Party may assign this Agreement and the rights, obligations and licenses granted hereunder to a Third Party in connection with a sale or transfer of all or substantially all of the assigning Party's business to which this Agreement relates or if a Party merges or consolidates with a Third Party.

(ii) in the event that this Agreement is assigned by either Party in connection with a sale or transfer of all or substantially all of the assigning Party's business to which this Agreement relates, such assignment shall not provide (A) the non-assigning Party with rights or access to Intellectual Property Rights of the assignee or acquirer of such Party, nor (B) the assignee or acquirer with rights or access to Intellectual Property Rights of the non-assigning Party.

14.4 <u>Change of Control</u>.

- (a) In the event of any Change of Control of Incyte, Incyte shall notify Novartis promptly, but in no event later than [***] following such Change of Control. Novartis shall have the right, by providing written notice within [***] following any such notice of Change of Control, to elect to terminate any or all of Incyte's rights under, or delete, in whole or in part, from this Agreement: Sections [***] and [***]. If Novartis makes any election as provided in this Section 14.4 to delete any Section, the Parties agree to adopt the replacement provisions set forth in Exhibit H in place of the relevant Sections in this Agreement, and no Party shall have any further obligations with respect to any such deleted Section. For the avoidance of doubt, Novartis shall be entitled, in its sole discretion, to make the elections provided for in this Section 14.4(a) upon each occurrence of a Change of Control.
- (b) In the event of any Change of Control of Novartis, Novartis shall notify Incyte promptly, but in no event later than [***] following such Change of Control. Incyte shall have the right, by providing written notice within[***] following any such notice of Change of Control, to elect to terminate any or all of Novartis' rights under, or delete, in whole or in part, from this Agreement: Sections [***] and [***]. If Incyte makes any election as provided in this Section 14.4 to delete any Section, the Parties agree to adopt the replacement provisions set forth in Exhibit H in place of the relevant Sections in this Agreement, and no Party shall have any further obligations with respect to any such deleted Section. For the avoidance of doubt, Incyte shall be entitled, in its sole discretion, to make the elections provided for in this Section 14.4(b) upon each occurrence of a Change of Control.
- (c) In the event of a Change of Control of a Party, the Development or Commercialization of a compound or product that, as of the date of such Change of Control, is being Developed or Commercialized by the acquirer of such Party or any Affiliate controlled by (as "controlled by" is defined in Section 1.3) such acquirer, shall not constitute a breach of this Agreement; provided that (i) such acquirer or Affiliate keeps such Development or Commercialization program for such other product separate from the Development and Commercialization programs for Licensed Products and (ii) the Party that experienced the Change of Control continues to meet its obligations hereunder.
- (d) In the event that any Group Company of a Party enters into an agreement with any Person pursuant to which a Change of Control would occur upon the closing of the transactions contemplated by such agreement, then during the period between entry into such agreement and the occurrence of the related Change of Control, the Party not entering into such agreement may elect to suspend the sharing of information and conduct of meetings

contemplated in Sections [***] and [***], in whole or in part, provided that if such agreement is subsequently terminated without the occurrence of the related Change of Control, then the Party not entering into such agreement may no longer elect to suspend such sharing of information and conduct of meetings.

- 14.5 <u>Entire Agreement; Amendments</u>. This Agreement, the Supply Agreement and the Exhibits referred to in this Agreement constitute the entire agreement between the Parties with respect to the subject matter hereof, and supersede all previous arrangements with respect to the subject matter hereof, whether written or oral, including the Prior Confidentiality Agreement. Any amendment or modification to this Agreement shall be made in writing signed by both Parties.
 - 14.6 <u>Notices</u>. Notices to Incyte shall be addressed to:

Incyte Corporation
Experimental Station, Route 141 & Henry Clay Road
Wilmington, Delaware 19880
Attention: Chief Commercial Officer
Facsimile No.: [***]

with a copy to:

Incyte Corporation
Experimental Station, Route 141 & Henry Clay Road
Building E336
Wilmington, Delaware 19880
Attention: General Counsel
Facsimile No.: [***]

Notices to Novartis shall be addressed to:

Novartis International Pharmaceutical Ltd. Attention: Board of Directors

Physical Address:

131 Front Street, Hamilton HM12 Bermuda

Mailing Address: P.O.Box 2899 Hamilton HM LX Bermuda Facsimile No.: [***] with a copy to:

Allen & Overy LLP 1221 Avenue of the Americas New York, New York 10020 Attention: Eric Shube Facsimile No.: [***]

Either Party may change its address to which notices shall be sent by giving notice to the other Party in the manner herein provided. All reports, approvals, and notices required or permitted by this Agreement to be given to a Party (each a "Notice") shall be given in writing, by personal delivery, telecopy or overnight courier, to the Party concerned at its address as set forth above (or at such other address as a Party may specify by written notice pursuant to this Section 14.6 to the other). All Notices shall be deemed effective, delivered and received (a) if given by personal delivery, or by overnight courier, when actually delivered and signed for, or (b) if given by facsimile, when such facsimile is transmitted to the facsimile number specified above and receipt therefor is confirmed.

- 14.7 <u>Force Majeure</u>. No failure or omission by either Party in the performance of any obligation of this Agreement shall be deemed a breach of this Agreement or create any liability if the same shall arise from any Force Majeure Event; <u>provided that</u> the Party affected by such Force Majeure Event promptly notifies the other Party and uses diligent efforts to cure such failure or omission as soon as is practicable after the occurrence of one or more Force Majeure Events.
- 14.8 <u>Compliance With Laws</u>. Each Party shall perform its obligations under this Agreement in compliance with all applicable Laws.
- 14.9 <u>Use Of Names, Logos Or Symbols</u>. Subject to Sections 6.5 and 12.3, no Party shall use the name, trademarks, logos, physical likeness, employee names or owner symbol of the other Party for any purpose, including private or public securities placements, without the prior written consent of the affected Party. Nothing contained in this Agreement shall be construed as granting either Party any rights or license to use any of the other Party's trademarks or trade names or the names of any employees thereof, without separate, express written permission of the owner of such trademark or trade name or name.
- 14.10 <u>Independent Contractors</u>. It is understood and agreed that the relationship between the Parties is that of independent contractors and that nothing in this Agreement shall be construed to create a joint venture or any relationship of employment, agency or partnership between the Parties to this Agreement. Neither Party is authorized to make any representations, commitments, or statements of any kind on behalf of the other Party or to take any action that would bind the other Party except as explicitly provided in this Agreement. Furthermore, none of the transactions contemplated by this Agreement shall be construed as a partnership for any tax purposes.

- 14.11 <u>Headings</u>. The captions or headings of the sections or other subdivisions hereof are inserted only as a matter of convenience or for reference and shall have no effect on the meaning of the provisions hereof.
- 14.12 <u>No Implied Waivers; Rights Cumulative</u>. No failure on the part of Incyte or Novartis to exercise, and no delay by either Party in exercising, any right, power, remedy or privilege under this Agreement, or provided by statute or at law or in equity or otherwise, shall impair, prejudice or constitute a waiver of any such right, power, remedy or privilege by such Party or be construed as a waiver of any breach of this Agreement or as an acquiescence therein by such Party, nor shall any single or partial exercise of any such right, power, remedy or privilege by a Party preclude any other or further exercise thereof or the exercise of any other right, power, remedy or privilege.
- 14.13 <u>Severability</u>. If, under applicable Laws, any provision of this Agreement is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement (such invalid or unenforceable provision, a "<u>Severed Clause</u>"), this Agreement shall endure except for the Severed Clause. The Parties shall consult one another and use good faith efforts to agree upon a valid and enforceable provision that is a reasonable substitute for the Severed Clause in view of the intent of this Agreement.
- 14.14 Execution In Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument. Signatures provided by facsimile transmission or in AdobeTM Portable Document Format (PDF) sent by electronic mail shall be deemed to be original signatures.
- 14.15 <u>No Third Party Beneficiaries</u>. No Person other than Novartis and Incyte (and their respective assignees) shall be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.
- 14.16 <u>Exhibits</u>. In the event of inconsistencies between this Agreement and any exhibits or attachments hereto, the terms of this Agreement shall control.

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IN WITNESS WHEREOF, the Parties have caused their duly authorized officers to execute and acknowledge this Agreement as of the date first written above.

NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD.

INCYTE CORPORATION

By: /s/ Simon Zivi

Name: Simon Zivi

By: /s/ Paul A. Friedman

Name: Paul A. Friedman

Title: Director Title: CEO

NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD.

By: /s/ Michael Jones

Name: Michael Jones
Title: Director

Exhibit A

<u>Incyte Patent Rights</u>

A-1 c-MET Patent Rights

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[***] Confidential material redacted and filed separately with the Commission.

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[***] Confidential material redacted and filed separately with the Commission.

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Exhibit B

Initial Information Transfer to Novartis

Described below are the items to be provided to Novartis by Incyte pursuant to Section 4.1(a)(i) of the Agreement, which include the material documents, information and data listed in this Exhibit B that are recorded in tangible form that are Incyte Know-How for c-MET Licensed Products and JAK Licensed Products, to the extent each of which exists as of the Effective Date and has not already been provided to Novartis. Within sixty (60) days after the Effective Date, Novartis will confirm in writing to Incyte whether Incyte's initial data transfer obligations, as described in Section 4.1(a)(i) of the Agreement, have been achieved. Subject to Section 4.3(c) of the Agreement, additional data may be requested by Novartis, and such requests as reasonably agreed will be addressed by Incyte in a timely fashion.

Clinical & Regulatory Documents and Information

Clinical study related documents, information and data that are recorded in tangible form, including those
currently possessed by CROs and other third party vendors
Regulatory Authority submissions, correspondence and all communications, including minutes from
teleconferences and contact reports (US and ex-US)
Regulatory Authority meeting briefing documents and related minutes (US and ex-US)
Pre-IND submissions
IND submissions
Annual reports to IND(s)
CTA/IMPD submissions
Annual Safety Reports submissions
Investigator's Brochures and any updates thereto
Safety reports (CIOMSs and/or Medwatch reports)
Documents related to serious adverse events ("SAEs")
Investigator Safety Letters, actions taken for safety reasons, and other relevant safety information
Safety pharmacology and toxicology study related documents, information and data that are recorded in
tangible form
Pharmacology and Absorption, Distribution, Metabolism, and Excretion (ADME) related documents,
information and data that are recorded in tangible form

c-MET Licensed Compound Documents

Incyte may retain (x) copies of all documents, information and data, including regulatory submissions, correspondence, and clinical trial data; (y) originals of regulatory submissions, correspondence, and clinical trial data until fifteen (15) Business Days after responsibility for the relevant regulatory filing or clinical trial has been transferred to Novartis in accordance with the Agreement and this Exhibit B, and (z) any other original documents, information and data to the extent, and only for as long as, required by Incyte to carry out its research and Development responsibilities under the Agreement, including Incyte's conduct of the Phase I study for INCB-28060 ("Study 28060-101"). Incyte will provide both a shared electronic depository and paper copies of all requested documents, information and data where both electronic and paper versions are currently available.

JAK Licensed Compound Documents

Incyte may retain (x) originals of all documents, information and data, including regulatory submissions, correspondence, and clinical trial data and (y) originals of regulatory submissions, correspondence, and clinical trial data directly related to Study 352 until fifteen (15) Business Days after responsibility for the relevant regulatory filing or clinical trial has been transferred to Novartis in accordance with the Agreement and this Exhibit B. Incyte will provide both a shared electronic depository and paper copies of all requested documents, information and data where both electronic and paper versions are currently available.

Manufacturing Know-How

Incyte will prepare and compile an inventory of relevant documents and transfer all Incyte Know-How for manufacturing c-MET Licensed Products and JAK Licensed Products including, but not limited to: laboratory notebook data, batch records, process data, stability data, summary reports, formulation folders, analytical methods, development reports, quality and regulatory documentation, validation reports and other material data related to the development, manufacturing, and/or distribution of Drug Substance and Drug Product. As part of the Know-How transfer, Incyte shall cooperate with Novartis to establish a transfer protocol and make resources available at Incyte's cost to enable the successful execution of the transfer protocol. Additionally, Incyte will disclose and transfer as necessary, any vendor sourcing and/or contracting information that Novartis may request.

[***] Confidential material redacted and filed separately with the Commission.

<u>C-1</u>

Out-of-Pocket Costs

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Clinical Supply Agreement

This Clinical Supply Agreement (this "Supply Agreement") is entered into as of [] between Incyte Corporation, a Delaware corporation having an office at Experimental Station, Route 141 & Henry Clay Road, Wilmington, Delaware ("Incyte"), and [Novartis International Pharmaceuticals Ltd.], a [] having an office at [] ("Novartis"). Novartis and Incyte are sometimes referred to herein individually as a "Party" and collectively as the "Parties".

WHEREAS, Incyte and Novartis have entered into a Collaboration and License Agreement, dated , 2009 ("Collaboration and License Agreement"); and

WHEREAS, Pursuant to the Collaboration and License Agreement, Incyte (or its designees) has agreed to manufacture, handle and supply the Drug Substance or the Drug Substance intermediate and Drug Product required by Novartis for use in Clinical Trials in accordance with the Development Plan on the terms and conditions set out in (i) this Supply Agreement and (ii) the Collaboration and License Agreement.

NOW THEREFORE, the Parties hereby agree as follows:

1. Defined Terms

Terms defined in the Collaboration and License Agreement shall have the same meaning when used in this Supply Agreement, unless expressly stated otherwise.

2. Supply and Packaging

- 2.1 In accordance with Section 5.1(b) of the Collaboration and License Agreement, Incyte agrees to use Commercially Reasonable Efforts to supply Novartis with any agreed Drug Substance intermediate, the Drug Substance and the Drug Product for use in the Clinical Trials on and subject to the terms and conditions of: (a) this Supply Agreement and (b) the Collaboration and License Agreement.
- 2.2 The Drug Substance intermediate, the Drug Substance and Drug Product delivered by Incyte pursuant to this Supply Agreement shall have attached an agreed form of label.
- 2.3 Incyte may either itself package the Drug Substance and Drug Product ("<u>Clinical Supplies</u>"), or use a Third Party or Affiliate subcontractor. The Out-of-Pocket cost and expense of packaging will be charged by Incyte to Novartis. Alternatively, Novartis may undertake the packaging itself or through a Third Party contractor at its own expense
- 2.4 For Clinical Supplies other than for Study 352, Incyte (or alternatively, Novartis) shall manufacture or purchase from a Third Party or Affiliate subcontractor the labels and packaging materials for the Clinical Supplies, in accordance with specifications to be agreed between the Parties in writing, and shall conduct quality assurance testing as

stipulated in a separate SOP agreed between the Parties. Both Parties shall be responsible for the design of all art work for such labels and packaging materials.

2.5 Each Party shall at all times comply with all Laws applicable to it in connection with the importation, supply and use of the Clinical Supplies.

3. Forecasts and Orders

- 3.1 Incyte and Novartis will mutually agree, on a monthly basis, to a rolling forecast of the quantities of Clinical Supplies required to carry out the Clinical Trials in accordance with the relevant Development Plan (each a "Clinical Trial Forecast").
- 3.2 Incyte and Novartis will mutually agree in the applicable JDC on a Clinical Supply plan for the Drug Substance intermediate, Drug Substance, and Drug Product and on the responsibilities of each Party in implementing the Clinical Supply plan, including a delivery date for each batch of Clinical Supplies to be delivered by Incyte to Novartis in accordance with paragraph 4.2. Based on this agreed Clinical Supply plan, Novartis will provide Incyte with a written signed request for Clinical Supplies, which shall constitute a binding order by Novartis (a "Clinical Trial Order"). The JDC shall track the actual use of the Clinical Supplies in accordance with the Development Plan to determine if any significant deviation occurs between the quantity used in the Clinical Trials and the Clinical Trial Forecast. If mutually agreed by Incyte and Novartis, Novartis may request changes to the delivery date(s), and the quantities of Clinical Supplies to be delivered on each delivery date, provided it gives Incyte at least [***] written notice in advance of the agreed delivery date.
- 3.3 Incyte shall use Commercially Reasonable Efforts to meet all orders placed by Novartis which are within the Clinical Trial Forecast by the delivery dates agreed on by the Parties, in accordance with Incyte's standard terms of delivery. Novartis agrees to purchase from Incyte all Clinical Supplies manufactured for Novartis by Incyte according to the Clinical Trial Orders, and use the Drug Substance intermediate, Drug Substance and Drug Product supplied by Incyte for the Clinical Trials.
- 3.4 Where a shortage in Clinical Supplies occurs while clinical trials in the Novartis Territory are ongoing, Incyte shall use Commercially Reasonable Efforts to supply Clinical Supplies as necessary for the conduct of all ongoing Clinical Trials of the Clinical Supplies.

4. Allocation, delivery and acceptance testing

- 4.1 Incyte shall be responsible for and shall conduct either by itself or by assigning a Third Party or Affiliate subcontractor the allocation of Clinical Supplies before delivery to Novartis. All costs and expenses relating to the allocation of Clinical Supplies shall be charged by Incyte to Novartis in accordance with paragraph 6.
- 4.2 Incyte (or any of its Affiliates) shall deliver the Clinical Supplies to Novartis, at Novartis's cost and expense. For the avoidance of doubt, Novartis shall be responsible for delivery of the Clinical Supplies to the site(s) of the Clinical Trials, and for all costs

and expenses relating thereto. Incyte shall use Commercially Reasonable Efforts to deliver the Clinical Supplies specified in Novartis's firm order to meet the requirements of the Development Plan.

- 4.3 Incyte shall conduct at Novartis's cost and expense appropriate release tests for the Drug Substance intermediate, Drug Substance and Drug Product as agreed between the Parties in a Quality Agreement.
- 4.4 Before delivery to Novartis, Incyte shall at its cost and expense conduct an acceptance test to check the quality of the Clinical Trial Order in order to determine whether the Clinical Trial Order has any observable defects. Incyte shall not package or deliver to Novartis any Clinical Supplies which have observable defects.

5. Clinical Products Standards

Incyte shall manufacture, handle and supply, or shall require its Third Party or Affiliate manufacturer, as applicable, to manufacture, handle and supply, all Clinical Supplies supplied by Incyte or its Affiliate to Novartis pursuant to this Supply Agreement and in conformance with appropriate international and country specific regulatory standards for cGMP compliance.

6. Fees, costs and expenses

6.1 Incyte (or Incyte Affiliate) shall invoice Novartis upon each delivery of the Clinical Supplies, for Incyte's [***] for the supply of Clinical Supplies under this Supply Agreement, which Novartis shall pay in full within [***] after receipt.

7. Duration and Termination

- 7.1 Without prejudice to paragraph 7.2, this Supply Agreement shall commence on the date of this Supply Agreement and shall continue in force until the earlier of: (i) Novartis' written notice of a termination of this Supply Agreement for convenience; (ii) the completion of all Clinical Trials and completion of performance of the obligations of both Parties hereunder; (iii) commercial launch of a JAK Licensed Product in the Novartis Territory for a myeloproliferative disease; or (iv) termination or the expiry of the Collaboration and License Agreement, whereupon it shall terminate.
- 7.2 If this Supply Agreement terminates as a result of (i) paragraph 7.1(i) or (ii) termination (but not expiry) of the Collaboration and License Agreement, the terms of this Supply Agreement shall continue to apply to all outstanding orders for Clinical Supplies that have been accepted by Incyte and Novartis shall pay Incyte in accordance with the terms of this Supply Agreement for all Clinical Supplies delivered to it in accordance with such outstanding orders.

8. General

ARTICLE XI (Representations and Warranties), Section 12.1 (Confidential Information), Section 12.2 (Permitted Disclosure), Section 12.6 (Return of Confidential Information),

ARTICLE XIII (Dispute Resolution) and ARTICLE XIV (Miscellaneous) of the Collaboration and License Agreement shall be incorporated into this Supply Agreement, *mutatis mutandis*.

IN WITNESS WHEREOF, the Parties have caused their duly authorized officers to execute and acknowledge this Supply Agreement as of the date first written above.

NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD.	INCYTE CORPORATION	
By: Name: Title:	By: Name: Title:	
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Exhibit D

<u>Initial Development Plans</u>

Exhibit D-1

c-MET Development Plan

Conduct of study in accordance with the protocol existing as of the Effective Date for c-MET Licensed Compound INCB28060, Study 101.

[***] Confidential material redacted and filed separately with the Commission.

Exhibit D-2

JAK Development Plan

- A. Conduct of study in accordance with the protocol existing as of the Effective Date for JAK Licensed Compound INCB018424, Study 352.
- B. [***].
- C. [***].

Exhibit E

c-MET Studies

- A. Initial Phase I Study in cancer patients, such study to be conducted in accordance with a mutually agreeable protocol. Incyte shall be responsible for all decisions with respect to the conduct of such Phase 1 Study and shall pay all costs in connection with such study until achievement of (i) plasma IC90, (ii) demonstrated IC90 tumor inhibition in at least three (3) subjects and (iii) completion of the food effect portion of the study as outlined in the protocol for study INCB28060 101. Thereafter, Novartis shall become responsible for any further Development as well as any additional costs.
- B. 3-month toxicology study in rat, such study to be conducted in accordance with a mutually agreeable protocol

Exhibit F Study 351 and Study 352

[***] Confidential material redacted and filed separately with the Commission.

Exhibit F-1 Out-of-Pocket Costs for Toxicology Studies

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Exhibit F-2

<u>Study 352</u>

Out-of-Pocket Costs for EMEA Registration Study

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Exhibit G

Press Release

Pamela M. Murphy Vice President, Investor Relations/Corporate Communications 302/498-6944

Incyte Announces Major Collaboration and License Agreement for Two Hematology-Oncology Programs

Novartis to Develop and Commercialize Incyte's Lead JAK1/JAK2 Inhibitor, INCB18424, for Territories Outside the US and Incyte's cMET inhibitor, INCB28060, Worldwide

Incyte May Receive Over \$1 Billion in Payments, including \$150 Million Upfront Plus an Immediate \$60 Million
Development Milestone in Addition to Future Potential Milestones and Royalties

WILMINGTON, DE, November 25, 2009 -- Incyte Corporation (NASDAQ: INCY) announced today that it has entered into a collaboration and license agreement with Novartis for two of its investigational hematology-oncology therapies: INCB18424, an oral JAK1/JAK2 inhibitor that is in Phase III development for myelofibrosis, a serious life-threatening neoplastic condition characterized by varying degrees of bone marrow failure, splenic enlargement and debilitating constitutional symptoms, and INCB28060, an oral cMET inhibitor that is about to enter Phase I development as a potential treatment for multiple cancers.

Paul A. Friedman, Incyte's president and CEO, stated, "This agreement reflects our objective to retain US rights to INCB18424 and puts us in a strong position to transition Incyte into a successful commercial company with sufficient resources to continue to advance other promising compounds in our pipeline. Additionally, the appreciation from Novartis for INCB18424's potential to treat the unmet patient need in myelofibrosis and other cancers, and their proven success in rapidly commercializing new targeted oncology treatments, were determining factors in our decision to choose Novartis as our collaborative partner."

Under the terms of the agreement, Incyte will retain exclusive rights for the development and potential commercialization of INCB18424 in the US. Novartis will have responsibility for the future development and commercialization of INCB18424 in all hematology—oncology indications outside of the US. Novartis will also be responsible for the future worldwide development of INCB28060.

Novartis will make an upfront payment of \$150 million to Incyte plus an immediate \$60 million milestone payment for the initiation of the European Phase III trial of INCB18424, COMFORT-II, that began in July of this year. Novartis will receive ex-US commercialization rights for Incyte's lead JAK inhibitor and global commercialization rights for the cMET inhibitor. Each company will be responsible for costs in their respective territories for the JAK inhibitor, with costs of collaborative studies shared

equally. Incyte may also be eligible over time for additional payments of up to approximately \$1.1 billion if future contingent development and commercialization milestones are achieved. Incyte is also eligible to receive tiered, double-digit royalty payments on future ex-US INCB18424 sales. Novartis will be responsible for all costs and activities for the cMET inhibitor after the Phase I clinical trial. Incyte is eligible to receive royalties on future sales of INCB28060 and has retained an option to co-develop and co-promote INCB28060.

About Myeloproliferative Neoplasms (MPNs)

MPNs are a related group of hematological neoplasms characterized by dysfunction of the bone marrow resulting in either over production of blood cells or ineffective hematopoiesis leading to production of blood cells in the spleen and resulting in massive splenomegaly. The three main MPNs are polycythemia vera (PV), essential thrombocythemia (ET) and myelofibrosis (MF). Approximately 10 to 20% of patients with PV and ET progress to MF and MF can also develop without a prior history of PV or ET. There are no adequately effective therapies to treat these disorders.

About INCB18424

INCB18424 is Incyte's lead internally developed JAK1/JAK2 inhibitor that has shown positive clinical activity in a number of hematology and inflammatory conditions. The compound is currently in Phase III for patients with MF and Phase II for patients with advanced PV and ET. Incyte has retained rights to develop a topical formulation of INCB18424 which has demonstrated positive clinical results in a recently completed Phase IIb trial in patients with mild to moderate psoriasis.

About INCB28060

cMET is a validated target with significant potential in multiple major oncology indications. INCB28060 is a potent cMET inhibitor that has demonstrated favorable pharmacologic activity in relevant cell and animal models and has demonstrated in those models that it can be dosed safely to achieve levels of cMET inhibition that are associated with tumor regression in multiple solid tumors. The investigational new drug application has been cleared by the US Food and Drug Administration.

About Incyte

Incyte Corporation is a Wilmington, Delaware-based drug discovery and development company focused on developing proprietary small molecule drugs for oncology, inflammation and diabetes. Incyte's most advanced compound, INCB18424, is in Phase III development for myelofibrosis. For additional information on Incyte, visit the Company's web site at www.incyte.com.

Forward-Looking Statements

Except for the historical information contained herein, the matters set forth in this press release, including statements with respect to the potential to receive up to approximately \$1.1 billion in future contingent milestone payments, plans and timing for

INCB28060 to enter Phase I development as a potential treatment for multiple cancers, statements regarding being put in a strong position to transition into a successful commercial company with sufficient resources to continue to advance other promising compounds in the pipeline, the potential indications and benefits of INCB18424 and INCB28060, and the potential benefits from and payments under the agreement, are all forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to risks and uncertainties that may cause the parties not to achieve some or all of the commercial and developmental milestones set forth in the collaboration agreement and that may otherwise cause Incyte's actual results and timing to differ materially, including the high degree of risk and uncertainty associated with drug development and clinical trials, the uncertainty associated with the regulatory approval processes, risks related to the timing of and patient enrollment in clinical trials, risks related to the potential failure of INCB18424 and INCB28060 to demonstrate safety and efficacy in clinical testing; risks and uncertainty associated with the therapeutic and commercial value of INCB18424 and INCB28060; risks relating to market competition, risks associated with Incyte's dependence on its relationship with its collaboration partners, and other risks detailed from time to time in Incyte's filings with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the guarter ended September 30, 2009. Incyte disclaims any intent or obligation to update these forward-looking statements.

Novartis gains rights to two oral targeted investigational therapies focusing on pat	ients
with life-threatening blood disorders and cancers	

Ex-US rights acquired for JAK inhibitor INCB18424 in Phase III development as first-in-class treatment for myelofibrosis, a life-threatening blood disorder	
 Global rights acquired for early-stage cMET inhibitor INCB28060 targeting tumor invasion and drug resistance in certain cancers including gastric, kidney and lung 	
Novartis to make payments of USD 150 million upfront and first milestone of USD 60 million; Incyte eligible for milestone payments and royalties on future sales	
Basel, November 25, 2009 — Novartis has gained exclusive rights to two oral targeted investigational therapies for patients with a range of life-threatening blood disorders and cancers that currently do not have effective treatment options.	
Under a licensing agreement with Incyte Corporation, Novartis will have responsibility for the future development of Incyte's investigational JAK inhibitor outside the US and for future development of an early-stage cMET inhibito globally.	
The lead compound is a Janus kinase (JAK) inhibitor with the investigational name INCB18424. This ora targeted therapy is in Phase III clinical trials for the treatment of myelofibrosis, a life-threatening neoplastic condition with no effective medical treatment¹ that is characterized by varying degrees of bone marrow failure splenomegaly (enlarged spleen) and debilitating symptoms. INCB18424 has the potential of becoming a first in-class therapeutic agent for the treatment of this and other hematologic diseases.	
The second compound covered in the licensing agreement, a mesenchymal-epithelial transition factor kinase (cMET) inhibitor with the investigational name INCB28060, is entering Phase I development. Compounds in this class are envisioned to become effective cancer therapies through their ability to block molecular signals leading to tumor cell angiogenesis, proliferation, survival, invasion and metastasis. Multiple cancers have shown to be dependent on activation of molecular signals by genetic alterations of the cMET gene ² . Emerging evidence indicates that cMET inhibition may be useful in the treatment of certain cancers, including gastric and kidney cancer ² , and may help to overcome resistance to some targeted therapies, such as gefitinib in non-small cell lung cancer ³ .	
"A key Novartis priority is to bring innovative medicines to patients as quickly as possible," said David Epstein, President and CEO, Novartis Oncology and Novartis Molecular Diagnostics. "This agreement leverages these two promising investigational drugs with Novartis Oncology's global development and commercialization expertise and our wide range of multi-targeted approaches to cancer treatment."	
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Terms of the agreement

Novartis will make an upfront payment of USD 150 million to Incyte and a first milestone payment of USD 60 million for initiation of the European Phase III trial of the JAK inhibitor INCB18424 that began in July of this year. The agreement covers ex-US commercialization rights for the JAK inhibitor and global commercialization rights for the cMET inhibitor INCB28060. Each company will be responsible for costs in their respective territories for the JAK inhibitor, with costs of collaborative studies shared equally. Novartis will be responsible for all costs and activities for the cMET inhibitor after the Phase I clinical trial. After the first milestone, Incyte will be eligible for additional payments based on achieving defined development and commercialization milestones and to receive royalties on future sales. Incyte also has an option to co-promote the cMET inhibitor in the US and to participate in the cMET inhibitor's global development.

Disclaimer

This release contains certain forward-looking statements relating to the exclusive agreement concluded between Novartis and Incyte. Such forward-looking statements are not historical facts and can generally be identified by the use of forward-looking terminology such as "to make," "eligible," "will," "potential," "about to enter," "envisioned to become," "may," "promising," or similar expressions, or by express or implied discussions regarding potential future sales or earnings of Novartis; or by discussions of strategy, plans, expectations or intentions or potential synergies, strategic benefits or opportunities that may result from the proposed acquisition. Such forward-looking statements reflect the current plans, expectations, objectives, intentions or views of Novartis with respect to future events and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. In particular, there can be no guarantee that the proposed acquisition will be completed in the expected form or within the expected time frame or at all. Nor can there be any guarantee that Novartis will achieve any particular future financial results or future growth rates or that Novartis will be able to realize any of the potential synergies, strategic benefits or opportunities as a result of the proposed acquisition. Among other things, the expectations of Novartis could be affected by unexpected regulatory actions or delays or government regulation generally, as well as other risks and factors referred to in Novartis AG's Forms 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this release as of this date and does not undertake any obligation to update any forward-looking statements as a result of new information, future events or otherwise.

About Novartis

Novartis provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in each of these areas. In 2008, the Group's continuing operations achieved net sales of USD 41.5 billion and net income of USD 8.2 billion. Approximately USD 7.2 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 99,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

References:

- 1. Hellman AJ. Myeloproliferative syndromes: diagnosis and therapeutic options. Pol Arch Med Wewn. 2008;118:756-759.
- Gentile A, Trusolino L, Comoglio PM. The Met tyrosine kinase receptor in development and cancer. Cancer Metastasis Rev. 2008 Mar: 27(1):85-94
- 3. Zucali PA, Ruiz MG, Giovannetti E, et al. Role of cMET expression in non-small-cell lung cancer patients treated with EGFR tyrosine kinase inhibitors. Ann Oncol. 2008 Sep;19(9):1605-12.

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Exhibit H

Replacement Provisions

1. The following shall replace the entirety of ARTICLE III upon a Change of Control (with the Party experiencing the Change of Control referred to as the "<u>CoC Party</u>" and the other Party being referred to as the "<u>Non-CoC Party</u>"):

"GOVERNANCE

- 1.1 Joint Steering Committee.
- (a) Establishment. The joint steering committee ("JSC") will have the responsibility for the overall coordination and oversight of the Parties' activities under this Agreement. Each Party's representatives and any substitute for a representative shall be bound by the obligations of confidentiality set forth in ARTICLE XII. A representative from the Non-CoC Party shall act as the chairperson of the JSC. The chairperson shall not have any greater authority than any other representative on the JSC and shall conduct the following activities of the JSC: (i) calling meetings of the JSC; (ii) preparing and issuing minutes of each such meeting within thirty (30) days thereafter; (iii) ensuring that any decision-making delegated to the JSC is carried out in accordance with Section 3.5; and (iv) preparing and circulating an agenda for the upcoming meeting; provided that the chairperson shall include any agenda items proposed by the CoC Party. Each Party shall be free to change its representatives on notice to the other or to send a substitute representative to any JSC meeting; provided, however, that each Party shall ensure that at all times during the existence of the JSC, its representatives on the JSC are appropriate in terms of expertise and seniority (including at least one member of senior management) for the then-current stage of Development and Commercialization of the Licensed Products and have the authority to bind such Party with respect to matters within the purview of the JSC.
- (b) <u>Responsibilities</u>. The JSC shall have responsibility for the ongoing exchange of information and cooperation necessary after the Change of Control.
- 1.2 <u>Subcommittees</u>. The JSC may establish and disband such subcommittees as deemed necessary by the JSC; <u>provided</u>, <u>however</u>, that the JIPC shall continue its responsibilities at least with respect to the INCY0039 Patent Rights in the Novartis Territory. Each Party shall be free to change its representatives on notice to the other or to send a substitute representative to any subcommittee meeting; <u>provided</u>, <u>however</u>, <u>that</u> each Party shall ensure that at all times during the existence of any subcommittee, its representatives on such subcommittee are appropriate in terms of expertise and seniority for the then-current stage of Development and Commercialization of the Licensed Product in the Field in the Territory and have the authority to bind such Party with respect to matters within the purview of the relevant subcommittee. Each Party's representatives and any substitute for a representative shall be bound by the obligations of confidentiality set forth in ARTICLE XII. Except as expressly provided in this Agreement, no subcommittee shall have the authority to bind the Parties hereunder and each subcommittee shall report to, and any decisions shall be made by, the JSC.

- 1.3 <u>Committee Meetings</u>. Except where a Party fails to appoint a member or members to the JSC or its subcommittees or fails to participate in meetings of the JSC or its subcommittees pursuant to Section 3.6, meetings of the JSC and the subcommittees, respectively, shall be effective only if at least one (1) representative of each Party is present or participating. The JSC and its subcommittees may meet either (i) in person at either Party's facilities or at such locations as the Parties may otherwise agree or (ii) by audio or video teleconference; <u>provided that</u> no less than one (1) meeting during each Calendar Year shall be conducted in person. Other representatives of each Party involved with the Licensed Product may attend meetings as non-voting participants, subject to the confidentiality provisions set forth in ARTICLE XII. Each Party shall be responsible for all of its own expenses incurred in connection with participating in all such meetings.
- 1.4 <u>Authority.</u> The JSC and any subcommittee shall have only the powers assigned expressly to it in this ARTICLE III and elsewhere in this Agreement, and shall not have any power to amend, modify or waive compliance with this Agreement. In furtherance thereof, each Party shall retain the rights, powers and discretion granted to it under this Agreement and no such rights, powers or discretion shall be delegated or vested in the JSC or any subcommittee unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing."
- 1. The following shall replace Section 4.3 upon a Change of Control:
 - "4.3 Development Activities.
- (c) <u>Termination of Joint Development Activities</u>. The Non-CoC Party shall, in its sole discretion, have the option to terminate any ongoing Joint Development Activities. In the event any ongoing Joint Development Activities are terminated,
 - (i) Each Party shall have the right to possess, retain and use all clinical and non-clinical data and related Regulatory Documentation Controlled by either Party and generated in the course of Joint Development Activities prior to the termination of such Joint Development Activity in order to Develop, obtain Regulatory Approval for and Commercialize JAK Licensed Products in the JAK Field in such Party's territory in accordance with the terms of this Agreement; and
 - (ii) each Party hereby grants to the other Party a Right of Reference or Use to any and all such Regulatory Documentation, and agrees to sign, and cause its Affiliates to sign, from time to time, promptly upon request, any instruments reasonably requested by such other Party in order to effect such grant.
- (d) <u>Ongoing Joint Development Activities</u>. With respect to ongoing Joint Development Activities which are not terminated pursuant to 4.3(a),
 - (i) Each Party shall have the right to possess, retain and use all clinical and non-clinical data and related Regulatory Documentation Controlled by either Party and generated in the course of Joint Development Activities in order to Develop, obtain Regulatory Approval for and Commercialize JAK

Licensed Products in the JAK Field in such Party's territory in accordance with the terms of this Agreement.

- (ii) each Party hereby grants to the other Party a Right of Reference or Use to any and all such Regulatory Documentation, and agrees to sign, and cause its Affiliates to sign, from time to time, promptly upon request, any instruments reasonably requested by such other Party in order to effect such grant;
- (iii) each Party shall maintain complete and accurate records of all results, data, and developments made pursuant to its efforts under the Development Plan. Such records shall appropriately reflect all work done and results achieved in the performance of Development activities in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes; and
- (iv) in any agreement between either Party and a clinical research organization related to a Joint Development Activity, the contracting Party shall use reasonable efforts to name the other Party as a third party beneficiary for the purpose of receiving data derived from Clinical Trials related to such Joint Development Activity from such clinical research organization in the event of a Bankruptcy Event of such Party."



Exhibit I

PHARMACOVIGILANCE AGREEMENT

[] November 2009

between

Incyte Corporation

Experimental Station,
Route 141 & Henry Clay Road
Wilmington, Delaware
USA
("Incyte")

and

Novartis Pharma AG

Lichtstrasse 35 4056 Basel Switzerland ("Novartis")

relating to Product(s): c-MET Licensed Products

JAK Licensed Products (together "the Product")

APPENDIX 2 – Contact Persons

16

Table of contents Table of contents 2 1 Purpose 3 2 Term 3 3 **Definitions and Abbreviations** 3 4 Databases 4 Detailed Description of the Pharmacovigilance System (DDPS) 5 4 6 Signal Detection (internally identified safety issues) 5 7 Maintenance of Labeling Documents 5 Exchange of Individual Case Reports 5 8.1 Scope 5 8.2 Format 6 8.3 Unblinding 6 8.4 Follow-up 7 7 8.5 **Timelines** Individual Report Assessment 8 9.1 8 Labelling 9.2 Requirement for Study Protocols: 8 8 Regulatory Reporting Responsibilities 10.1 Individual Case Safety Reports 8 10.2 **Investigator Notifications** 8 10.3 Preparation and Submission of Annual Reports from Clinical Trials and other Cumulative 9 Safety Reports 10.4 Periodic SUSAR Reports 9 9 10.5 Responses to Regulatory Authority Questions 10.6 Risk Management Plans 10 10.7 **PSUR** 10 11 **SOPs** 10 12 Audits 10 13 Dispute Resolution 12 14 Contact Persons 12 15 Miscellaneous 12 APPENDIX 1 - Definitions and Abbreviations 13 **Definitions** 16.1 13 16.2 15 Acronyms

Pharmacovigilance Agreement for c-MET and JAK Licensed Products

1 Purpose

WHEREAS, Incyte and Novartis International Pharmaceutical Ltd. ("NIP") entered into a Collaboration and License Agreement dated as of November ______, 2009 (the "Collaboration Agreement");

WHEREAS, the Collaboration Agreement required that Incyte enter into this Pharmacovigilance Agreement with Novartis;

WHEREAS, the purpose of this Phamacovigilance Agreement is to define how the Parties are to cooperate to enable each of them to comply with its respective obligations under applicable laws, regulations and guidelines with regard to Adverse Event data collection, analysis and reporting for the Product, and to enable each Party to satisfy its duty of care;

WHEREAS, under this agreement each Party is obliged to inform the other Party immediately in case of Pharmacovigilance issues (such as risk management communication, Dear Doctor Letters, urgent safety restrictions) to ensure that communication between the Parties is aligned, especially if any Regulatory Authorities are involved;

WHEREAS, nothing in this Pharmacovigilance Agreement is intended to limit or restrict either of the Parties' obligations under applicable laws, regulations and guidelines; and

WHEREAS, nothing in this Pharmacovigilance Agreement is intended to prevent either of the Parties from taking any action that it reasonably considers to be necessary to comply with applicable laws, regulations and guidelines.

NOW, THEREFORE, the Parties hereto hereby agree as follows:

2 Term

This Pharmacovigilance Agreement shall become effective on the date hereof and, unless earlier terminated in accordance with the Collaboration Agreement, shall continue in force for as long as both of the Parties have a legitimate interest in receiving the information, reports, and notifications provided for. This applies to the c-MET program as long as Incyte holds the relevant c-MET IND and is responsible for the conduct of clinical studies.

At the latest this Pharmacovigilance Agreement shall be updated before product launch and in time to meet the requirements for handling and reporting spontaneous reports from marketed use.

3 Definitions and Abbreviations

The definitions of terms and abbreviations used in this Pharmacovigilance Agreement are set out in Appendix 1. If any of the relevant regulatory definitions of the corresponding terms are amended (for example those in the ICH E2A and ICH E2C Guidelines, or in the US CFR (21

CFR Part 314.80(a) and 312.32(a)), then the Parties shall assess whether the definitions in this Pharmacovigilance Agreement need to be amended to make them consistent and, if any amendments are necessary, shall seek to reach written agreement in good faith on such amendments.

The language of all communications and exchanges under this Pharmacovigilance Agreement shall be English.

4 Databases

Novartis shall establish, hold and maintain the global safety database for the Product, into which it shall enter information on all SAE/SRs concerning the Product occurring anywhere in the world and reported to either of the Parties. For the term of this Pharmacovigilance Agreement, this shall be the reference database for signal detection. Such database shall comply in all material respects with all laws reasonably applicable to pharmacovigilance anywhere where the Products are being or have been Developed or Commercialized (each as defined in the Collaboration Agreement). Appropriate personnel at Incyte shall have access to updated data in the database within [***] after such data are entered in the database. Incyte shall be authorized to submit such data to applicable regulatory authorities as required or permitted by law.

The Parties acknowledge that, prior to signature of this Pharmacovigilance Agreement, Incyte provided to Novartis all SAEs (including expected, unrelated, placebo and comparator cases) reported to Incyte for the product as of the date of such transfer, on CIOMS forms or in another format acceptable to Novartis allowing Novartis to complete the global safety database.

Incyte may hold and maintain a parallel safety database for the Product as needed or required according to local laws, regulations and other legal requirements.

Each Party is responsible for ensuring that all applicable reports are dispatched to the other Party in accordance with this Pharmacovigilance Agreement. Novartis and Incyte will perform routine verification and reconciliation according to their respective SOPs to ensure that all adverse event reports, both initial and follow up, have been exchanged per Section 9 of this Pharmacovigilance Agreement.

If discrepancies are noted either through the verification process, reconciliation, or during the course of routine business, both Novartis and Incyte will work to remediate the discrepancy until resolved to the mutual satisfaction of both Parties.

5 Detailed Description of the Pharmacovigilance System (DDPS)

If required, Incyte shall provide Novartis, within [***] from the date requested, with a Detailed Description of its Pharmacovigilance System in the format specified by the EMEA (Volume 9A of Rules Governing Medicinal Products in the European Union; Section 2.2) which may be submitted to the Regulatory Authorities as required. The DDPS should comprise an overview of Incyte's Pharmacovigilance System, providing information on the key elements of the System. Such descriptions should include all vendors and contracted third parties who have direct involvement in the collection of adverse events for the Product.

Pharmacovigilance Agreement for c-MET and JAK Licensed Products

Each Party shall inform the other in a timely manner of any significant changes to the Pharmacovigilance System as documented.

EU-QPPV: Novartis has an established and dedicated EU-QPPV. In case of any change, Novartis shall inform Incyte of the new appointment within [***].

6 Signal Detection (internally identified safety issues)

Using the global safety database, Novartis shall be primarily responsible for signal detection activities according to its SOP.

In case either of the Parties becomes aware of:

- a) potential signals for new adverse reactions;
- b) increased incidence of known adverse reactions:
- c) increased severity of known adverse reactions;
- d) major findings from newly completed animal studies; or
- e) any proposed changes in the labeling documents,

that Party shall promptly notify the other Party in writing (as soon as possible but no later than [***] after the Party becoming aware of the issue), for discussion and comment and to agree whether any further action is required.

A safety committee with clinical and safety and regulatory representatives from each Party shall be established and shall discuss on a regular basis, or as required, the handling of specific or general safety and process issues (eg. reviewing safety signals, issuing Dear Doctor Letters, ASR preparation meeting [***] prior to the data lock point, etc.). Each Party shall keep the other Party informed of any newly identified safety signal, which then will be evaluated by the Parties in close cooperation, including updates to core safety information. No measures will be taken without prior consultation and discussion except in situations where immediate action is required to protect the health of patients.

7 Maintenance of Labeling Documents

Investigator's Brochure: The Parties shall use an Investigator's Brochure with a common core safety section.

8 Exchange of Individual Case Reports

8.1 Scope

Individual Case Safety Reports concerning the Product which shall be exchanged under this Pharmacovigilance Agreement include:

8.1.1 Solicited Reports:

All Serious Adverse Events (SAEs) occurring in clinical trials which are received by either of the Parties, including blinded, comparator and placebo cases.

8.1.2 Other including final study reports:

In addition, the Parties shall exchange all other clinical safety-related information concerning the Product as may be required or reasonably requested by the Parties to fulfill the purpose of this Pharmacovigilance Agreement, including the timely exchange of safety information contained in interim or final clinical study reports.

Data or special arrangements required to fulfill a Risk Management Plan, if necessary, shall also be included.

8.2 Format

Individual Case Reports shall be exchanged on CIOMS forms and sent by fax or secure e-mail if available and mutually agreed upon.

Each Party shall assign a company case identification number to each case on which information is exchanged under this Pharmacovigilance Agreement, and shall identify each piece of information concerning that case with this number.

The receiving Party shall maintain the integrity of the sending Party's narrative, but shall add to the case narrative the name of the sending Party and the sending Party's case identification number to aid identification of duplicate reports.

8.3 Unblinding

Unless otherwise agreed with applicable regulatory authorities, for company sponsored studies, the blind will be broken for serious, unexpected suspected/related ADRs on an ongoing basis as reasonably required for regulatory reporting by the sponsor in real time to meet the exchange timelines specified below. All other SAE's (not suspected and/or expected) will be exchanged as blinded during the ongoing clinical trial. Details of the treatment given shall be distributed only on a need-to-know basis.

In exceptional circumstances such as upon receipt of a request from a Regulatory Authority or a safety data monitoring committee to do so, the Party receiving the request may need to break the code for any case type(s), or request the Party sponsoring the relevant clinical trial to do so. In such an event, details of the treatment given shall be distributed only on a need-to-know basis.

At the conclusion of Novartis sponsored clinical trials, Novartis shall transmit the unblinded ICSRs to Incyte within a reasonable time frame but no later than [***] of receipt of randomization codes by the safety group, unless study size or complexity requires a longer period, to be notified within [***] of receipt of randomization codes.

At the conclusion of Incyte sponsored clinical trials, Incyte will provide Novartis with the randomization codes within a reasonable time frame but no later than [***] of receipt of randomization codes by the safety group. ICRS exchange will not apply in this situation.

8.4 Follow-up

The Party first receiving the SAE or any other kind of report falling within the scope of this Pharmacovigilance Agreement shall be responsible for obtaining any follow-up information

from the reporter, which shall be processed as described for the corresponding type of initial report in this Section 9. This shall include any targeted follow up required for risks included in the Risk Management Plan.

Each Party may request the other Party to contact the reporter and obtain additional information if necessary, including missing reporter causality. Follow-up information shall be exchanged with the same company case identification number as the original report.

8.5 Timelines

SAEs from clinical trials received by Novartis:

Novartis shall notify Incyte of all SAEs from clinical trials which are received by Novartis or its Affiliates according to the following timelines:

- a) Causally Suspected and/or study-related fatal or Life-threatening SAEs (irrespective of labelling) within 4 (four) calendar days of first notification of the event to any employee of Novartis or its Affiliates;
- b) Other Causally Suspected and/or study-related SAEs (irrespective of labelling) within 8 (eight) calendar days of first notification of the event to any employee of Novartis or its Affiliates; and
- c) Causally Non-suspected SAEs (i.e. there is no suspected connection between the study and the SAE) within twenty (20) calendar days or more rapidly if required for the data-lock for the IND annual safety report preparation.

SAE reports from clinical trials received by Incyte:

Incyte shall notify Novartis of all SAEs from clinical trials which are received by Incyte or its Affiliates according to the following timelines:

- a) Causally Suspected and/or study-related fatal or Life-threatening SAEs (irrespective of labelling) within four (4) calendar days of first notification of the event to any employee of Incyte or its Affiliates;
- b) Other Casually Suspected and/or study-related SAEs (irrespective of labelling) within 8 (eight) calendar days of first notification of the event to any employee of Incyte or its Affiliates; and
- c) Causally Non-suspected SAEs (i.e. there is no suspected connection between the Product and the SAE) within twenty (20) calendar days.

9

Individual Report Assessment

It is agreed between the Parties that each will follow its own procedures for seriousness, causality and expectedness assessment.

9.1 Labelling

Assessment of Listedness/Expectedness:

For purposes of databasing in the global safety database, the assessment of whether the SAE or other kind of report is Listed/Expected shall be made by Novartis against the Investigator's Brochure.

For the purposes of reporting to the Regulatory Authorities, the assessment of expectedness shall be made according to the appropriate Investigator's Brochure by the Party responsible for submitting the report to the Regulatory Authority.

Assessment of expectedness for comparator and placebo associated reports shall be made by the Parties according to their respective SOPs.

9.2 Requirement for Study Protocols:

Interventional Trials: At the first occurrence of an SAE in a particular clinical trial at the latest, the Party reporting the SAE shall make available to the other Party a copy of the relevant study protocol or summary of the study design. This is to provide a clear understanding of the nature of the exposure to the Product and to allow a meaningful interpretation of the SAE.

10 Regulatory Reporting Responsibilities

10.1 Individual Case Safety Reports

The Party holding the Regulatory Authority Authorisation for the Product for clinical trials in a country shall be responsible for submitting SAE reports to the Regulatory Authority in that country according to the current applicable laws, regulations and guidelines, regardless of whether the report originated from that Party or not. Information on which Party holds the Regulatory Authority Authorisation for the clinical trials will be exchanged and updated at the time of the transfer of the reports to the other Party.

The Party holding the Regulatory Authority Authorisation for clinical trials shall be responsible for the electronic submission to the EMEA of all reportable cases for the Product to Clinical Trial Modules, as required.

10.2 Investigator Notifications

Each Party shall prepare and distribute Investigator Notifications according to their respective SOPs and applicable laws, regulations and guidelines. Each Party shall make reasonable efforts to notify the other Party of an IN, allowing [***] for comment. Each Party shall

Pharmacovigilance Agreement for c-MET and JAK Licensed Products

exchange the final Investigator Notifications to the other Party no more than [***] after receipt of the original report which prompted the Investigator Notification.

10.3 Preparation and Submission of Annual Reports from Clinical Trials and other Cumulative Safety Reports

As long as Incyte holds an IND for the Product, Incyte will have the responsibility for the compilation of the IND annual safety reports for the Product using its own data and data provided by Novartis as required.

Novartis shall prepare a common European Union Annual Safety Report for clinical studies. All relevant studies, including investigator initiated studies, shall be included. Upon request to support preparation of these reports for Incyte or Novartis studies. Incyte or Novartis shall provide data, including

	A list of studies (including IIT) that are planned, initiated or ongoing with a synopsis of the study, phase and the countries involved
	Planned and total number of patients enrolled in Incyte or Novartis sponsored studies (including IIT), the actual enrollment and number of patients receiving active drug during the reporting period.
	A list of Incyte or Novartis studies that have been analyzed during the reporting period, including a summary of new safety findings
	Any new study safety results with potential impact on risk-benefit profile
ie re	quest for information shall be made at least [***] prior to each Data Lock-Point, and be provided so that it is

The request for information shall be made at least [***] prior to each Data Lock-Point, and be provided so that it is received no later than [***] after the Data Lock-Point. The final report shall be provided to Incyte allowing [***] for review/ comment.

The same report shall be submitted by both companies, if both companies have study sponsorship in the EU.

10.4 Periodic SUSAR Reports

Novartis will be responsible for the preparation of periodic SUSAR reports and for the submission of the report to investigators, competent authorities and Ethics Committees, where and when applicable. Incyte has the right to review and comment.

10.5 Responses to Regulatory Authority Questions

Each Party shall attempt to immediately notify the other (via their respective appointed pharmacovigilance representatives) upon being contacted by a Regulatory Authority on any significant regulatory matter pertaining to the safety profile of the Product or to the subject-matter of this Pharmacovigilance Agreement, including but not limited to risk management communication, Dear Doctor Letters, urgent safety restrictions or labelling changes, to ensure that communication between the Parties is aligned. Each Party shall allow the other to review

its proposed response to any question or request prior to submission to the Regulatory Authority, unless there is a public health need to respond immediately.

If requested to do so, Novartis shall assist Incyte to respond to questions or requests for information by Regulatory Authorities by promptly providing data from the master safety database.

Each Party shall copy to the other all significant communication regarding clinical safety information concerning the Product.

10.6 Risk Management Plans

The Parties agree that there will be one Global Risk Management Plan for each Licensed Product, authored by Novartis. The Global Risk Management Plan will be prepared by Novartis in collaboration with Incyte. Incyte shall provide feedback within [***] of receipt from Novartis, or such other time as the Parties mutually agree.

If a REMS (Risk Evaluation and Mitigation Strategy) is required for the Products by the FDA, Incyte shall be responsible for the authorship and submission. There shall be no material differences in the description of the important safety risks between the Global Risk Management Plan and REMS, as the risks are considered the same in all territories. The REMS will be prepared in collaboration between Novartis and Incyte. Novartis shall provide feedback within [***] of receipt from Incyte, or such other time as the Parties may mutually agree.

The Parties will exchange all information reasonably requested by a Party that is necessary to fulfill regulatory requirements (e.g. mandatory PSUR updates) for the Global Risk Management Plan. These include, but are not limited to, providing updates on: safety studies and other pharmacovigilance measures, progress in implementing risk minimization activities, and assessment of the performance of any aspect of risk management/minimization related to the Products. Prior to submission of the Global Risk Management Plan to a Regulatory Authority, Novartis shall provide such plan to Incyte for review and Incyte shall have [***] to provide comments, which Novartis shall reasonably consider.

10.7 PSUR

The Parties agree that Novartis will be responsible for the authoring of the PSUR, the Core Data Sheet and Investigator Brochure. Novartis shall provide drafts of such documents to Incyte within [***] after the data lock point, and Incyte shall have [***] to review and provide comments, which Novartis shall reasonably consider.

11 SOPs

Each Party shall adhere to its own SOPs unless otherwise explicitly stated here in this Pharmacovigilance Agreement.

12 Audits

The Parties agree that its pharmacovigilance systems/operations or contracted pharmacovigilance activities will be audited at reasonable intervals to ensure elements set forth in the pharmacovigilance agreement are being fulfilled for the appropriate product. Both

[***]Confidential material redacted and filed separately with the Commission. Confidential Pharmacovigilance Agreement for c-MET and JAK Licensed Products

Page 11

Novartis

Parties will discuss and agree in good faith on how such an audit will be conducted (audit plan, duration of audit, audit report and corrective actions). Each Party's routine audit will be scheduled no more frequently than once every [***], with a minimum of [***] notice.

Audits must be reasonable in scope and in relationship to the Product and must take place during normal business hours. Parties will correct audit observations in a timely manner and communicate those actions to the other Party.

In the case of a serious suspected breach of compliance with this Pharmacovigilance Agreement, a directed audit will be performed by either Party or *an independent* third party with notification only and a minimum of [***]. The possibility of a directed audit for serious breach is therefore agreed upon by way of execution of this agreement.

Parties shall allow foreign and local health authorities to inspect their pharmacovigilance operations as it is necessary for either Party to maintain registration in the countries where the Product is marketed. A representative from the other Party may participate in such inspections.

Parties shall communicate urgent or critical issues affecting the other Parties pharmacovigilance activities within [***] of receipt of documented findings cited during a health authority inspection. Once corrective actions are determined, the inspected Party will provide a summary of the relevant inspection findings with associated corrective actions where the other Party is impacted.

13 Dispute Resolution

In case of dispute over PSURs, responses to queries or labelling activities, for example CCSI, every effort will be made to achieve a consensus and resolve the dispute by the pharmacovigilance department of each Party. If disputes cannot be resolved they will be referred to upper drug safety management of the Parties for resolution. If disputes cannot be resolved at the upper management level they will be resolved in accordance with the Collaboration Agreement.

14 Contact Persons

The contact persons for each Party are identified in Appendix 2.

Each Party may change its contact persons by notifying the other Party in writing in accordance with Section 15.6 of the Collaboration Agreement.

15 Miscellaneous

Place/Date:

The provisions of Sections 15.1-15.3, 15.5 and 15.7-15.16 of the Collaboration Agreement shall be deemed incorporated into this Pharmacovigilance Agreement to the same extent as if set forth herein.

This Pharmacovigilance Agreement has been agreed and signed in duplicate by the following respective Parties.

Place/Date:

16 APPENDIX 1 - Definitions and Abbreviations

16.1 Definitions

- 16.1.1 "Spontaneous Reports" from Patient Support Programs or Marketing Research Programs includes all Adverse Reactions reported from any program designed to encourage the HCP or consumer to voluntarily contact the company for educational material or support. Any program which does not systematically include any questions that request safety information in response.
- 16.1.2 "Solicited Reports" from Patient Support Programs or Marketing Research Programs includes all Adverse Reactions reported from a program where targeted safety questions are systematically included (in either the script or contact form).
- 16.1.3 "Adverse Drug Reaction" means all noxious and unintended responses to a medicinal product related to any dose. The 'responses to a medicinal product' means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility.
- 16.1.4 "Adverse Event" means any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.
- 16.1.5 "Causally Suspected Adverse Event" means an Adverse Event (experience) for which a causal relationship between a medicinal product and itself is at least a reasonable possibility. In general, all SRs are considered suspected for expediting purposes.
- 16.1.6 "Causally Non-suspected Adverse Event" means an Adverse Event (experience) for which a causal relationship between a medicinal product and itself is not a reasonable possibility. In general, all SRs are considered "suspected" for expediting purposes.
- 16.1.7 "Collaboration Agreement" shall have the meaning set forth in Section 1 of this Pharmacovigilance Agreement.
- 16.1.8 "Company Core Safety Information" means all relevant safety information contained in the Company Core Data Sheet prepared by the Marketing Authorisation Holder and which the Marketing Authorisation Holder requires to be listed in all countries where the company markets the drug, except when the local regulatory authority specifically requires a modification.
- 16.1.9 "Expected Adverse Event" means an adverse event (experience), the specificity or severity of which is consistent with the Investigator's Brochure for an unapproved investigational product.
- 16.1.10 "International Birthdate" means the date of the first marketing authorisation for the drug or product granted in any country.
- 16.1.11 "Investigator's Brochure" means a compilation of the clinical and non-clinical data about an investigational drug or product that is relevant to its study in humans.
- 16.1.12 "Investigator Notification" or "IN" means a notification for all participating investigators of any Serious Adverse Event (experience) which is unexpected and suspected or any findings that suggest a significant risk for the patient.

Novartis	Confidential Page 14 Pharmacovigilance Agreement for c-MET and JAK Licensed Products
16.1.13	"Labelled Adverse Event" means any Adverse Event (experience), the specificity or severity of which is consistent with the local package insert for an approved product.
16.1.14	"Life-threatening Adverse Event" means an Adverse Event (experience) that places the patient or subject in the view of the Investigator, at immediate risk of death from the event (experience) as it occurred, i.e. does not include an Adverse Event (experience) that, had it occurred in a more serious form, might have caused death. "Life-threatening Serious Adverse Event" shall have the corresponding meaning in relation to Serious Adverse Events.
16.1.15	"Listed" means any Adverse Event (experience), the specificity or severity of which is consistent with the Company Core Safety Information.
16.1.16	"Party" means one of the parties set forth in the heading to this Pharmacovigilance Agreement, and "Parties" means both parties.
16.1.17	"Product" means the product defined in the heading of this Pharmacovigilance Agreement.
16.1.18	"Regulatory Authority" means any governmental agency responsible for granting health or pricing approvals, registrations, import permits, and other approvals required before the Product may be used in a clinical trial or marketed in any country.
16.1.19	"Regulatory Authority Authorisation" means an approval granted by a Regulatory Authority to conduct a clinical trial (e.g. IND) or to market a product (NDA) in a particular country.
16.1.20	"Serious Adverse Event" means any untoward medical occurrence that at, any dose: (a) results in death; (b) is life-threatening; (c) requires inpatient hospitalization or prolongation of existing hospitalization; (d) results in persistent or significant disability/incapacity; or (e) is a congenital anomaly/birth defect. In the case of other significant events, medical and scientific judgment should be exercised in deciding whether expedited reporting is appropriate. Such events may be important medical events that may not be immediately life-threatening or result in death or hospitalization but which may increading the national or may require intervention to prevent one of the other extremes.
	death or hospitalization but which may jeopardize the patient or may require intervention to prevent one of the other outcomes listed in the definition above. Such events should usually be considered Serious Adverse Events.

- 16.1.21 "Spontaneous Adverse Event Report" means any Adverse Event (experience) spontaneously reported by health professionals, consumers, Health Authorities or other regulatory bodies, scientific papers, poison centres, pharmacovigilance institutes, lawyers, or any other source
- "Study Protocol" means a document that describes the objective(s), design, methodology, statistical considerations, and 16.1.22 organization of a trial. The protocol usually also gives the background and rationale for the trial. This term includes all amendments to the protocol.
- 16.1.23 "Unexpected Adverse Event" means an adverse event (experience), the specificity or severity of which is not consistent with the Investigator's Brochure for an unapproved investigational product.
- 16.1.24 "Unlabelled" means any Adverse Event (experience), the specificity or severity of which is not consistent with the local package insert for an approved product.
- 16.1.25 "Unlisted" means any Adverse Event (experience), the specificity or severity of which is/is not consistent with the Company Core Safety Information.

Page 15

16.2	Acronyms	
16.2.1	ASR	Annual Safety Report for the EMEA (Clinical Studies)
16.2.2	CFR	Code of Federal Regulations
16.2.3	CIOMS	Council for International Organisations of Medical Sciences
16.2.4	FDA US	Food and Drug Administration
16.2.5	EMEA	European Medicines Evaluation Agency
16.2.6	GCP	Good Clinical Practice
16.2.7	IB	Investigator's Brochure
16.2.8	ICH for Human U	International Conference on Harmonisation of the Technical Requirements for Registration of Pharmaceuticals se
16.2.9	IN	Investigator's Notification
16.2.10	IND	Investigational New Drug
16.2.11	NDA	New Drug Application
16.2.12	PSUR	Periodic Safety Update Report
16.2.13	SAE	Serious Adverse Event
16.2.14	SOP	Standard Operating Procedure
16.2.15	SR	Spontaneous Adverse Event Report

APPENDIX 2 – Contact Persons 17

Incyte [***]

Novartis [***]

Schedule 1.14

c-MET Licensed Back-Up Compounds

Schedule 1.60

JAK Licensed Back-Up Compounds

Schedule 4.1

<u>Schedule 4.1(c)(i)</u>

Schedule 11.3

Exceptions to Representations and Warranties

EXTENSION OF CONFIDENTIAL TREATMENT REQUESTED: Certain identified information, marked by [***], has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company, if publicly disclosed. An extension of confidential treatment for such information has been requested. An unreducted version of this document has been filed separately with the Securities and Exchange Commission (the "Commission").

AMENDMENT NO. 4

TO

COLLABORATION AND LICENSE AGREEMENT

THIS AMENDMENT NO. 4 TO COLLABORATION AND LICENSE AGREEMENT (this "<u>Amendment No. 4</u>") is entered into as of the 5th day of April, 2016 (the "<u>Effective Date</u>"), by and between Incyte Corporation, a Delaware corporation having an office at 1801 Augustine Cut-Off, Wilmington, Delaware ("<u>Incyte</u>"), and Novartis International Pharmaceutical Ltd., a limited company organized under the laws of Bermuda having an office at 131 Front Street, Hamilton, Bermuda HM 12 ("<u>Novartis</u>").

WHEREAS, Incyte and Novartis entered into that certain Collaboration and License Agreement dated as of November 24, 2009 (as amended to date, the "Original Agreement"); and

WHEREAS, Incyte and Novartis wish to amend the Original Agreement pursuant to and in accordance with the terms and conditions of this Amendment No. 4.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE I

DEFINITIONS

1.1 <u>Definitions</u>. Capitalized terms used in this Amendment No. 4 but not defined herein shall have the meaning ascribed to them in the Original Agreement.

ARTICLE II

AMENDMENTS

2.1 New Definitions.

- (a) The Original Agreement is hereby amended to insert the following new definition into ARTICLE I immediately after Section 1.42:
 - "1.42a "Graft-Versus-Host Disease Field" means the treatment, control, mitigation, prevention or cure of all graft-versus-host disease Indications as defined in subsections 279.50 through 279.53 of the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) as set forth in Exhibit J to this Agreement. [***]"

<u>Schedule I</u> attached to this Amendment No. 4 sets forth the terms of the Exhibit J referred to in the preceding amendment.

- (b) The Original Agreement is hereby amended such that Section 1.59 thereof is hereby deleted and replaced in its entirety with the following new definition:
 - "1.50 "JAK Field" means the Hematology Field, the Oncology Field and the Graft-Versus-Host Disease Field, and includes all forms of administration except topical."
- (c) The Original Agreement is hereby amended to insert the following new definitions into ARTICLE 1 immediately after Section 1.68:
 - "1.68a "<u>Lilly</u>" means Eli Lilly and Company, an Indiana corporation having an office at Lilly Corporate Center, Indianapolis, Indiana 46285.
 - 1.68b "<u>Lilly Agreement</u>" means the License, Development and Commercialization Agreement dated as of December 18, 2009, by and between Incyte and Lilly, as amended effective June 22, 2010, as further amended effective August 1, 2011 and as further amended effective March 31, 2016."
- (d) The Original Agreement is hereby amended to insert the following new definition into ARTICLE I immediately after Section 1.105:
 - "1.105a "Ruxolitinib Backup Compound" means any JAK Licensed Compound other than ruxolitinib."
- 2.2 <u>Rights Granted by Incyte to Novartis</u>. The Original Agreement is hereby amended to delete Section 2.1(b) and replace it in its entirety with the following:
 - "(b) JAK License Grant; Option for Ruxolitinib Backup Compounds in GVHD.
 - (i) Subject to the terms of this Agreement, Incyte hereby grants Novartis, during the Term, an exclusive (even as to Incyte and its Affiliates),

royalty-bearing, non-transferable (except in accordance with Section 14.3) license, with the right to sublicense (subject to Section 2.3), under Incyte IP and Incyte's and its Affiliates' interests in Joint IP, to (i) research, Develop, Commercialize, make, have made, use, offer for sale, sell and import JAK Licensed Compounds and JAK Licensed Products in the Novartis JAK Territory in the Hematology Field and the Oncology Field (including all forms of administration except topical) and (ii) research, Develop, make and have made JAK Licensed Compounds and JAK Licensed Products in the Incyte Territory for the sole purpose of using, offering for sale and selling JAK Licensed Products in, and importing JAK Licensed Compounds and JAK Licensed Products into, the Novartis JAK Territory in the Hematology Field and the Oncology Field (including all forms of administration except topical); provided however, that Novartis may not, directly or indirectly, conduct Clinical Trials or other clinical studies, including any investigator initiated studies, utilizing JAK Licensed Compounds or JAK Licensed Products in the Hematology Field or the Oncology Field in the Incyte Territory without the prior approval of the JSC.

Subject to the terms of this Agreement, Incyte hereby grants Novartis, during the Term, an exclusive (even as to Incyte and its Affiliates), royalty-bearing, non-transferable (except in accordance with Section 14.3) license, with the right to sublicense (subject to Section 2.3), under Incyte IP and Incyte's and its Affiliates' interests in Joint IP, to (i) research, Develop, Commercialize, make, have made, use, offer for sale, sell and import ruxolitinib, any Ruxolitinib Backup Compounds with respect to which Novartis has exercised a Rux Backup Compound Option (as defined below) and JAK Licensed Products in the Novartis JAK Territory in the Graft-Versus-Host Disease Field (including all forms of administration except topical) and (ii) research, Develop, make and have made ruxolitinib, such Ruxolitinib Backup Compounds and JAK Licensed Products in the Incyte Territory for the sole purpose of using, offering for sale and selling ruxolitinib, such Ruxolitinib Backup Compounds and JAK Licensed Products in, and importing ruxolitinib, such Ruxolitinib Backup Compounds and JAK Licensed Products into, the Novartis JAK Territory in the Graft-Versus-Host Disease Field (including all forms of administration except topical); provided however, that Novartis may not, directly or indirectly, conduct Clinical Trials or other clinical studies, including any investigator initiated studies, utilizing ruxolitinib, any such Ruxolitinib Backup Compounds or JAK Licensed Products in the Graft-Versus-Host Disease Field in the Incyte Territory without the prior approval of the JSC. For purposes of this Section 2.1(b)(ii), the license grant to JAK Licensed Products in the case of a JAK Licensed Product containing a Ruxolitinib Backup Compound shall be effective from and after the exercise by Novartis of the Rux Backup Compound Option with respect to such Ruxolitinib Backup Compound.

If at any time during the Term, Incyte or its Affiliates acquires (in any form of agreement or other arrangement, including a waiver under or amendment, termination or expiration of any agreement or other arrangement) Control of a Ruxolitinib Backup Compound or any rights therein in any Indication within the Graft-Versus-Host Disease Field anywhere in the world, it shall provide Novartis with prompt written notice thereof (which notice shall include a description in reasonable detail of such Ruxolitinib Backup Compound or any rights therein, as the case may be, and the circumstances under which Incyte gained Control thereof) (the "Incyte Rux Backup Compound Notice"), together with a Rux Backup Compound Information Package (as defined below). Novartis shall have the right to request and, within [***] of receipt of such request Incyte shall provide, any other information or data reasonably relevant to the Novartis' determination as to whether or not to exercise the Rux Backup Compound Option with respect to such Ruxolitinib Backup Compound or rights therein. Novartis shall have the exclusive option (a "Rux Backup Compound Option") to acquire rights with respect to any or all of such Ruxolitinib Backup Compound or rights therein, as the case may be, in the Graft-Versus-Host Disease Field on the terms set forth in this Section 2.1(b)(iii) without any additional consideration to Incyte therefor (including any payment, grant of rights or assumption of obligations). If Novartis desires to exercise the Rux Backup Compound Option, it shall provide written notice thereof to Incyte within [***] of Novartis' receipt of all of the following: (x) the Incyte Rux Backup Compound Notice, (y) the Rux Backup Compound Information Package and (z) all information and data requested by Novartis in accordance with this section. Such notice shall include a description of the Rux Backup Compound or rights therein with respect to which Novartis is exercising the Rux Backup Compound Option. Whether or not to exercise a Rux Backup Compound Option and whether to exercise the Rux Backup Compound Option with respect to all or some of the Ruxolitinib Backup Compound or any rights therein shall be in Novartis' sole discretion. If Novartis exercises a Rux Backup Compound Option, then the license granted to Novartis pursuant to Section 2.1(b)(ii) shall, from and after such exercise, include such Ruxolitinib Backup Compound or rights therein, as the case may be, with respect to which Novartis has exercised the Rux Backup Compound Option. For clarity, Novartis' rights under this Section 2.1(b)(iii) with respect to any Ruxolitinib Backup Compound or rights therein, as the case may be, shall be unaffected by any previous exercise or failure to exercise of a Rux Backup Compound Option by Novartis. For purposes hereof, "Rux Backup Compound Information Package" means, with respect to a Ruxolitinib Backup Compound or rights therein, all material pre-clinical and clinical data, information relevant to the Intellectual Property Rights Controlled by Incyte or its Affiliates with respect to such Ruxolitinib Backup Compound or rights therein and any other information or data Controlled by Incyte or its Affiliates and reasonably relevant to the Development,

Manufacture or Commercialization of such Ruxolitinib Backup Compound or rights therein in the Graft-Versus-Host Disease Field."

2.3 Non-Compete – JAK 2 Inhibitor Compounds and JAK Licensed Compounds.

- (a) The Original Agreement is hereby amended to delete Section 2.6(b)(i) and replace it in its entirety with the following:
 - "(i) During the JAK Program Term, Incyte agrees not to, and shall cause its Affiliates not to, directly or indirectly, including through any ownership interest in any other entity (other than through an ownership interest of [***] of a public company), Develop or Commercialize any JAK2 Inhibitor Compounds in the JAK Field anywhere in the world, other than as expressly permitted under this Agreement (including Section 4.5). Notwithstanding the foregoing, nothing in this Agreement shall prohibit Incyte or its Affiliates from Developing or Commercializing (x) any JAK Excluded Compound in any field anywhere in the world or (y) baricitinib and its back-up compounds [***] in the Graft-Versus-Host Disease Field anywhere in the world."
- (b) The Original Agreement is hereby amended to delete Section 2.6(b)(iii) and replace it in its entirety with the following:
 - "(iii) For the avoidance of doubt, neither Novartis nor its Affiliates will Develop or Commercialize any JAK Licensed Compounds anywhere in the world for the treatment of any Inflammatory Disease other than ruxolitinib and other than any Ruxolitinib Backup Compounds with respect to which Novartis has exercised a Rux Backup Compound Option in the Graft-Versus-Host Disease Field in the Novartis Territory."

2.4 <u>Milestone Payments</u>.

(a) Sections 8.2(c) and (d) of the Original Agreement are each hereby amended to add the following note at the end of such Sections:

"For clarity, achievement of any milestone in an Indication in the Graft-Versus-Host Disease Field will not constitute achievement of any milestone under this Section. [***]"

- (b) Section 8.2 of the Original Agreement is hereby amended to insert the following immediately after Section 8.2(d):
 - "(d1) <u>Graft-Versus-Host Disease Milestones</u>.

- (i) US\$25,000,000 upon FPFV in a [***] Phase III Study that is a Novartis Sponsored Study [***]
 - (ii) [***]
 - (iii) [***]

The payment terms set forth in Section 8.2(i) shall apply with respect to any milestone payment under this Section 8.2(d1). For clarity, in no event will milestones paid under this Section 8.2(d1) exceed US\$75,000,000 in the aggregate."

- (c) The Original Agreement is hereby amended to delete Section 8.2(f) and replace it in its entirety with the following:
 - "(f) Except as expressly otherwise specified herein, none of the payments listed in this Section 8.2, including any Graft-Versus-Host Disease Milestone Payments, shall be payable more than once, and, subject to the foregoing, each shall be payable at the first achievement of a milestone event for a Licensed Product and shall not be payable again if subsequently another Licensed Product achieves the same milestone event. [***]"
- (d) The Original Agreement is hereby amended to add Exhibit J at the end of the Original Agreement. For purposes of clarity, a JAK Licensed Product containing ruxolitinib or any Ruxolitinib Backup Compounds with respect to which Novartis has exercised a Rux Backup Compound Option in an Indication in the Graft-Versus-Host Disease Field shall be deemed to be a JAK Licensed Product for all purposes, including, without limitation, Section 8.2(e)(ii) (JAK Licensed Product Sales Milestones) and Section 8.3(a)(ii) (Royalties JAK Licensed Products).

ARTICLE III

PAYMENTS

3.1 <u>Upfront Payment</u>. Novartis shall pay to Incyte a one-time, non-creditable, non-refundable payment of US\$5,000,000 within [***] after receipt of an invoice therefor, which invoice may not be submitted prior to the Effective Date.

ARTICLE IV

REPRESENTATIONS AND WARRANTIES

4.1 <u>Representation of Authority; Consents.</u> Incyte and Novartis each represents and warrants to the other Party that:

4;

(b) as of the Effective Date, this Amendment No. 4 has been duly executed by such Party and constitutes a legal, valid and binding obligation of such Party, enforceable in accordance with its terms, except as

as of the Effective Date, it has full right, power and authority to enter into this Amendment No.

- constitutes a legal, valid and binding obligation of such Party, enforceable in accordance with its terms, except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other Laws relating to or affecting creditors' rights generally and by general equitable principles and public policy constraints (including those pertaining to limitations and/or exclusions of liability, competition Laws, penalties and jurisdictional issues including conflicts of Laws); and
- (c) as of the Effective Date, all necessary consents, approvals and authorizations of all government authorities and other persons (including, in the case of Incyte, Lilly) required to be obtained by such Party in connection with the execution, delivery and performance of this Amendment No. 4 have been obtained.
 - 4.2 <u>No Conflict.</u> Each Party represents and warrants to the other Party that the execution and delivery of this Amendment No. 4 and the performance of such Party's obligations hereunder (a) do not conflict with or violate such Party's corporate charter and bylaws or any requirement of applicable Laws and (b) do not and shall not conflict with, violate or breach or constitute a default or require any consent under, any oral or written contractual obligation of such Party (including in the case of Incyte, the Lilly Agreement). Each Party agrees that it shall not during the term of the Original Agreement grant any right, license, consent or privilege to any Third Party (including, in the case of Incyte, to Lilly) or otherwise undertake any action, either directly or indirectly, that would conflict with the rights granted to the other Party or interfere with any obligations of such Party set forth in this Amendment No. 4.
 - 4.3 <u>No Ruxolitinib Backup Compounds</u>. Incyte represents and warrants to Novartis that, as of the Effective Date, it does not Control any Ruxolitinib Backup Compounds for use in any Indication within the Graft-Versus-Host Disease Field

ARTICLE V

INDEMNIFICATION

5.1 <u>By Novartis</u>.

(a)

(a) Novartis agrees, at Novartis's cost and expense, to defend, indemnify and hold harmless the Incyte Indemnified Parties from and against any losses, costs, damages, fees or expenses arising out of any Third Party claim relating to or alleging any facts that would constitute a breach by Novartis of any of its representations, warranties or obligations pursuant to this Amendment No. 4.

(b) Sections 10.1(b) and (c) of the Original Agreement shall apply *mutatis mutandis* to this Amendment No. 4 as if set forth herein in full.

5.2 By Incyte.

- (a) Incyte agrees, at Incyte's cost and expense, to defend, indemnify and hold harmless the Novartis Indemnified Parties from and against any losses, costs, damages, fees or expenses arising out of any Third Party claim relating to or alleging any facts that would constitute a breach by Incyte of any of its representations, warranties or obligations pursuant to this Amendment No. 4.
- (b) Sections 10.2(b) and (c) of the Original Agreement shall apply *mutatis mutandis* to this Amendment No. 4 as if set forth herein in full.

ARTICLE VI

MISCELLANEOUS

- 6.1 <u>Effect on Original Agreement</u>. Except to the extent amended pursuant to this Amendment No. 4, the Original Agreement shall continue in full force and effect in accordance with its terms.
- 6.2 <u>Publicity.</u> Except as required by judicial order or applicable Law, neither Party shall make any public announcement concerning this Amendment No. 4 without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed. Except in the case of the initial press release announcing the execution of this Amendment 4, the Party preparing any such public announcement shall provide the other Party with a draft thereof at least [***] prior to the date on which such Party would like to make the public announcement. Notwithstanding the foregoing, Incyte may issue a press release in the form attached as Schedule II within one (1) Business day after the Effective Date. Either Party shall be permitted to disclose publicly any information which was previously approved for public disclosure pursuant to this Section 6.2.
- 6.3 <u>Miscellaneous Provisions</u>. The following provisions of the Original Agreement shall apply to this Amendment No. 4 as if set forth herein in full: <u>Section 14.1</u> (Governing Law); <u>Section 14.2</u> (Consent to Jurisdiction); <u>Section 14.6</u> (Notices); <u>Section 14.11</u> (Headings); <u>Section 14.12</u> (No Implied Waivers; Rights Cumulative); <u>Section 14.13</u> (Severability); <u>Section 14.14</u> (Execution in Counterparts); <u>Section 14.16</u> (Exhibits).

[THE REMAINDER OF THIS PAGE HAS BEEN INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the Parties have caused their duly authorized officers to execute and acknowledge this Amendment No. 4 as of the date first written above.

NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD.

INCYTE CORPORATION

By: /s/ Michael Jones

Name: Michael Jones

Title: Director

By: /s/ Hervé Hoppenot Name: Hervé Hoppenot Title: President and CEO

NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD.

By: /s/ M. Tonesan Amissah

Name: M. Tonesan Amissah Title: Alternate Director

Exhibit J

Graft-Versus-Host Disease Field (ICD-9-CM)

279.50 Graft-versus-host disease, unspecified (including prophylaxis of Graft-versus-host disease)
279.51 Acute graft-versus-host disease
279.52 Chronic graft-versus-host disease
279.53 Acute on chronic graft-versus-host disease

Press Release

See Attached.

EXTENSION OF CONFIDENTIAL TREATMENT REQUESTED: Certain identified information, marked by [***], has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company, if publicly disclosed. An extension of confidential treatment for such information has been requested. An unredacted version of this document has been filed separately with the Securities and Exchange Commission (the "Commission").

LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

by and between

Incyte Corporation

Experimental Station, Route 141 & Henry Clay Road Wilmington, Delaware

and

Eli Lilly and Company

Lilly Corporate Center Indianapolis, Indiana 46285

TABLE OF CONTENTS

ARTICLE I Definitions		1
ARTICLE	II Licenses	13
2.1	Rights Granted by Incyte to Lilly	13
2.1	Sublicense Rights	13
2.2	Section 365(n) of The Bankruptcy Code	14
2.3	Field Expansion	14
2.5	Retained Rights	15
2.6	Non-Compete	15
ARTICLE	III Governance	17
2.1	Joint Development Committee	17
3.1	Joint Development Committee.	17
3.2 3.3	Subcommittees Committee Meetings	18 18
3.3	Committee Meetings	18
3.4	Authority Decisions.	18
3.5	Committee Membership.	19
3.7	Future Adjustments in Governance	19
ARTICLE	IV Development; Regulatory Matters; Supply	20
4.1	Initial Transfer	20
4.1	Conduct of Development Activities	20
4.2	Development Reports	23
4.4	Licensed Product Co-Development Option	23
4.5	Regulatory Matters Related to Licensed Products	25
4.6	Manufacture and Supply	26
ARTICLE	V Commercialization	26
5.1		26
5.1	Commercialization Diligence	26
5.2	Marketing Responsibilities For Licensed Products	28
5.3	Trademarks.	28
5.4	Co-Promotion.	28
ARTICLE	VI Intellectual Property Ownership, Protection and Related Matters	30
6.1	Inventorship; Ownership	30
6.2	Prosecution and Maintenance of Patent Rights	30
6.3	Third Party Infringement	32
6.4	Patent Marking	33
	·	
	-i-	

ARTICLE	VII Financial Provisions	33
7.1	License Fee	33
7.2	Milestone Payments	33
7.3	Royalties	37
7.4	Royalty Reports; Payments	39
7.5	Financial Records	40
7.6	Audits	40
7.7	Tax Matters	40
7.8	Currency Exchange	40
7.9	Late Payments	41
ARTICLE	VIII Term and Termination	41
0.1	A consequent Trans	41
8.1	Agreement Term	41
8.2	Termination.	41
8.3	Effects Of Termination.	42
ARTICLE	IX Indemnification; Limitation of Liability	45
9.1	By Lilly	45
9.1	By Incyte	45
9.2	Limitation of Liability	46
9.3	Limitation of Elability	40
ARTICLE	X Representations and Warranties and Covenants	46
10.1	Representation Of Authority; Consents	46
10.1	No Conflict	47
10.2	Additional Incyte Representations and Warranties	47
10.3	Disclaimer of Warranty	48
10.4	Standstill	48
10.5	Standstill	40
ARTICLE	XI Confidentiality	50
11 1	Confidential Information	50
11.1	Confidential Information	50
11.2	Permitted Disclosure	50
11.3	Publicity; Attribution; Terms of this Agreement; Non-Use of Names.	51
11.4	Publications	52
11.5	Term	53
11.6	Return of Confidential Information	53
ARTICLE	XII Dispute Resolution	54
12.1	Dispute Resolution Process	54
12.1	Injunctive Relief	54
12.2		31

ARTICLE XIII Miscellaneous		54
13.1	Governing Law	54
13.2	Consent to Jurisdiction	54
13.3	Assignment	55
13.4	Entire Agreement; Amendments	55
13.5	Notices	55
13.6	Force Majeure	56
13.7	Compliance With Laws	56
13.8	Use Of Names, Logos Or Symbols	57
13.9	Independent Contractors	57
13.10	Headings	57
13.11	No Implied Waivers; Rights Cumulative	57
13.12	Severability	57
13.13	Execution In Counterparts	57
13.14	No Third Party Beneficiaries.	57
13.15	Performance by Affiliates.	58
13.16	Exhibits	58

Exhibits

Exhibit A: Incyte Patent Rights
Exhibit A-1: Genus Patent Rights
Exhibit A-2: Selection Patent Rights
Exhibit B: Initial Information Transfer
Exhibit C: Initial Development Plans
Exhibit D: Initial Press Release

Exhibit E: Hematology Field and Oncology Field

Schedules

Schedule 1.43: [***]

Schedule 1.48: Initial Licensed Back-Up Compounds

LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

THIS LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT (the "<u>Agreement</u>") is entered into as of the 18th day of December, 2009 ("<u>Effective Date</u>"), by and between Incyte Corporation, a Delaware corporation having an office at Experimental Station, Route 141 & Henry Clay Road, Wilmington, Delaware ("<u>Incyte</u>"), and Eli Lilly and Company, an Indiana corporation having an office at Lilly Corporate Center, Indianapolis, Indiana 46285 ("<u>Lilly</u>").

WHEREAS, Incyte and Lilly are each in the business of discovering, developing and commercializing pharmaceutical products;

WHEREAS, Incyte has discovered and commenced Development of the Licensed Compounds (as defined below);

WHEREAS, Incyte has agreed to grant to Lilly a license to develop and commercialize the Licensed Compounds;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE I

DEFINITIONS

When used in this Agreement, each of the following terms shall have the meanings set forth in this ARTICLE I:

- 1.1 "<u>Accounting Standards</u>" with respect to a Party means that such Party shall maintain records and books of accounts in accordance with (a) US GAAP (United States Generally Accepted Accounting Principles) or (b) to the extent applicable, IFRS (International Financial Reporting Standards).
- 1.2 "Affiliate" means any Person that, directly or indirectly, controls, is controlled by or is under common control with a Party. For the purposes of this Section 1.2, the word "control" (including, with correlative meaning, the terms "controlled by" or "under common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such entity, whether by the ownership of [***] of the Voting Stock of such entity, by contract or otherwise. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than [***], and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity.

- 1.3 "<u>Annual Net Sales</u>" means aggregate Net Sales of a Licensed Product by Lilly or its Affiliates or sublicensees in any Calendar Year, or in the first and last years of the term of this Agreement, the portion of such Calendar Year during which this Agreement is in effect.
- 1.4 "<u>Business Day</u>" means a day other than a Saturday or Sunday or Federal holiday in Wilmington, Delaware or Indianapolis, Indiana.
- 1.5 "<u>Calendar Quarter</u>" means a calendar quarter ending on the last day of March, June, September or December.
- 1.6 "<u>Calendar Year</u>" means a period of time commencing on January 1 and ending on the following December 31.
- 1.7 "<u>Clinical Trial</u>" means a Phase I Study, a Phase II Study, a Phase III Study, a Phase III Study, a Phase IV Study or a combination of two (2) of any of the foregoing studies.
- 1.8 "<u>Commercialization</u>" or "<u>Commercialize</u>" means any activities directed to obtaining pricing and/or reimbursement approvals, marketing, promoting, distributing, importing, offering to sell, and/or selling a product (including establishing the price for such product).
- 1.9 "Commercially Reasonable Efforts" of a Party means, with respect to an objective, the reasonable, diligent, good faith efforts of a Party, (including the efforts of its Affiliates, and sublicensees) of the type to accomplish such objective as a similarly situated (with respect to size, stage of development, and assets) biotechnology or pharmaceutical company, as the case may be, would normally use to accomplish a similar objective under similar circumstances, it being understood and agreed that, with respect to efforts to be expended in relation to a product (including implementation of Development and Commercialization strategies to support the pursuit of multiple Indications in accordance with Exhibit C), such efforts shall be substantially equivalent to those efforts and resources that a similarly situated biotechnology or pharmaceutical company, as the case may be, would typically devote to its own internally discovered compound or product, which compound or product is at a similar stage in its Development or product life and is of similar market and economic potential as products expected to result from the Licensed Compounds at a similar stage in their Development or product life, taking into account the risks of development, the commercial potential for the Product, its proprietary position and other relevant factors.
- 1.10 "<u>Confidential Information</u>" means (a) all confidential or proprietary information relating to Licensed Compounds, and (b) all other confidential or proprietary documents, technology, Know-How or other information (whether or not patentable) actually disclosed by one Party to the other pursuant to this Agreement or the Prior Confidentiality Agreement.
- 1.11 "Control" or "Controlled" means, with respect to any (a) material, document, item of information, method, data or other Know-How or (b) Patent Rights or other Intellectual Property Rights, the possession by a Party or its Affiliates (whether by ownership or license (other than by a license granted under this Agreement)), of the ability to grant to the other Party access, a license and/or a sublicense as provided herein without requiring the consent of a Third Party or violating the terms of any agreement or other arrangement with any Third Party, in each

case as of the Effective Date, or if any of the same are acquired or created after the Effective Date, at the date it is acquired or created by the relevant Party or its Affiliate.

- 1.12 "Cover", "Covering" or "Covered" with respect to a product, technology, process or method, means that, but for a license granted to a Person under a Valid Claim included in the Patent Rights under which such license is granted, the Development, manufacture, Commercialization and/or other use of such product or the practice of such technology, process or method, by such Person would infringe such Valid Claim (or, in the case of a Valid Claim that has not yet issued, would infringe such Valid Claim if it were to issue).
- 1.13 "<u>CPI</u>" means the Consumer Price Index Urban Wage Earners and Clerical Workers, U.S. City Average, All Items, 1982-84 = 100, published by the United States Department of Labor, Bureau of Statistics (or its successor equivalent index).
- 1.14 "<u>Detail</u>" means face-to-face discussions or other direct communication (e.g. *e*detailing) with physicians and other health care practitioners who are permitted under applicable Laws to prescribe a Licensed Product for the purpose of promoting a Licensed Product to such physicians or practitioners.
- 1.15 "<u>Development</u>" or "<u>Develop</u>" means, with respect to a compound, preclinical and clinical drug development activities, including, among other things: the conduct of Clinical Trials, test method development and stability testing, toxicology, formulation and delivery system development, process development, pre-clinical and clinical drug substance and clinical drug product supply, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control procedure development and performance with respect to clinical materials, statistical analysis and report writing and clinical studies, regulatory affairs, and all other pre-Regulatory Approval activities. When used as a verb, "Develop" means to engage in Development.
- 1.16 "Development Costs" means the costs and expenses incurred by or on behalf of a Party attributable to, or reasonably allocable to, the Development of Licensed Products and that are materially consistent, as applicable, with the Development Plan and Development Budget. Development Costs shall not include [***]. "Development Costs" shall include (a) the costs of Clinical Trials, the preparation, collation and/or validation of data from such Clinical Trials and the preparation of medical writing and publishing; (b) the FTE costs of the relevant Party or its Affiliates; (c) all Out-of-Pocket Costs incurred by the Parties or their Affiliates, including payments made to Third Parties with respect to any of the foregoing (except to the extent that such costs have been included in FTE costs); (d) Out-of-Pocket Costs incurred by or on behalf of a Party in connection with the preparation and filing of regulatory submissions for Licensed Product and obtaining of Regulatory Approvals; and (e) the cost of contract research organizations (CROs) and clinical supply, including: (i) costs, packaging and distribution of Licensed Products used in Clinical Trials; (ii) expenses incurred to purchase and/or package comparator drugs; and (iii) costs and expenses of disposal of clinical samples.
 - 1.17 "EMEA" means the European Medicines Agency, or a successor agency thereto.

- 1.18 "Exchange Act" means the Securities Exchange Act of 1934, as amended.
- 1.19 "Excluded Field" means any and all Indications in humans and animals in the Hematology Field and the Oncology Field.
- 1.20 "Executive Officers" means the Chief Executive Officer of Incyte (or a senior executive officer of Incyte designated by Incyte's Chief Executive Officer) and the Vice President Autoimmune Product Development of Lilly (or a senior executive officer of Lilly or its Affiliate as designated by the Vice President Autoimmune Product Development of Lilly).
 - 1.21 "FDA" means the United States Food and Drug Administration, or a successor agency thereto.
- 1.22 "Field" means the treatment, control, management, mitigation, prevention or cure of any and all Inflammatory Disease Indications in humans and animals in any formulation or dosage form, process or delivery method, but not including the Topical Field.
- 1.23 "<u>First Commercial Sale</u>" means, with respect to a Licensed Product, the first sale of commercially relevant quantities of such Licensed Product intended for use by a patient, to a Third Party by, as applicable, Lilly or its Affiliates or sublicensees in a country following applicable Regulatory Approval (other than applicable governmental price and reimbursement approvals) of such Licensed Product in such country. For the avoidance of doubt, sales or transfers of Licensed Product for Clinical Trial or other Development purposes, or for compassionate or similar use, shall not be considered a First Commercial Sale.
- 1.24 "<u>Force Majeure Event</u>" means an event, act, occurrence, condition or state of facts, in each case outside the reasonable control of a Party, including acts of God; acts of any government; any rules, regulations or orders issued by any governmental authority or by any officer, department, agency or instrumentality thereof; fire; storm; flood; earthquake; accident; war; rebellion; insurrection; riot; terrorism and invasion, that interfere with the normal business operations of such Party.
- 1.25 "FTE" means a full-time equivalent person year (consisting of a total of [***] hours per year) of scientific or technical work undertaken by a Party's or its Affiliates' employees, or a Third Party licensee/sublicensee to the extent (a) mutually agreed by the Parties and (b) permitted and in accordance with the terms and conditions of this Agreement.
- 1.26 "FTE Rate" means the rate per FTE (which may be prorated on a daily basis as necessary) of [***] and [***], with respect to Development and manufacturing activities conducted pursuant to this Agreement, subject to annual adjustment by the rate of the Employment Cost Index for total compensation for the "management, professional and related" occupational group, as published by the United States Department of Labor, Bureau of Labor Statistics (or any similar index agreed upon by the Parties if such index ceases to be compiled and published).

1.27 "Generic Competition" means, with respect to a Licensed Product in any country in a given Calendar Year, if, during such Calendar Year one or more Generic Products shall be commercially available in such country and such Generic Products shall in the aggregate have a market share of [***] of the aggregate market share of such Licensed Product and Generic Products (based on data provided by IMS International or, if such data is not available, such

other reliable data source as agreed by the Parties (such agreement not to be unreasonably withheld)) as measured by unit sales in such country.

- 1.28 "Generic Product" means any pharmaceutical product that (a) contains a Licensed Compound; (b) is sold by a Third Party that is not a licensee or sublicensee of Lilly or its Affiliates, under a marketing authorization granted by a Regulatory Authority to such Third Party; [***].
- 1.29 "<u>Hematology Field</u>" means the treatment, control, mitigation, prevention, cure, or diagnosis of all hematologic Indications as defined in subsections 280 289 (Diseases of the blood and blood-forming organs) of the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), as set forth in <u>Exhibit E</u>.
- 1.30 "HSR Act" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (15 U.S.C. §18a), and the rules and regulations promulgated thereunder.
 - 1.31 "Incyte IP" means Incyte Know-How and Incyte Patent Rights.
- 1.32 "<u>Incyte Know-How</u>" means all Know-How that (a) is Controlled by Incyte or any of its Affiliates as of the Effective Date or during the Term; and (b) is necessary or useful to Develop, manufacture or Commercialize any Licensed Compounds or Licensed Products.
- 1.33 "Incyte Patent Rights" means all Patent Rights that (a) are Controlled by Incyte or any of its Affiliates as of the Effective Date or during the Term; and (b) (i) Covers a Licensed Compound or Licensed Product, a composition containing Licensed Compound, a formulation containing a Licensed Product or (ii) are otherwise necessary to Develop, manufacture or Commercialize any Licensed Compounds or Licensed Products. The Incyte Patent Rights that exist as of the Effective Date are set forth in Exhibit A (A-1 and A-2).
- 1.34 "IND" means an Investigational New Drug Application filed with the FDA under 21 C.F.R. Part 312 or similar non-United States application or submission in any country or group of countries for permission to conduct human clinical investigations.
 - 1.35 "Indication" means any disease, condition or syndrome.
- 1.36 "Inflammatory Disease" means any inflammatory disease, including the following Indications: rheumatoid arthritis (and other arthritides including juvenile RA, ankylosing spondylitis, sero-negative spondyloarthropathies and psoriatic arthritis), inflammatory bowel disease (ulcerative colitis and Crohn's Disease), asthma, chronic obstructive pulmonary disease, multiple sclerosis, systemic lupus erythmatosus and psoriasis. Notwithstanding the foregoing, Inflammatory Disease specifically excludes any Indication included in the Excluded Field.

- 1.37 "Intellectual Property Rights" means Patent Rights, trade secrets, copyrights and other forms of proprietary or industrial rights pertaining to inventions, Know-How, original works, and other forms of intellectual property.
- 1.38 "<u>Inventions</u>" means all patentable inventions, discoveries, improvements and other technology and any Patent Rights based thereon, that are discovered, made or conceived

during and in connection with the research, Development, manufacture and Commercialization of Licensed Compounds or Licensed Products.

- 1.39 "JAK" means human Jak Tyrosine Kinase.
- 1.40 "JAK1" means Jak1 Tyrosine Kinase.
- 1.41 "JAK2" means Jak2 Tyrosine Kinase.
- 1.42 "JAK Excluded Compound" means [***].
- 1.43 "JAK2 Inhibitor Compound" means [***] in Schedule 1.43.
- 1.44 "Know-How" means any information, ideas, data, inventions, works of authorship, trade secrets, technology, or materials, including formulations, molecules, assays, reagents, compounds, compositions, human or animal tissue, samples or specimens, and combinations or components thereof, whether or not proprietary or patentable, or public or confidential, and whether stored or transmitted in oral, documentary, electronic or other form, including all Regulatory Documentation, but excluding any such information or materials publicly disclosed in Patent Rights.
- 1.45 "<u>Law</u>" means any law, statute, rule, regulation, ordinance or other pronouncement having the effect of law, of any federal, national, multinational, state, provincial, county, city or other political subdivision, including (a) good clinical practices and adverse event reporting requirements, guidance from the International Conference on Harmonization or other generally accepted conventions, and all other rules, regulations and requirements of the FDA and other applicable Regulatory Authorities; (b) the Foreign Corrupt Practices Act of 1977, as amended, or any comparable laws in any country; and (c) all export control laws.
- 1.46 "<u>Lead Compound</u>" means (a) the Initial Lead Compound or (b) the first Licensed Back-Up Compound to achieve initiation of a Phase IIb Study (the "Follow-On Lead Compound").
 - 1.47 "Licensed Back-Up Compounds" means all Licensed Compounds other than the Initial Lead Compound.
- 1.48 "<u>Licensed Compounds</u>" means (a) the compound known as INCB28050 (the chemical structure of which has been previously disclosed to Lilly) (the "<u>Initial Lead</u>

Compound"); (b) the back-up compounds set forth on Schedule 1.48 (the chemical structures of which have previously been disclosed to Lilly) (each an "Initial Licensed Back-Up Compounds"); (c) all other JAK2 Inhibitor Compounds (other than JAK Excluded Compounds) Covered [***], within the Selection Patent Rights that exist as of the Effective Date; (d) all salts, prodrugs, esters, metabolites, solvates, stereoisomers and polymorphs of the foregoing; and (e) all derivatives of the foregoing containing one or more atoms substituted with a radio isotope (including derivatives containing deuterium).

1.49 "<u>Licensed Product</u>" means a product or product candidate that contains one or more Licensed Compounds in any formulation as the active ingredient, including all dosages of

such Licensed Compounds and all processes and delivery systems that incorporate such Licensed Compounds, but not including the Topical Field.

- 1.50 "Major EU Countries" means [***].
- 1.51 "Major Market Country" means [***].
- 1.52 "Marketing and Sales Support" means any direct support (internal or external, but excluding any allocation of general, corporate or administrative overhead) relating to the sale, promotion and marketing of Licensed Products, including: (a) Detailing or such other contact regarding Licensed Products; (b) sample drops and any activities performed by medical information scientists, market development specialists, managed care account directors and other personnel; (c), market research, marketing communications, managed care, sales meetings, sales force training, product hotlines, reimbursement support, contracting, pricing, and telemarketing services; (d) advertising through any means, including television and radio advertisements, advertisements appearing in journals, newspapers, magazines or other media, packaging design, visual aids and other selling materials, hospital formulary committee presentations and presentations to state and other governmental formulary committees; and (e) any public relations activity relating to a Licensed Product.
 - 1.53 "MHLW" means the Japanese Ministry of Health, Labor and Welfare, or a successor agency thereto.
- 1.54 "NDA" means (a) (i) a New Drug Application submitted to the FDA, or any successor application or procedure, as more fully defined in 21 C.F.R. § 314.50 et. seq.; or (ii) any non-United States counterpart of such a New Drug Application; and (b) all supplements and amendments, including supplemental New Drug Applications (and any non-United States counterparts) that may be filed with respect to the foregoing.
- 1.55 "Net Sales" means, with respect to any Licensed Product, the gross amount invoiced by Lilly or its Affiliates, or sublicensees on sales or other dispositions of Licensed Product to Third Parties, or otherwise directly or indirectly paid to or earned by Lilly or its Affiliates or sublicensees with respect to the sale of Licensed Product, less the following:
- (a) trade, cash and/or quantity discounts not already reflected in the amount invoiced, to the extent related to the gross amount invoiced;

- (b) allowances and adjustments credited or payable, including credit for spoiled, damaged, outdated, recalled and returned Licensed Product, to the extent related to the gross amount invoiced and substantiated by reasonable documentation;
- (c) freight, insurance and other transportation charges incurred in shipping a Product to Third Parties, to the extent identified as such in the invoice to the Third Party, to the extent included in the gross amount invoiced;
- (d) amounts repaid or credited by reason of rejections, defects, recalls or returns or because of chargebacks, refunds, rebates (including wholesaler inventory management fees, retroactive price reductions, commissions, discounts or billing errors, and any other allowances which effectively reduce the net selling price);
- (e) all tariffs, duties, excises, sales taxes, or other taxes (including VAT) and custom duties imposed on Licensed Products, in each case to the extent invoiced to customers or otherwise included within gross amounts invoiced;
 - (f) allowance for distribution expenses; and
 - (g) other similar and customary deductions which are in accordance with US GAAP.

Net Sales will not include sales between or among Lilly and its Affiliates and/or sublicensees; provided, however, that any resale to Third Parties shall be included in Net Sales.

Net Sales shall be calculated in accordance with Lilly's standard internal policies and procedures, which must be in accordance with Accounting Standards. In the case of any sale or other disposal for value, such as barter or countertrade, of Licensed Product, or part thereof, other than in an arm's length transaction exclusively for cash, Net Sales shall be calculated as above on the value of the non-cash consideration received or the fair market price (if higher) of the Licensed Product in the country of sale or disposal, as determined in accordance with Accounting Standards. Donated product will be excluded from Net Sales.

In the event the Licensed Product is sold in a finished dosage form containing the Licensed Product in combination with one or more other active ingredients (a "Combination Product"), the Net Sales of the Licensed Product, for the purposes of determining royalty payments, shall be determined by multiplying the Net Sales (as defined above in this Section) of the Combination Product by the fraction, A/(A+B) where A is the weighted (by sales volume) average sale price in a particular country of the Licensed Product in the prior Calendar Year when sold separately in finished form and B is the weighted average sale price in that country in the prior Calendar Year of the other product(s) sold separately in finished form.

In the event that the weighted average sale price of the Licensed Product can be determined but the weighted average sale price of the other product(s) cannot be determined, Net Sales for purposes of determining royalty payments shall be calculated by multiplying the Net Sales of the Combination Product by the fraction A / C where A is the weighted average sale price of the Licensed Product when sold separately in finished form and C is the weighted average sale price of the Combination Product.

In the event that the weighted average sale price of the other product(s) can be determined but the weighted average sale price of the Licensed Product cannot be determined, Net Sales for purposes of determining royalty payments shall be calculated by multiplying the Net Sales of the Combination Product by the following formula: one (1) minus B / C where B is the weighted average sale price of the other product(s) when sold separately in finished form and C is the weighted average sale price of the Combination Product.

In the event that such average sale price cannot be determined for both the Licensed Product and the other product(s) in combination, Net Sales for purposes of determining royalty payments shall be agreed by the Parties based on the relative value contributed by each component, such agreement shall not be unreasonably withheld.

In the initial Calendar Year, a forecasted weighted average sale price will be used for the Licensed Product, other product(s), or Combination Product. Any over or under payment due to a difference between forecasted and actual weighted average sale prices will be paid or credited in the first royalty payment of the following Calendar Year.

- 1.56 "Oncology Field" means the treatment, control, mitigation, prevention, cure, or diagnosis of any oncology Indications as defined in subsections 140 239 (Neoplasms) of the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) as set forth in Exhibit E, including all hematologic malignancies, solid tumors and myeloproliferative diseases (including Myelofibrosis, Polycythemia Vera and Essential Thrombocythemia) as listed in ICD-9-CM.
- 1.57 "Out-of-Pocket Costs" means, with respect to certain activities hereunder, direct expenses paid or payable by either Party or its Affiliates to Third Parties (other than employees of such Party or its Affiliates) that are specifically identifiable and incurred to conduct such activities for Licensed Products and have been recorded in accordance with Accounting Standards.
 - 1.58 "Party" means Lilly or Incyte. "Parties" means Lilly and Incyte.
- 1.59 "Patent Rights" means all patents and patent applications in any country in the world, including any continuations, continuations-in-part, divisions, provisionals or any substitute applications, any patent issued with respect to any such patent applications, any reissue, reexamination, renewal, term adjustment, restoration, or extension (including any supplemental protection certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent, and all non-United States counterparts of any of the foregoing.
- 1.60 "<u>Patent Term Extension</u>" means any patent term extension, adjustment or restoration or supplemental protection certificates.
- 1.61 "<u>Person</u>" means any natural person, general or limited partnership, corporation, limited liability company, limited liability partnership, firm, association or organization or other legal entity.

- 1.62 "Phase I Study" means a study in humans which provides for the first introduction into humans of a product, conducted in healthy volunteers or patients to obtain information on product safety, tolerability, pharmacological activity or pharmacokinetics, as more fully defined in 21 C.F.R. § 312.21(a) (or the non-United States equivalent thereof).
- 1.63 "Phase II Study" means a study in humans of the safety, dose ranging and efficacy of a product, which is prospectively designed to generate sufficient data (if successful) to commence pivotal clinical trials, as further defined in 21 C.F.R. § 312.21(b) (or the non-United States equivalent thereof).
- 1.64 "Phase IIb Study" means a well-controlled, dose ranging, multicenter Phase II Study in patients with the disease or condition under study which is conducted after a proof of concept study and that is adequately powered to further evaluate efficacy and safety and define the dosage regimen of a product in the target indication and which is intended to be among the last clinical trials in the patient population performed prior to the initiation of Phase III Studies. A Phase IIb Study could include several hundred patients but not to the extent required for registration.
- 1.65 "Phase III Study" means a controlled study in humans of the efficacy and safety of a product, which is prospectively designed to demonstrate statistically whether such product is effective and safe for use in a particular Indication in a manner sufficient to file an NDA to obtain regulatory approval to market the product, as further defined in 21 C.F.R. § 312.21(c) (or the non-United States equivalent thereof).
- 1.66 "Phase IV Study" means a human clinical trial which is conducted on a product after Regulatory Approval of the product has been obtained from an appropriate Regulatory Authority, and includes (a) trials conducted voluntarily for enhancing marketing or scientific knowledge of an approved Indication or (b) trials conducted after Regulatory Approval due to request or requirement of a Regulatory Authority or as a condition of a previously granted Regulatory Approval.
- 1.67 "<u>Prior Confidentiality Agreement</u>" means the Confidentiality Agreement between Incyte and Lilly, dated April 23, 2009.
- 1.68 "<u>Publication</u>" means any publication in a scientific journal, any abstract to be presented to any scientific audience, any presentation at any scientific conference, including slides and texts of oral or other public presentations, any other scientific presentation and any other oral, written or electronic disclosure directed to a scientific audience which pertains to the Licensed Compound, the Licensed Product or the use of the Licensed Product.
- 1.69 "<u>Regulatory Approval</u>" means all approvals (including any applicable governmental price and reimbursement approvals), licenses, registrations, and authorizations of any federal, national, multinational, state, provincial or local Regulatory Authority, department, bureau and other governmental entity that are necessary for the marketing and sale of a Licensed Product in a country or group of countries.
- 1.70 "<u>Regulatory Authority</u>" means, with respect to a country, the regulatory authority or regulatory authorities of such country with authority over the testing, manufacture, use,

storage, importation, promotion, marketing, pricing or sale of a pharmaceutical product in such country.

1.71 "Regulatory Documentation" means, with respect to the Licensed Compounds and Licensed Products, all INDs and other regulatory applications submitted to any Regulatory Authority, copies of Regulatory Approvals, regulatory materials, drug dossiers, master files (including Drug Master Files, as defined in 21 C.F.R. 314.420 and any non-United States equivalents), and any other reports, records, regulatory correspondence and other materials relating to Regulatory Approval of a Licensed Compound or Licensed Product, or required to

manufacture, distribute or sell the Licensed Products, including any information that relates to pharmacology, toxicology, chemistry, manufacturing and controls data, batch records, safety and efficacy, and any safety database required to be maintained for Regulatory Authorities.

- 1.72 "Regulatory Exclusivity" means that Third Parties are prevented from legally Developing, manufacturing or Commercializing a product that could compete with a Licensed Product in a country, either through data exclusivity rights, orphan drug designation, or such other rights conferred by a Regulatory Authority in such country, other than through Patent Rights.
- 1.73 "<u>Right of Reference or Use</u>" means a "Right of Reference or Use" as that term is defined in 21 C.F.R. §314.3(b) or any successor regulatory scheme, and any non-United States equivalents.
- 1.74 "Selection Patent Rights" means the Incyte Patent Rights that are designated as INCY0086 and Joint IP Covering the Licensed Compounds and Licensed Products. The Selection Patent Rights that exist as of the Effective Date are set forth on Exhibit A-2.
 - 1.75 "<u>Territory</u>" means the entire world.
 - 1.76 "Third Party" means any Person other than a Party or any of its Affiliates.
- 1.77 "<u>Topical Field</u>" means any topical, intranasal, ophthalmic or other non-systemic formulations or dosage forms (e.g. cream, ointment, lotion, solution, spray, suspension, emulsion, etc.) that are administered with the intent to achieve a local/non-systemic pharmacologic activity that provides a localized treatment [***]. For avoidance of doubt, Topical Field does not include the administration of a drug through any route if the primary intent of said administration is to achieve a systemic pharmacologic effect.
- 1.78 "Valid Claim" means (a) a claim of an issued patent that has not expired or been abandoned, or been revoked, held invalid or unenforceable by a patent office, court or other governmental agency of competent jurisdiction in a final and non-appealable judgment (or judgment from which no appeal was taken within the allowable time period) or (b) a claim within a patent application [***] and which claim has not been revoked, cancelled, withdrawn, held invalid or abandoned.

- 1.79 "Voting Stock" means securities of any class or series of a corporation, limited liability company, association or other entity, the holders of which are ordinarily, in the absence of contingencies, entitled to vote generally in matters put before the shareholders or members of such corporation, limited liability company, association or other entity, including the right to vote for the election of directors or members of an equivalent governing body.
- 1.80 <u>Additional Definitions</u>. Each of the following definitions is set forth in the section of this Agreement indicated below:

<u>DEFINITION</u>	<u>SECTION</u>
Abandoned Commercialization Abandoned Development Additional Field Agreement Bankruptcy Code Breaching Party Combination Product Co-Promotion Option Development Budget	5.1(b) 4.2(b)(iii) 2.4 Preamble 2.3 8.2(b) 1.55 5.4(a) 4.2(a)(iii)C
Development Plan	4.2(a)(iii)
Development Plan Disclosing Party Effective Date Follow-On Lead Compound Future Incyte Patent Rights Genus Patent Rights Global Safety Database Incyte Incyte Indemnified Parties Incyte Phase IIa Study Initial Development Plan Initial Lead Compound Initial Licensed Back-Up Compound JDC Joint IP Lilly	4.2(a)(iii) 11.1 Preamble 1.46 6.2(a) 6.2(a) 4.5(c) Preamble 9.1(a) 4.2(a)(iii) 4.2(a)(iii) 1.48 1.48 3.1(a) 6.1(b) Preamble
Lilly Indemnified Parties	9.2(a)
[***] [***] Non-Breaching Party Notice Ongoing Studies Promotional Plan Receiving Party Royalty Term SEC Severed Clause	2.4 2.4 8.2(b) 13.5 4.2(a)(i) 5.4(a) 11.1 7.3(b) 11.3(b) 13.12

<u>DEFINITION</u>	<u>SECTION</u>
Subcommittee	3.2
Term	8.1
Third-Party Infringement	6.3(a)
UCC	5.4(b)(iii)
Voting Securities	10.5(a)(i)

- 1.81 <u>Construction</u>. In construing this Agreement, unless expressly specified otherwise:
- (a) references to Articles, Sections, Exhibits and Schedules are to articles and sections of, and exhibits and schedules to, this Agreement;
- (b) except where the context otherwise requires, use of either gender includes the other gender, and use of the singular includes the plural and vice versa;
- (c) headings and titles are for convenience only and do not affect the interpretation of this Agreement;
- (d) any list or examples following the word "including" shall be interpreted without limitation to the generality of the preceding words;
 - (e) except where the context otherwise requires, the word "or" is used in the inclusive sense;
 - (f) all references to "dollars" or "\$" herein shall mean U.S. Dollars; and
- (g) each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions.

ARTICLE II

LICENSES

- 2.1 <u>Rights Granted by Incyte to Lilly.</u> Subject to the terms of this Agreement, Incyte hereby grants Lilly, during the Term, an exclusive (even as to Incyte and its Affiliates), royalty-bearing, non-transferable (except in accordance with Section 13.3) license, with the right to sublicense (subject to Section 2.2), under Incyte IP, to research, Develop, Commercialize, make, have made, use, offer for sale, sell and import Licensed Compounds and Licensed Products in the Territory in the Field.
- 2.2 <u>Sublicense Rights</u>. Lilly shall have the right to grant sublicenses within the scope of the license under Section 2.1 solely to its Affiliates and to (a) Bona Fide Collaborators; (b) Third Parties for the purpose of distributing, importing, marketing, promoting and selling a Licensed Product in the Field (i) in any country other than a Major Market Country and (ii) in a Major Market Country [***];

- or (c) Third Parties for the purpose of engaging such Third Parties as contract research organizations, contract manufacturers, contract sales forces and academic institutions in connection with Development and/or Commercialization of Licensed Compounds and Licensed Products in the Field in the Territory; provided that any sublicense granted under this Agreement shall be pursuant to a written agreement that subjects such sublicensee to all relevant restrictions and limitations set forth in this Agreement. If Lilly grants a sublicense to a Third Party pursuant to subclause (a) or (b) to research, Develop or Commercialize Licensed Products in the United States, Major EU Countries or Japan, as permitted by Section 2.2(a) or (b), then Lilly shall provide Incyte with prompt written notice thereof and shall provide Incyte with an executed copy of any such sublicense (redacted as necessary to protect confidential or commercially sensitive information). Except as otherwise agreed by the Parties in writing, Lilly shall be jointly and severally responsible with its sublicensees to Incyte for failure by its sublicensees to comply with, and Lilly guarantees the compliance by each of its sublicensees with, all such applicable restrictions and limitations in accordance with the terms and conditions of this Agreement. For the purposes this Section 2.2, a "Bona Fide Collaborator" means a Third Party that has entered into a collaboration with Lilly for the research. Development or Commercialization of Licensed Compounds and/or Licensed Products in which Lilly plays a significant role in the decision-making process with respect to the Development and/or Commercialization of such Licensed Compound and/or Licensed Product. For purposes of clarity, a Third Party that is granted a sublicense in accordance with Section 2.2(b) or 2.2(c) shall not be deemed a Bona Fide Collaborator.
- 2.3 Section 365(n) of The Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement, including the licenses granted under this ARTICLE II and the rights granted under Section 4.1(c), are and will otherwise be deemed to be for purposes of Section 365(n) of the United States Bankruptcy Code (Title 11, U.S. Code), as amended (the "Bankruptcy Code"), licenses of rights to "intellectual property" as defined in Section 101(35A) of the Bankruptcy Code. Lilly will retain and may fully exercise all of its respective rights and elections under the Bankruptcy Code. Incyte agrees that Lilly, as licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the Bankruptcy Code or any other provisions of applicable Law outside the United States that provide similar protection for "intellectual property." Incyte further agree that, in the event of the commencement of a bankruptcy proceeding by or against Incyte under the Bankruptcy Code or analogous provisions of applicable Law outside the United States, Lilly will be entitled to a complete duplicate of (or complete access to, as Lilly deems appropriate) such intellectual property and all embodiments of such intellectual property, which, if not already in Lilly's possession, will be promptly delivered to it upon Lilly's written request thereof. Any agreements supplemental hereto will be deemed to be "agreements supplementary to" this Agreement for purposes of Section 365(n) of the Bankruptcy Code.
- 2.4 <u>Field Expansion</u>. From time to time during the Term, Lilly shall have the right, upon written notice to Incyte, to request to expand the Field to [***] (each an "<u>Additional Field</u>") in which Lilly has a good faith intention to seek to Develop and Commercialize Licensed Compounds and Licensed Products, which right shall be subject to any agreement which Incyte may have entered into with a Third Party with respect to such

Additional Field(s). Following Incyte's receipt of such written notice, and upon mutual agreement of the Parties, the Field may be expanded to include such Additional Field(s). The milestone payments set forth in Section 7.2(a)(i) shall apply as follows for the Lead Compound and in Section 7.2(a)(ii) for a Licensed Back-Up Compound when Developed for such Additional Field: (a) [***] payments shall apply for [***] means an [***] in [***]; and (b) [***] payments shall apply for [***] means an [***] in [***].

2.5 <u>Retained Rights</u>.

(a) <u>No Implied Licenses or Rights</u>. Except as expressly provided in Section 2.1 or elsewhere in this Agreement, all rights in and to the Incyte IP, and any other Patent Rights or Know-How of Incyte and its Affiliates, are hereby retained by Incyte and its Affiliates.

(b) Other Retained Rights.

- (i) Notwithstanding the exclusive licenses granted to Lilly pursuant to Section 2.1, Incyte retains the right to practice under the Incyte IP solely to perform (and to sublicense Third Parties to perform) its obligations under this Agreement (including the manufacture and supply of Licensed Compound and Licensed Product to Lilly).
- (ii) For purposes of clarity, the license granted to Lilly in Section 2.1 shall not require Incyte to remove any Licensed Compounds from Incyte's compound library, provided, however, that Incyte shall have no right to Develop or Commercialize any Licensed Compound or Licensed Product, even if included in Incyte's compound library.

2.6 <u>Non-Compete</u>.

- (a) Incyte agrees not to, and shall cause its Affiliates not to, directly or indirectly, including through any ownership interest in any other entity (other than through an ownership interest of [***] or less of a public company), (i) Develop prior to the First Commercial Sale of the first Licensed Product; and (ii) Commercialize prior to the First Commercial Sale of the first Licensed Product, and First Commercial Sale of the first Licensed Product, any JAK2 Inhibitor Compound in the Field anywhere in the world, other than a Licensed Compound in accordance with the terms of this Agreement.
- (b) Incyte shall cause its licensees of the Incyte Patent Rights (other than Lilly with respect to Licensed Compounds pursuant to this Agreement) not to use such Incyte Patent Rights to, directly or indirectly, including through any ownership interest in any other entity (other than through an ownership interest of [***] or less of a public company), (i) Develop prior to the First Commercial Sale of the first Licensed Product; and (ii) Commercialize prior to the First Commercial Sale of the first Licensed Product and for a period of [***] from the First Commercial Sale of the first Licensed Product, any JAK2 Inhibitor

Compound in the Field anywhere in the world, other than a Licensed Compound in accordance with the terms of this Agreement.

- (c) Lilly agrees not to, and shall cause its Affiliates and sublicensees not to, directly or indirectly, including through any ownership interest in any other entity (other than through an ownership interest of [***] or less of a public company), (i) Develop prior to the First Commercial Sale of the first Licensed Product; and (ii) Commercialize prior to the First Commercial Sale of the first Licensed Product and for a period of [***] from the First Commercial Sale of the first Licensed Product, any JAK2 Inhibitor Compound in the Field anywhere in the world, other than a Licensed Compound in accordance with the terms of this Agreement.
- (d) Notwithstanding the foregoing: (i) nothing in this Agreement shall prohibit either Party from Developing or Commercializing any JAK Excluded Compound (other than any JAK Excluded Compound Covered [***]) in any field anywhere in the world and (ii) neither Party shall Develop or Commercialize any JAK Excluded Compound Covered [***] anywhere in the world in or outside the Field.
- (e) During the Term, Lilly shall not, nor shall Lilly allow its Affiliates or sublicensees to, Develop or Commercialize any Licensed Compounds anywhere in the world in the Excluded Field.
- (f) During the Term, Incyte shall not, nor shall Incyte allow its Affiliates or its licensees of the Incyte Patent Rights (other than Lilly in the Field in the Territory) to use such Incyte Patent Rights to, Develop or Commercialize any Licensed Compounds anywhere in the world in or outside the Field.
- (g) In the event that this Agreement is assigned by Incyte in connection with the sale or transfer of all or substantially all of the business and assets of Incyte or Incyte merges with or is consolidated with a Third Party, the Development, manufacture or Commercialization of a compound or product that, as of the date of such sale, transfer, merger or consolidation, is being Developed, manufactured or Commercialized by the assignee or acquirer of Incyte or any Affiliate controlled by (as "controlled by" is defined in Section 1.2) such assignee or acquirer, shall not constitute a breach of this Agreement; provided that (i) such compound or product is not a Licensed Product or Licensed Compound; (ii) such assignee or acquirer or Affiliate keeps such Development, manufacture or Commercialization program for such other product separate from the Development, manufacture and Commercialization programs for Licensed Products, and ensures that no Lilly Confidential Information is utilized in such program; (iii) [***]; and (iv) Incyte continues to meet its obligations hereunder.
- (h) In the event Lilly acquires control of any Third Party, the activities of such Third Party shall not constitute a breach of this Agreement provided that (i) within no later than [***],

Lilly takes appropriate action, through divestiture of assets or otherwise, to cause Lilly to come into compliance with the terms of this Agreement; (ii) Lilly keeps such activities separate from the Development, manufacture and Commercialization programs for Licensed Products, and ensures that no Incyte Confidential Information is utilized in such activities; and (iii) Lilly continues to meet its other obligations hereunder.

(i) Notwithstanding the foregoing, nothing in this Agreement shall prohibit either Party or an Affiliate of the Party from having or controlling separate Development and/or Commercialization programs directed toward the use of a JAK2 Inhibitor Compound outside the Field, provided that the JAK2 Inhibitor Compound is not a Licensed Product or Licensed Compound, and the separate Development and/or Commercialization program activities are separate from the Development and Commercialization programs for Licensed Products, and such Party ensures that no Confidential Information received from the other Party or Joint IP is utilized in such activities.

ARTICLE III

GOVERNANCE

3.1 <u>Joint Development Committee</u>.

- (a) Establishment. The Parties shall establish a joint development committee ("JDC") within thirty (30) days after the Effective Date that will have the responsibility for the overall coordination and oversight of the Development of Licensed Compounds and Licensed Products under this Agreement. As soon as practicable following the Effective Date (but in no event more than thirty (30) days following the Effective Date), each Party shall designate its initial three (3) representatives on the JDC. Each Party's representatives and any substitute for a representative shall be bound by the obligations of confidentiality set forth in ARTICLE XI. A representative from Lilly shall act as the chairperson of the JDC. The chairperson shall not have any greater authority than any other representative on the JDC and shall conduct the following activities of the JDC: (i) calling meetings of the JDC; (ii) preparing and issuing minutes of each such meeting within thirty (30) days thereafter; (iii) ensuring that any decision-making delegated to the JDC is carried out in accordance with Section 3.5; and (iv) preparing and circulating an agenda for the upcoming meeting; provided that the chairperson shall include any agenda items proposed by Incyte. Each Party shall be free to change its representatives on notice to the other or to send a substitute representative to any JDC meeting; provided, however, that each Party shall ensure that at all times during the existence of the JDC, its representatives on the JDC are appropriate in terms of expertise and seniority for the then-current stage of Development of the Licensed Products.
- (b) <u>Responsibilities</u>. The JDC shall have responsibility for: (i) overseeing the initial transfer of information and designated activities from Incyte to Lilly relating to the clinical Development of Licensed Compounds and Licensed Products; (ii) the general oversight of the Development of Licensed Compounds and Licensed Products, including the periodic review and approval of the Development Plans (and any material updates, amendments and modifications thereto) and the review and evaluation of the progress under the Development Plans; (iii)

reviewing, amending and approving the Development Budget(iv) selecting Indications for Development in the Field; (v) reviewing the regulatory approach and filing strategy with respect to seeking and obtaining Regulatory Approval of Licensed Products in the Field in the Territory; and (vi) performing such other functions as appropriate to further the purposes of this Agreement, as mutually agreed upon by the Parties in writing.

- 3.2 <u>Subcommittees.</u> The JDC may establish and disband such subcommittees as deemed necessary by the JDC (each a "<u>Subcommittee</u>"). Each Subcommittee shall consist of the same number of representatives designated by each Party, which number shall be mutually agreed by the Parties. Each Party shall be free to change its representatives on notice to the other or to send a substitute representative to any Subcommittee meeting; <u>provided</u>, <u>however</u>, <u>that</u> each Party shall ensure that at all times during the existence of any Subcommittee, its representatives on such Subcommittee are appropriate in terms of expertise and seniority for the then-current stage of Development of the Licensed Product in the Field in the Territory and have the authority to bind such Party with respect to matters within the purview of the relevant Subcommittee. Each Party's representatives and any substitute for a representative shall be bound by the obligations of confidentiality set forth in ARTICLE XI. Except as expressly provided in this Agreement, no Subcommittee shall have the authority to bind the Parties hereunder and each Subcommittee shall report to, and any decisions shall be made by, the JDC.
- 23.3 Committee Meetings. The JDC and each of the Subcommittees shall each hold at least one (1) meeting per Calendar Quarter at such times during such Calendar Quarter as the chairperson elects to do so. Except where a Party fails to appoint a member or members to the JDC or the Subcommittees or fails to participate in meetings of the JDC or the Subcommittees pursuant to Section 3.6, meetings of the JDC and the Subcommittees, respectively, shall be effective only if at least one (1) representative of each Party is present or participating. The JDC and the Subcommittees may meet either (i) in person at either Party's facilities or at such locations as the Parties may otherwise agree or (ii) by audio or video teleconference; provided that no less than one (1) meeting during each Calendar Year shall be conducted in person. Other representatives of each Party involved with Licensed Products (including representatives of such Party's alliance management function) may attend meetings as non-voting participants, subject to the confidentiality provisions set forth in ARTICLE XI. Additional meetings of the JDC and the Subcommittees may also be held with the consent of each Party, or as required under this Agreement, and neither Party shall unreasonably withhold its consent to hold such additional meetings. Each Party shall be responsible for all of its own expenses incurred in connection with participating in all such meetings.
- 3.4 <u>Authority</u>. The JDC and any Subcommittee shall have only the powers assigned expressly to it in this ARTICLE III and elsewhere in this Agreement, and shall not have any power to amend, modify or waive compliance with this Agreement. In furtherance thereof, each Party shall retain the rights, powers and discretion granted to it under this Agreement and no such rights, powers or discretion shall be delegated or vested in the JDC or any Subcommittee unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing.

3.5 <u>Decisions</u>.

- (a) <u>Initial Dispute Resolution Procedures</u>. Subject to the provisions of this Section 3.5, actions to be taken by the JDC and each of the Subcommittees shall be taken only following a unanimous vote, with each Party having one (1) vote. If any Subcommittee fails to reach unanimous agreement on a matter before it for decision for a period in excess of thirty (30) days, either Party shall have the right to refer the matter to the JDC.
- (b) <u>Final Decision-Making</u>. If the JDC fails to reach unanimous agreement on a matter properly before it (in accordance with this ARTICLE III) for decision for a period in excess of thirty (30) days, the JDC representatives appointed by Lilly shall have the deciding vote on any matter. Incyte shall have the right to appeal any such decision of the JDC to the Lilly Executive Officer or a designee of the Lilly Executive Officer with decision-making authority for resolution. In such case, the Lilly Executive Officer or designee shall have the final decision-making authority on such issue.
- (c) Notwithstanding the foregoing, Lilly shall not exercise its right to finally resolve a dispute pursuant to Section 3.5(b): (i) in a manner that expands Lilly's rights or excuses Lilly from any of its obligations specifically enumerated under this Agreement; (ii) in a manner that negates any consent rights or other rights specifically allocated to Incyte under this Agreement; (iii) to resolve any dispute regarding whether a milestone event set forth in Section 7.2 has been achieved; or (iv) in a manner that would require Incyte to perform any act that it reasonably believes to be inconsistent with any Law or any approval, order, policy or guidelines of a Regulatory Authority.

3.6 <u>Committee Membership</u>.

- (a) <u>Appointment is a Right</u>. The appointment of members of the JDC and any Subcommittees is a right of each Party and not an obligation and shall not be a "deliverable" as referenced in any existing authoritative accounting literature. Each Party shall be free to determine not to appoint members to the JDC or any Subcommittee.
- (b) <u>Consequence of Non-Appointment</u>. If a Party does not appoint members of the JDC or any Subcommittee, it shall not be a breach of this Agreement, nor shall any consideration be required to be returned, and unless and until such members are appointed, the Party that has made the requisite appointments may unilaterally discharge the roles of the JDC or any Subcommittee for which members were not appointed, <u>provided that</u> neither Party shall unilaterally discharge the roles of the JDC or any Subcommittee as permitted under this Section 3.6(b) unless the other Party has not appointed any members within thirty (30) days after the first Party has completed its appointment of its members.
- 3.7 <u>Future Adjustments in Governance</u>. The Parties may at any time by mutual agreement create or delete governance committees or subcommittees or make other modifications to the governance structures contemplated by this Agreement in order to promote the efficient operation of the collaboration.

ARTICLE IV

DEVELOPMENT; REGULATORY MATTERS; SUPPLY

4.1 <u>Initial Transfer.</u>

- [***] after the Effective Date, Incyte shall make available to Lilly, in a mutually-agreed upon format, the material clinical data and manufacturing Know-How included in the Incyte Know-How and that is described in Exhibit B; and (ii) from the Effective Date through [***], Incyte shall make its relevant scientific and technical personnel reasonably available to Lilly at Incyte's offices, at reasonable times during Incyte's normal business hours and upon reasonable prior notice, to answer any questions or provide instruction as reasonably requested by Lilly concerning the information delivered pursuant to this Section 4.1. Thereafter, with respect to any information that constitutes Incyte Know-How not transferred to Lilly as contemplated above, Incyte will, upon request by Lilly, use its good faith efforts to make available to Lilly such Incyte Know-How as Lilly may reasonably request.
- (b) <u>Transfer of Regulatory Documentation</u>. Upon Lilly's request after payment of the license fee in accordance with Section 7.1, Incyte shall transfer ownership to Lilly of any Regulatory Documentation Controlled by Incyte and existing as of the Effective Date.
- (c) <u>Right of Reference or Use</u>. Incyte hereby grants to Lilly, solely for the purposes set forth in this Agreement, a Right of Reference or Use to any and all Regulatory Documentation Controlled by Incyte relating to Licensed Products and existing as of the Effective Date or generated from any Clinical Trial commenced by Incyte prior to the Effective Date, and agrees to sign, and cause its Affiliates to sign, any instruments reasonably requested by Lilly in order to effect such grant. Notwithstanding the foregoing, nothing in this Section 4.1 is intended to imply the existence of any particular data, information, drug master file or other Regulatory Documentation.
- (d) <u>Applicability of Bankruptcy Code</u>. For the avoidance of doubt, rights granted under this ARTICLE IV shall be deemed to be license of rights to "intellectual property" as defined in Section 101 (35A) of the Bankruptcy Code and shall otherwise be subject to Section 2.3.

4.2 <u>Conduct of Development Activities</u>.

(a) <u>Generally</u>.

(i) Except as provided in Section 4.2(a)(ii), from and after the Effective Date, Lilly will, subject to the terms of this Agreement, be responsible, at its expense, for the Development of Licensed Products in the Field in the Territory. Without limiting the foregoing, except as provided in Section 4.2(a)(ii), Lilly shall be responsible for all Out-of-Pocket Costs, including costs for contract research organizations and drug substance and drug product costs, associated with studies 28050-103, 102 and 110 (the "Ongoing Studies") that are incurred after the Effective Date, it being understood that Incyte shall be responsible for all costs

incurred prior to the Effective Date, whether billed prior to the Effective Date or thereafter. Incyte shall transfer the Ongoing Studies to Lilly within [***] after the Effective Date. Incyte shall invoice Lilly for Incyte's Out-of-Pocket Costs incurred after the Effective Date and FTE costs in connection with the management and supervision of such Ongoing Studies after the Effective Date.

- (ii) Incyte shall continue to advance, at its expense, all clinical Development conducted by Incyte for the Initial Lead Compound through the completion of the ongoing Phase IIa trial, Study INCB28050-201 (the "Incyte Phase IIa Study").
- (iii) The Development of Licensed Products shall be governed by Development plans that describe the proposed overall program of Development for Licensed Products (the "<u>Development Plan</u>"); including:
 - A. overall goals of the program;
- B. the activities to be performed (including all Clinical Trials and Regulatory Approvals required for manufacturing, marketing and selling Licensed Products in the Territory), as well as the characterization of studies:
- C. a detailed budget of Development Costs, including the overall costs for each study, annualized over the course of each such study ("<u>Development Budget</u>");
 - D. anticipated timelines for performance; and
 - E. specific deliverables.
- (iv) A current draft of a summary development plan for the Initial Lead Compound is attached hereto as Exhibit C (the "Initial Development Plan"). Lilly shall have the sole right and responsibility for preparing the Development Plan for each Licensed Product in the Field in the Territory. Except as otherwise provided in this Agreement, with respect to Licensed Product in the Field in the Territory, all decisions with respect to the creation, modification and implementation of the Initial Development Plan, all other Development Plans and all Development activities shall be made by Lilly in its sole discretion; provided that Lilly will present a draft Development Plan for each Licensed Product and any material changes to the Initial Development Plan to the JDC and will give due consideration to any comments of Incyte thereto. Notwithstanding the foregoing, each Development Plan, as initially prepared and as created, modified and implemented, will reflect and be consistent with the use of Commercially Reasonable Efforts to Develop Licensed Products.

(b) <u>Diligence</u>.

(i) Lilly shall use Commercially Reasonable Efforts to (A) Develop Licensed Compounds and Licensed Products in the Field in the Territory in accordance with the Development Plans; and (B) seek and obtain Regulatory Approval for Licensed Products in the Field in the Territory. Incyte shall reasonably cooperate with Lilly to obtain Regulatory

Approval for Licensed Products in the Field in the Territory, including by providing Lilly access to Incyte Know-How and Incyte personnel and consultants.

- (ii) Within either the later of (A) [***] after receipt of the [***] clinical study results generated in the Phase IIa Study INCB28050-201 for rheumatoid arthritis; or (B) [***] after receipt of the [***] clinical study results generated in the Phase IIa Study INCB28050-201 for rheumatoid arthritis, Lilly shall initiate a Phase IIb Study; provided that (1) the Phase IIa Study INCB28050-201 supports initiation; (2) the clinical trial protocol is approved and does not require any specialized equipment, testing, or site preparation; (3) the clinical trial material is acceptable; (4) there are no delays caused by a Regulatory Authority; and (5) there are no other factors that cause a delay that could not have been reasonably avoided by Lilly.
- (iii) Lilly shall Develop, including seeking Regulatory Approval for, at least [***]. If at any point in time prior to First Commercial Sale of a Licensed Product, no Development activities conducted in good faith with the intention of advancing at least [***] (and not for the sole purpose of preserving rights hereunder), have occurred during at least the preceding [***] and (x) no significant constraints on such Development imposed by a Regulatory Authority or a Force Majeure Event have been in effect during such period and (y) during such period Lilly has not engaged in bona fide sublicensing negotiations with a Third Party with respect to the Development of Licensed Compounds and Licensed Products in the United States and the Major EU Countries (provided that the time period in which such negotiations have taken place does not exceed [***]), then Lilly shall be deemed to have abandoned Development of Licensed Compounds and Licensed Product ("Abandoned Development"). For purposes of clarity, [***]. If Incyte concludes that Lilly has Abandoned Development, then Incyte shall deliver written notice to Lilly setting out the basis for Incyte's conclusion. If Lilly disagrees with Incyte's conclusion that Lilly has Abandoned Development, then the Parties will meet within [***] to discuss the disagreement. If the Parties cannot agree after such discussion, then the terms of 8.2(e) shall apply to resolve the dispute. If Lilly has Abandoned Development, then:
- A. If Lilly has not previously been properly deemed to have Abandoned Development, then within [***] from receipt of notice from Incyte that Lilly has Abandoned Development, Lilly shall either: (1) [***]; or (2) provide Incyte with written notice that [***], in which case Incyte shall have the right to terminate this Agreement in accordance with Section 8.2(d). In the event that Lilly elects to take the actions described in this subclause (A), Lilly shall have an additional [***] from the delivery of [***] to initiate and diligently pursue such steps that will result in Lilly not being deemed to have Abandoned Development. If Lilly fails to take such actions within such [***] period, then Incyte may terminate this Agreement in accordance with Section 8.2(d).

- B. If Lilly has previously been properly deemed to have Abandoned Development and had previously elected to take the actions described in subclause (A) above, Incyte shall have the right to terminate this Agreement in accordance with Section 8.2(d).
- 4.3 <u>Development Reports</u>. Lilly shall provide the JDC with a written report at least [***] summarizing in reasonable detail Lilly's and its Affiliates' activities and progress related to the Development of Licensed Products in the Field in the Territory, including information concerning the conduct of non-clinical activities and Clinical Trials, applications for and securing of Regulatory Approvals, First Commercial Sale of the Licensed Product on a country-by-country basis and any future planned Development activities.
- 4.4 <u>Licensed Product Co-Development Option</u>. On a Licensed Product-by-Licensed Product basis, for each Indication for which (x) Lilly anticipates initiating a Phase IIb Study and (y) there is a means to separately track the Annual Net Sales of such Licensed Product for such Indication (each a "<u>Co-Development Indication</u>") based on a new formulation or a new targeted prescribing specialist group [***], and provided that Incyte has not exercised the Incyte Development Opt Out in accordance with Section 4.4(c)(ii) for any Licensed Product, Incyte shall have the option to co-fund Development of such Co-Development Indication (the "Co-Development Option") as follows:
- (a) Within [***] prior to the anticipated initiation of a Phase IIb Study for the Co-Development Indication, Lilly shall notify Incyte of such anticipated initiation and shall provide Incyte with the following information: all material pre-clinical and clinical data and related analysis and regulatory information submitted to any Regulatory Authorities prior to the applicable time-period mentioned above, and Lilly's then current Development Plans and total global Development Budget (including the overall costs for each study, annualized over the course of each such study) with respect to such Co-Development Indication (the "Co-Development Indication Budget"). Incyte shall have the option to co-fund Development of such Co-Development Indication, exercisable by (i) providing Lilly written notice within [***] after receipt of such information and (ii) co-funding thirty percent (30%) of Lilly's total global Development Costs for such Co-Development Indication incurred after the date of such notice through the Regulatory Approval of such Co-Development Indication on a country by country basis ("Incyte Target Global Funding"). As used herein in this Section 4.4, Regulatory Approval costs include costs for any post-launch studies required by a Regulatory Authority.
- (b) If Incyte timely delivers such notice, within [***] following the end of each Calendar Quarter after Incyte has delivered such notice, Lilly shall prepare and deliver to Incyte a quarterly report detailing its Development Costs incurred during such period with respect to such Co-Development Indication. Lilly shall submit any supporting information reasonably requested by Incyte related to such Development Costs included in its report within [***] after its receipt of such request. Lilly shall issue an invoice to Incyte for thirty percent (30%) of the Development Costs identified in such report. Incyte shall pay all amounts payable under any such invoice within [***] after its receipt of such invoice, subject to Section 4.4(c). Incyte shall have the right to audit the records of Lilly with respect to any purported Development Costs included in such reports, in accordance with Section 7.6.

(c) If Incyte exercises its Co-Development Option with respect to a Licensed Product, in addition to
the royalty rates set forth in Section 7.3, Lilly shall pay Incyte an incremental [***] royalty (the "Target Co-
<u>Development Royalty</u> ") on Annual Net Sales of such Licensed Product for the Co-Development Indication, provided
that:

(i) The JDC shall review and, as necessary, amend the Co-Development Indication Budget
no later than October 30th of each year and any interim changes must be reviewed and approved by the JDC. In the
event that the actual global Development Costs in a Calendar Year exceed (A) [***] of the annualized Co-Development
Indication Budget approved by the JDC for such Calendar Year no later than October 30th of the preceding year or (B)
[***] of the projected total Development Costs for a particular study as set forth in the Co-Development Indication
Budget approved by the JDC that was in effect immediately prior to the initiation of such study (the "Development
<u>Cap</u> "), then Incyte may elect, by providing Lilly with written notice of such election within [***] after receipt of an
invoice pursuant to 4.4(b) that would result in a payment above the Development Cap, not to fund the Co-Development
Indication Budget for that year above the Development Cap (the "Funding Cap Option"). Except where the
Development Cap has been reached pursuant to Section 4.4(c)(i)(B), Incyte shall resume its payment obligation
pursuant to 4.4(b) on January 1 following each such election of the Funding Cap Option. In the event that Incyte elects
the Funding Cap Option, such election of the Funding Cap Option shall not constitute a violation of this Section
4.4. Such Funding Cap Option does not impact the Target Co-Development Royalty for the Co-Development
Indication; however, Incyte agrees to reimburse Lilly for all unpaid Incyte Target Global Funding pursuant to this
Section 4.4(c)(i) solely in the form of a reduction of future milestone payments and/or royalty payments as requested by
Lilly: and

(ii) In the event that Incyte provides Lilly with written notice within [***] after receipt of an
nvoice pursuant to 4.4(b) of its election not to fund the entire amount of Incyte Target Global Funding for a Licensed
Product ("Incyte Development Opt Out"), then the Target Co-Development Royalty will be adjusted based on the
Cormula:

[***]

By way of example, if [***].

(iii) Further, election of the Incyte Development Opt Out for a Licensed Product thereby terminates Incyte's option to co-fund further Development Costs for any Licensed Product and Incyte's contribution to actual global Development Costs is determined upon notice to Lilly that Incyte elects to exercise the Incyte Development Opt Out.

4.5 <u>Regulatory Matters Related to Licensed Products.</u>

(a) <u>Regulatory Submissions</u>. Lilly shall oversee, monitor and coordinate all regulatory actions, communications and filings with, and submissions to all Regulatory Authorities with respect to Licensed Products in the Field in the Territory. Lilly shall keep the JDC reasonably informed in connection with the preparation of all Regulatory Documentation, Regulatory Authority review of Regulatory Documentation, and Regulatory Approvals, annual reports, annual re-assessments, and variations and labeling, in each case with respect to the Licensed Product in the Field; <u>provided that</u> Lilly shall have the right to redact any information to the extent not related to Licensed Product in the Field. Lilly shall respond within a reasonable time frame to all reasonable inquiries by Incyte with respect to any information provided pursuant to this Section 4.5(a). Unless already the Confidential Information of Incyte, any information disclosed pursuant to this Section 4.5(a) shall be the Confidential Information of Lilly. Lilly shall use Commercially Reasonable Efforts to promptly take the actions described in this Section 4.5(a).

(b) <u>Regulatory Meetings and Correspondence</u>.

- (i) Lilly shall be responsible for interfacing, corresponding and meeting with the FDA, EMEA, MHLW and other Regulatory Authorities with respect to Licensed Products in the Field in the Territory.
- (ii) Incyte shall have the right to have a senior, experienced employee reasonably acceptable to Lilly, participate as an observer in material or scheduled face-to-face meetings, video conferences and any teleconferences, involving participation of personnel beyond regulatory experts, with the FDA, EMEA, and MHLW, and shall be provided with advance access to Lilly's material documentation prepared for such meetings. Prior to submission of material correspondence to the applicable Regulatory Authority, Lilly shall, sufficiently in advance for Incyte to review and comment, provide Incyte any material correspondence with the FDA, EMEA and MHLW related to such meetings. Lilly shall also provide Incyte with copies of any material correspondence with the FDA, EMEA, and MHLW relating to Development of, or the process of obtaining Regulatory Approval for, Licensed Products in the Field, and respond within a reasonable time frame to all reasonable inquiries by Incyte with respect thereto.
- (c) <u>Global Safety Database</u>. Following the Effective Date, Lilly shall establish, hold and maintain the global safety databases for each Licensed Product (the "<u>Global Safety Database</u>") into which it shall enter information on all serious adverse events and suspected reactions concerning the Licensed Product occurring anywhere in the world and reported to either of the Parties. Such database shall comply in all material respects with all Laws

reasonably applicable to pharmacovigilance anywhere where the Licensed Products are being or have been Developed or Commercialized.

4.6 <u>Manufacture and Supply</u>.

- (a) As soon as reasonably practicable after the Effective Date, Incyte and Lilly shall agree upon an appropriate manufacturing transfer plan and Incyte shall use Commercially Reasonable Efforts to transition the responsibility for manufacturing Licensed Compound and Licensed Product to Lilly in accordance with such plan. Lilly shall have the option, exercisable within [***] following the Effective Date, to obtain Incyte's existing inventory of Licensed Product and any related raw materials or supplies at a price equal to [***] of Incyte's Out-of-Pocket Costs for such inventory of Licensed Product. Lilly may exercise such option by written notice to Incyte during such [***] period. In addition, to the extent Incyte has contracts with Third Party contract manufacturers or others relating to its manufacturing operations for Licensed Compounds and Licensed Products, if Lilly so requests, Incyte will use its Commercially Reasonable Efforts to assign such agreements to Lilly or otherwise facilitate Lilly's efforts to continue to utilize such manufacturers or suppliers.
- (b) Without limiting the foregoing, if Lilly does not assume direct responsibilities for the manufacture of Licensed Compound and Licensed Product within [***] after the Effective Date, Incyte will invoice Lilly for all Out-of-Pocket Costs incurred by Incyte after the Effective Date for the manufacture and supply of Licensed Compound and Licensed Product for Lilly as well as Incyte's FTEs required to manage and supervise such manufacture and supply.
- (c) Notwithstanding anything in this Agreement to the contrary, Incyte shall not conduct any manufacturing related activities following the Effective Date without the express written consent of Lilly, except for those activities incidental to the transfer of manufacturing responsibility to Lilly in accordance with the manufacturing transfer plan contemplated above. If requested by Lilly and agreed to by Incyte, Incyte shall supply Lilly with clinical supplies of Licensed Product under the terms of a mutually acceptable manufacturing agreement, quality agreement, and manufacturing requirements document relating to Incyte's activities, all upon commercially reasonable terms consistent with this Agreement.

ARTICLE V

COMMERCIALIZATION

- 5.1 <u>Commercialization Diligence</u>. During the Term, Lilly shall be solely responsible for Commercializing Licensed Products in the Territory for use in the Field.
- (a) Lilly shall use Commercially Reasonable Efforts, at its expense, to Commercialize Licensed Products in the Field in the Territory after receipt of Regulatory Approval therefor. Notwithstanding the foregoing, Lilly shall (i) Commercialize [***] after receipt of the relevant Regulatory Approval; (ii) Commercialize [***] in at least [***]

after receipt of the relevant Regulatory Approval; (iii) maintain minimum combined Marketing and Sales Support (aggregated for all markets) per each [***] period following First Commercial Sale for such Licensed Product of the lesser of [***] or [***] of total sales of such Licensed Product in such Calendar; and (iv) reach or contact, the top [***] of highest prescribing rheumatologists or other appropriate specialist in the United States and the Major EU Countries on average [***] times or more per Calendar Year, beginning in the second full Calendar Year following First Commercial Sale, provided that there are no significant constraints on such Commercialization or contacts imposed by a Regulatory Authority in the respective jurisdictions. These provisions will apply for the first Regulatory Approval of the Licensed Product, and not per Indication. These provisions will not apply in the event that there are any outstanding negotiations related to Regulatory Approval with any Regulatory Authority (REMS, label(s), marketing materials or other related matters), or in the event that Lilly is prevented from meeting the obligations by any other factors that could not have been reasonably avoided by Lilly. In the event that this Agreement is assigned by Lilly in connection with the sale or transfer of all or substantially all of the business and assets of Lilly or an Affiliate controlled by (as "controlled by" is defined in Section 1.2) Lilly merges with or is consolidated with a Third Party, and such sale, transfer, merger or consolidation results in the stockholders of Lilly immediately prior to such transaction owning less than [***] of the voting power of the Voting Stock of the acquirer or surviving entity, as the case may be, immediately after such transaction, then for [***] following such sale, transfer, merger or consolidation, Lilly shall maintain Marketing and Sales Support for each Licensed Product in each country in the Territory equal to no less than the level of Marketing and Sales Support that Lilly maintained with respect to such Licensed Product in such country in the [***] prior to such sale, transfer, merger or consolidation, unless the relevant Licensed Product is within [***] of the anticipated end of the Royalty Term for such country.

(b) If at any point in time after First Commercial Sale of a Licensed Product, Lilly does not promote such Licensed Product in at least [***] during the preceding [***] and during that period (i) Lilly has not reasonably determined that promotion in at least [***], as applicable, is likely to reduce the overall commercial viability of such Licensed Product in the Territory; (ii) no significant constraint on such promotion imposed by a Regulatory Authority have been in effect in the jurisdictions in which such promotion failed to occur; (iii) no Force Majeure Event has been in effect in any jurisdictions in which such promotion failed to occur; and (iv) Lilly is not actively seeking Regulatory Approval (including pricing and reimbursement approval) in at least [***], as applicable in the jurisdiction in which such promotion failed to occur; then Lilly shall be deemed to have abandoned Commercialization of Licensed Compounds and Licensed Products in that country ("Abandoned Commercialization"). For purposes of clarity, [***]. If Incyte concludes that Lilly has Abandoned Commercialization, then Incyte shall deliver written notice to Lilly setting out the basis for Incyte's conclusion. If Lilly disagrees with Incyte's conclusion that Lilly has Abandoned Commercialization, then the Parties will meet within [***] to discuss the

disagreement. If the Parties cannot agree after such discussion, then the terms of 8.2(e) shall apply to resolve the dispute. If Lilly has Abandoned Commercialization, then:

- (i) If Lilly has not previously been properly deemed to have Abandoned Commercialization, then within [***] from receipt of notice from Incyte that Lilly has Abandoned Commercialization, Lilly shall either (1) [***] not being deemed to have [***]; or (2) provide Incyte with written notice that it chooses not to provide [***], in which case Incyte shall have the right to terminate this Agreement in accordance with Section 8.2(d). In the event that Lilly elects to take the actions described in this subclause (i), Lilly shall have an additional [***] from the delivery of [***] to initiate and diligently pursue such steps that will result in Lilly not being deemed to have Abandoned Commercialization. If Lilly fails to take such actions within such [***] period, then Incyte may terminate this Agreement in accordance with Section 8.2(d).
- (ii) If Lilly has previously been properly deemed to have Abandoned Commercialization and had previously elected to take the actions described in subclause (i) above, Incyte shall have the right to terminate this Agreement in accordance with Section 8.2(d).
- Marketing Responsibilities For Licensed Products. Subject to the provisions of Section 5.1, all business decisions regarding Commercialization of Licensed Products in the Field in the Territory, including the design, sale, pricing, and promotion of Licensed Products in the Field in the Territory under this Agreement, shall be within the sole discretion of Lilly and its Affiliates. All materials used in the promotion of all Licensed Products in the Field in the Territory, including product packaging, materials used in Detailing doctors, product messaging and content used in the promotion of such Licensed Products, shall be approved solely by Lilly.

5.3 <u>Trademarks</u>.

- (a) Lilly and its Affiliates shall select their own trademarks under which they will market Licensed Products (provided that no such trademark shall contain the word "Incyte") and shall own such trademarks.
- (b) Lilly shall use, in connection with all packaging, literature, labels and other printed matters, to the extent permitted by Law, an expression to the effect that the Licensed Products were developed under license from Incyte, together with the Incyte logo.

5.4 Co-Promotion.

(a) <u>Co-Promotion Option</u>. [***] Incyte shall have the option to co-promote Licensed Products on a Licensed Product-by-Licensed Product basis in the United States on the terms and conditions set forth in this Section 5.4 ("<u>Co-Promotion Option</u>"). Lilly shall notify Incyte at least [***] prior to the anticipated launch of each Licensed Product in the United States and shall provide Incyte with the following information: Lilly's then-current Commercialization plans ("<u>Promotional Plan</u>") with respect to each such Licensed Product, which plan shall include (i) a description of the short- and long-term vision for

the Licensed Product and Licensed Product positioning; (ii) a Strengths, Weaknesses, Opportunities and Threats (SWOT) analysis; (iii) a summary of the minimum level of sales efforts to be dedicated to the promotion of the Licensed Product, including the anticipated number of Details and targets of such Details; and (iv) a detailed budget for the Commercialization activities. Incyte may exercise its Co-Promotion Option by providing Lilly written notice at any time after receipt of Lilly's notice and not later than [***] prior to the initial anticipated launch of such Licensed Product in the United States.

- (b) <u>Effects of Exercise of Co-Promotion Option</u>. If Incyte exercises its Co-Promotion Option:
- (i) The Parties shall, no later than [***] prior to the initial anticipated launch of such Licensed Product in the United States, set out the number of FTE sales representatives Detailing such Licensed Product in the United States. In no event shall Incyte be responsible for a number of FTE sales representatives Detailing such Licensed Product which exceeds [***] of the total FTEs for such Licensed Product in the United States.
- (ii) Incyte shall be responsible for its costs in conducting co-Detailing activities; <u>provided that Lilly shall reimburse Incyte [***]</u>. Incyte shall provide an invoice to Lilly for such expense on a quarterly basis, and Lilly shall pay such invoice within [***] after receipt.
- (iii) The Parties shall establish a joint U.S. Commercialization Committee ("<u>UCC</u>") to oversee the Detailing of the relevant Licensed Product in the U.S. Incyte shall be entitled to have one (1) representative sit on the UCC or any group carrying out the UCC's function after the Effective Date but prior to the UCC's establishment. The UCC shall have responsibility for general oversight of all promotion and Detailing activities with respect to such Licensed Product in the United States. The UCC (or any group carrying out the UCC's function after the exercise of the Co-Promotion Option but prior to the UCC's establishment) will meet quarterly or more frequently as agreed by the Parties. The term of the UCC will be determined by the Parties. Lilly shall have the right to make the final decision with respect to all matters within the purview of the UCC related to Commercialization of the relevant Licensed Product.
- (iv) Incyte's sales representatives will be included in training programs with respect to the applicable Licensed Product that Lilly provides to its own sales representatives Detailing such Licensed Product. Such training shall be provided by Lilly to Incyte [***], but Incyte shall be responsible for all of its costs related to such training programs, including travel and lodging, for its sales representatives.
- (v) Incyte's sales representatives shall be provided, at Lilly's expense, with the same promotional materials, including literature and samples, as Lilly provides to its own similarly-situated representatives.

(vi) Prior to the initiation of the co-promotion efforts contemplated hereby, the Parties shall enter into a mutually acceptable co-promotion agreement containing terms consistent with this Agreement. Such co-promotion agreement shall require Incyte to comply with all applicable Laws, with Lilly's Good Promotional Practices and other compliance related practices and procedures, and with the terms of any order or consent decree applicable to Lilly's promotional activities.

ARTICLE VI

INTELLECTUAL PROPERTY OWNERSHIP, PROTECTION AND RELATED MATTERS

6.1 <u>Inventorship</u>; Ownership.

- (a) <u>Inventorship</u>. Inventorship of Inventions conceived or reduced to practice during the course of the performance of activities pursuant to this Agreement shall be determined in accordance with the patent Laws of the United States.
- Ownership. As between the Parties, all Inventions made or information created by a Party's or any of its Affiliates' employees, independent contractors or consultants, in the course of conducting activities under this Agreement, together with all Intellectual Property Rights therein, shall be owned by such Party. All inventions or discoveries made, or information created, jointly by each Party's (or any of its Affiliates') employees, independent contractors or consultants, in the course of conducting activities under this Agreement, together with all Intellectual Property Rights therein, shall be jointly owned by the Parties and are "Joint IP". Joint IP shall be owned jointly by Incyte and Lilly on the basis of an undivided interest without a duty to account to the other Party and shall be deemed to be Controlled by each Party. Notwithstanding anything to the contrary herein, each Party shall have the right to use such Joint IP, or license such Joint IP to its Affiliates or any Third Party, or sell or otherwise transfer its interest in such Joint IP to its Affiliates or a Third Party, in each case without the consent of the other Party, so long as such use, sale, license or transfer is subject to the licenses granted pursuant to this Agreement and is otherwise consistent with this Agreement. The Parties, through the JDC, shall determine which Party shall be responsible for the filing, prosecution and maintenance of Joint IP on a case-by-case basis; provided that Lilly shall have the first right to prosecute such Joint IP in accordance with Section 6.2(b) if such Joint IP Covers Licensed Products. Each Party hereby authorizes and grants the other Party its permission and consent to assume, directly or through its authorized agents, attorneys, or representatives, the responsibilities set forth in Section 6.2.

6.2 Prosecution and Maintenance of Patent Rights.

(a) [***] Prosecution and Maintenance of Incyte Patent Rights. [***] shall have the sole right to file, prosecute and maintain, at [***] expense, the Incyte Patent Rights designated as INCY0039 (the "Genus Patent Rights") (the Genus Patent Rights that exist as of the Effective Date are set forth on Exhibit A-1). [***] shall, subject to Section 6.2(a)(i), have the sole right to file, prosecute and maintain, at [***] expense, the Incyte Patent Rights other than the Genus Patent Rights and the Selection Patent Rights (the "Future Incyte Patent Rights")

in the Territory. If [***] declines to file, prosecute or maintain any Future Incyte Patent Rights in any country in the Territory, desires to allow any Future Incyte Patent Rights to lapse in any country in the Territory, or desires to abandon any Future Incyte Patent Rights in any country in the Territory before all appeals within the respective jurisdiction have been exhausted, then:

- (i) [***] may, in its sole discretion, provide [***] with reasonable written notice of such decision so as to permit [***] to decide whether to file, prosecute or maintain such Future Incyte Patent Right in such country and to take any necessary action.
- (ii) Following notice from [***] pursuant to clause (i), [***] may, by providing prompt written notice thereof to [***], assume control of the filing, prosecution and/or maintenance of such Future Incyte Patent Right in such country, at [***] expense.
- (b) [***] Prosecution and Maintenance of Selection Patent Rights. [***] shall have the first right to file, prosecute and maintain, at Lilly's expense, the Selection Patent Rights in the Territory [***]. If [***] declines to file, prosecute or maintain any Selection Patent Rights in any country in the Territory, desires to allow any Selection Patent Rights to lapse in any country in the Territory, or desires to abandon any Selection Patent Rights in any country in the Territory before all appeals within the respective jurisdiction have been exhausted, then:
- (i) [***] shall provide [***] with reasonable written notice of such decision so as to permit [***] to decide whether to file, prosecute or maintain such Selection Patent Right in such country and to take any necessary action.
- (ii) Following notice from [***] pursuant to clause (i), [***] may, by providing prompt written notice thereof to [***], assume control of the filing, prosecution and/or maintenance of such Selection Patent Right in such country, at [***] expense.
- (c) <u>Cooperation</u>. For the purposes of rights and obligations described in Section 6.2, an individual Party responsible for the filing, prosecution and maintenance of a Selection Patent Right will be referred to as the "Controlling Party" and the other Party will be referred to as the "Non-Controlling Party".
- (i) The Non-Controlling Party shall, at the Controlling Party's expense and reasonable request, assist and cooperate in the filing, prosecution and maintenance of or any related necessary action for Future Incyte Patent Rights and Selection Patent Rights.
- (ii) The Controlling Party shall provide the Non-Controlling Party sufficiently in advance, where reasonable, for the Non-Controlling Party to comment, with copies of all patent applications and other material submissions and communications (including oral communications) with any patent counsel or patent authorities pertaining to Future Incyte Patent Rights and Selection Patent Rights.
- (iii) The Controlling Party shall give due consideration to the Non-Controlling Party's comments, but shall have the final say in determining whether or not to incorporate such comments.

- (iv) [***] shall whenever possible provide [***] in advance with copies of all material submissions or other communications with patent authorities relating to the Genus Patent Rights, or, to the extent that [***] has the right to do so, to communications with Third Parties relating to enforcement of the Genus Patent Rights, in each case to the extent the same may be material to Selection Patent Rights or Future Incyte Patent Rights, and consider in good faith any comments [***] may make.
- (v) Each Party shall provide the other with copies of all material communications received from any patent counsel or patent authorities pertaining to such Future Incyte Patent Rights and Selection Patent Rights.
- (vi) As used in this Section 6.2(c) "<u>material</u>" means that the submission or communication could affect the patentability or scope of the patents Covering the Licensed Compounds or Licensed Products.
- (d) <u>Patent Term Extensions</u>. [***] may select which, if any, Selection Patent Rights for which a Patent Term Extension is to be sought or obtained. [***] may select which, if any, Genus Patent Rights and Future Incyte Patent Rights for which a Patent Term Extension is to be sought or obtained.

6.3 Third Party Infringement.

(a) Notice. Each Party shall immediately provide the other Party with written notice reasonably detailing any (i) known or alleged infringement of Joint IP or any Selection Patent Rights by a Third Party which is infringing the Joint IP or any Selection Patent Rights by making, using or selling a product that competes with a Licensed Product in the Field in the Territory; (ii) "patent certification" filed in the United States under 21 U.S.C. §355(b)(2) or 21 U.S.C. §355(j)(2) or similar provisions in other jurisdictions; and (iii) any declaratory judgment, opposition, or similar action alleging the invalidity, unenforceability or non-infringement of any such Intellectual Property Rights (collectively "Third-Party Infringement"). Within [***] after receipt of such notice, the Parties shall consult to determine the response to any Third Party Infringement.

(b) Enforcement.

(i) If within [***] after meeting pursuant to Section 6.3(a) the Parties fail to agree on a joint course of action with respect to a Third Party Infringement, [***] will have the first right to bring and control any legal action in the Territory in connection with the Third Party Infringement against a Third Party which is infringing the relevant Intellectual Property Rights by making, using or selling a product that competes with a Licensed Product in the Field in the Territory, at its own expense as it reasonably determines appropriate, and [***] may choose, at its own expense, to be represented in any such action by counsel of its own choice. If required, [***] agrees to be joined as a necessary party to such action, wherein as a necessary party, [***] agrees to be joined only to the extent necessary, and [***] shall not actively direct, control or otherwise participate in the legal action; provided that [***] shall pay [***] reasonable expenses associated therewith. At the request and expense of [***], [***] shall provide reasonable assistance to [***] in connection therewith, including by executing

reasonably appropriate documents, cooperating in discovery and joining as a party to the action. In connection with any such proceeding, [***] shall not enter into any settlement admitting the invalidity of, or otherwise impairing [***] rights in, Joint IP or any Selection Patent Rights without the prior written consent of [***]. Any recoveries resulting from such an action relating to a claim of Third Party Infringement shall be applied as follows:

A. First, to reimburse each Party for all Out-of-Pocket Costs in connection with such proceeding (on a pro rata basis, based on each Party's respective litigation costs, to the extent the recovery was less than all such litigation costs); and

B. [***]

- (ii) If within [***] after [***] receipt of a notice of a Third Party Infringement with respect to Joint IP or any Selection Patent Rights, [***] does not bring legal action as permitted hereunder against a Third Party who is infringing such Intellectual Property Rights by making, using or selling a product that competes with a Licensed Product in the Territory, [***] may, subject to the following sentence, in its sole discretion, bring and control any legal action in connection therewith at its sole expense. At the request and expense of [***], [***] shall provide reasonable assistance to [***] in connection therewith, including by executing reasonably appropriate documents, cooperating in discovery and joining as a party to the action. In connection with any such proceeding, [***] shall not enter into any settlement admitting the invalidity of or otherwise impairing [***] rights under the Joint IP or such Selection Patent Rights without the prior written consent of [***]. Any recoveries resulting from such an action relating to a claim of Third Party Infringement (after payment of each Party's costs and expenses) will be retained by [***].
- 6.4 <u>Patent Marking</u>. If permitted and to the extent that Lilly does so with respect to its other products in the same geographic market, Lilly shall, and shall cause its Affiliates, distributors and sublicensees, to (a) mark the Licensed Products with the number of each issued patent under the Incyte Patent Rights that apply to the Licensed Product and which Lilly determines reasonably should be listed or marked and (b) comply with the patent marking statutes in each country in which the Licensed Product is manufactured by or on behalf of Lilly or its Affiliates.

ARTICLE VII

FINANCIAL PROVISIONS

- 7.1 <u>License Fee.</u> Within [***] after the Effective Date, Lilly shall pay to Incyte a one-time, non-creditable, non-refundable license fee of Ninety Million U.S. Dollars (US\$90,000,000).
 - 7.2 <u>Milestone Payments</u>.
 - (a) <u>Development and Regulatory Milestones</u>.

(i) Lilly shall pay Incyte the following one-time, non-refundable, non-creditable milestone payments within [***] after the first achievement by Lilly, its Affiliates or its sublicensees, or with respect to the milestone event in Section 7.2(a)(i)(A), Incyte or one of Incyte's Affiliates, of the corresponding milestone events set forth below with respect to a Lead Compound (provided that with respect to the Follow-On Lead Compound, such Follow-On Lead Compound shall only be eligible for the milestone payments set forth below if such payments have not previously been made with respect to the Initial Lead Compound):

Milestone Event	First Indication	[***]	[***]
[***] Incyte Phase IIa Study	US \$30,000,000 [***]	[***]	[***]
Efficacy			
[***] First patient treated in a	US\$50,000,000	US\$30,000,000	US\$20,000,000
Phase III Study			
[***] First NDA submission to	US\$35,000,000		
the FDA for Regulatory			
Approval of a Licensed Product			
[***] First submission to the	US\$20,000,000		
EMEA for Regulatory Approval			
of a Licensed Product			
[***] Regulatory Approval of a	US \$100,000,000	[***]	[***]
Licensed Product from the FDA			
[***]	[***]	[***]	[***]
[***] Regulatory Approval of a	US\$15,000,000	[***]	[***]
Licensed Product from the			
MHLW			

With respect to the milestone set forth in [***], the milestone payment shall be contingent [***] with a

[***].

[***]	[***]*	[***]*
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

^{* [***]}

(ii) Lilly shall pay Incyte the following non-refundable, non-creditable (subject to Section 7.2(c)) milestone payments within [***] after the first achievement by Lilly, its Affiliates or its sublicensees of the corresponding milestone events set forth below with respect to a Licensed Back-Up Compound (provided that with respect to the Follow-On Lead Compound, such Follow-On Lead Compound shall only be eligible for any such milestone payment if it is not eligible for the comparable one-time Lead Compound milestone payment set forth in Section 7.2(a)(i)):

Milestone Event	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

(iii) For the avoidance of doubt, the registrations of line extensions (i.e., different dosage forms or delivery) shall not be eligible for milestone payments set forth in this Section 7.2(a). Additionally, any Combination Products containing a Lead Compound and a Licensed Back-Up Compound, wherein the Licensed Back-Up Compound is only available in combination with such Lead Compound, shall be solely eligible for the one-time Lead Compound milestone payments set forth in Section 7.2(a)(i) and shall not additionally be eligible for a Licensed Back-Up Compound milestone set forth in Section 7.2(a)(ii).

(b) <u>Sales Milestones</u>.

(i) Lilly shall make the following non-refundable, non-creditable, one-time payments to Incyte within [***] upon the first achievement of aggregate Annual Net Sales of all Licensed Products in the Territory that meet or exceed the thresholds set forth below if such Licensed Products contain or incorporate a Lead Compound:

Annual Net Sales of Licensed Products in the Territory Threshold	Milestone Payment
(A) Annual Net Sales of Licensed Products equal to or greater than [***]	[***]
(B) Annual Net Sales of Licensed Products equal to or greater than [***]	[***]
(C) Annual Net Sales of Licensed Products equal to or greater than [***]	[***]

(ii) Lilly shall make the following non-refundable, non-creditable, one-time payments to Incyte within [***] upon the first achievement of aggregate Annual Net Sales of all Licensed Products in the Territory that meet or exceed the thresholds set forth below if such Licensed Products contain or incorporate a Licensed Back-Up Compound (other than the Follow-On Lead Compound which, for purposes of clarity, is subject to subsection (i) above):

Annual Net Sales of Licensed Products in the Territory Threshold	Milestone Payment
(A) Annual Net Sales of Licensed Products equal to or greater than [***]	[***]
(B) Annual Net Sales of Licensed Products equal to or greater than [***]	[***]
(C) Annual Net Sales of Licensed Products equal to or greater than [***]	[***]

Achievement of the milestone events above in this Section 7.2(b) shall be determined based on Annual Net Sales of the Licensed Products made by Lilly and its Affiliates and sublicensees throughout the Territory. More than one of the sales milestone payments may be earned concurrently based on the same Annual Net Sales of the Licensed Products. By way of example, if in the first Calendar Year following the First Commercial Sale of a Licensed Product, the Annual Net Sales for Licensed Products that contain the Lead Compound is equal to or exceeds [***], but is less than [***], then Lilly shall pay Incyte the milestone payments set forth in both Sections 7.2(b)(i)(A) and (B) (total [***]).

- (c) Except as otherwise specified, none of the payments listed in this Section 7.2 shall be payable more than once, and each shall be payable at the first achievement of a milestone event for a Licensed Product and shall not be payable again if subsequently another Licensed Product achieves the same milestone event. For clarification, if a milestone is paid for a Licensed Compound, that milestone will not be paid again for a back-up compound.
- (d) In the event that a milestone event described in Section 7.2(a) is achieved, all milestones prior to that stage of Development for that Indication shall be deemed to have been achieved as well, and if the related payment for any such preceding milestone has not been previously paid, the previously unpaid payments that would be due for the preceding milestones shall also become due and payable, even though the missing milestone has not been achieved; provided that the foregoing shall not apply to Section 7.2(a)(i)(A) milestone 1b.

7.3 Royalties.

(a) Royalty Rates.

(i) Lilly shall pay to Incyte royalties on aggregate worldwide Net Sales of all Licensed Products that contain or incorporate a Lead Compound in the Territory, on a Licensed Product-by-Licensed Product basis, at the following rates:

Annual Net Sales of Licensed Product in the Territory	Royalty Rate
On Annual Net Sales less than or equal to [***]	[***]
On Annual Net Sales greater than [***] and less than or equal to [***]	[***]
On Annual Net Sales greater than [***] and less than or equal to [***]	[***]
On Annual Net Sales greater than [***]	20%

(ii) Lilly shall pay to Incyte royalties on aggregate worldwide Net Sales of all Licensed Products that contain or incorporate a Licensed Back-Up Compound (other than the Follow-On Lead Compound which, for purposes of clarity, is subject to subsection (i) above) in the Territory, on a Licensed Product-by-Licensed Product basis, at the following rates:

Annual Net Sales of Licensed Product in the Territory	Royalty Rate
On Annual Net Sales less than or equal to [***]	[***]
On Annual Net Sales greater than [***] and less than or equal to [***]	[***]
On Annual Net Sales greater than [***] and less than or equal to [***]	[***]
On Annual Net Sales greater than [***]	[***]

- (iii) [***]
- (iv) The royalty rates set forth in Section 7.3(a)(i) (and not Section 7.3(a)(ii)) shall apply to Annual Net Sales of any Combination Products containing a Lead Compound and a Licensed Back-Up Compound, wherein the Licensed Back-Up Compound is only available in combination with such Lead Compound.
- (b) Royalties payable under this Section 7.3 shall be paid by Lilly on a Licensed Product-by-Licensed Product and country-by-country basis from the date of First

Commercial Sale of each Licensed Product with respect to which royalty payments are due for a period which is the longer of: (i) the last to expire of any Valid Claim of Incyte Patent Rights Covering such Licensed Product in such country; (ii) [***] following the date of First Commercial Sale of such Licensed Product in such country; and (iii) the expiration of Regulatory Exclusivity for such Licensed Product in such country (each such term with respect to a Licensed Product and a country, a "Royalty Term").

- (c) Notwithstanding the foregoing, in the event that either (i) the Royalty Term continues solely due to Section 7.3(b)(ii) (i.e. in a specific country the Licensed Product is not Covered by a Valid Claim of Incyte Patent Rights nor is such Licensed Product protected by Regulatory Exclusivity); or (ii) Generic Competition exists with respect to a Licensed Product in the Field in a country in the Territory in a Calendar Year, then the royalty rates in such country for such Licensed Product for such Calendar Year will be reduced to [***] of the applicable rate in Section 7.3(a); provided that any reduction of the applicable rate in Section 7.3(a) pursuant to subclause (ii) due to the existence of Generic Competition shall be retroactively applied for the relevant Calendar Year.
- (d) If Lilly (i) determines in good faith that, in order to avoid infringement of any Patent Right not licensed hereunder, it is reasonably necessary to obtain a license from a Third Party in order to Develop, Commercialize, make, have made, use, offer for sale, sell or import the Licensed Product in the Field in a country in the Territory and to pay a royalty or other consideration under such license (including in connection with the settlement of a patent infringement claim); or (ii) shall be subject to a final court or other binding order or ruling requiring any payments, including the payment of a royalty to a Third Party patent holder in respect of the Development, Commercialization, making, having made, using, offering for sale, selling and importing of a Licensed Product in the Field in a country in the Territory, then the amount of Lilly's royalty payments under Section 7.3(a) with respect to Net Sales for such Licensed Product in such country shall be reduced by [***] of the amount payable by Lilly to such Third Party that are reasonably and appropriately allocable to the Licensed Product in the Field in the Territory, provided, however, that in no event shall the aggregate deductions under this Section 7.3(d) reduce any royalty payment made by Lilly in respect of Net Sales of such Licensed Product pursuant to Section 7.3(a) by more than [***].
- (e) Upon the expiration of the Royalty Term with respect to a Licensed Product in a country, the licenses granted by Incyte to Lilly pursuant to Section 2.1 shall be deemed to be fully paid-up, irrevocable and perpetual with respect to such Licensed Product in such country.
- 7.4 <u>Royalty Reports; Payments</u>. Lilly shall deliver to Incyte, within [***] after the end of each Calendar Quarter, a royalty report for such Calendar Quarter, together with the required payments. Such reports shall indicate, on a country-by-country basis, the Net Sales and the calculation of royalties from Net Sales with respect thereto, each determined in accordance with this Agreement and, with respect to sales of Licensed Product in the United States, such reports shall include gross sales and all deductions taken from gross sales. All payments due to Incyte pursuant to this Agreement shall be made in United States dollars by wire transfer in immediately available funds from a Lilly account in the United States to an account designated in advance by Incyte.

- 7.5 <u>Financial Records</u>. Lilly shall keep complete and accurate books and records in accordance with Accounting Standards. Lilly will keep such books and records for at least [***] following the end of the Calendar Year to which they pertain. Such books of accounts shall be kept at the principal place of business of the financial personnel with responsibility for preparing and maintaining such records. With respect to royalties, such records shall be in sufficient detail to support calculations of royalties due to Incyte.
- 7.6 Audits. [***] during each Calendar Year for the Term, Incyte may retain an independent certified public accountant reasonably acceptable to Lilly to audit the records described in Section 7.5, upon at least [***] prior notice to Lilly. Incyte shall bear the costs of such audit, except as provided below. The results of such audit shall be made available to both Parties, but shall be considered Lilly's Confidential Information. If the audit demonstrates that the payments owed under this Agreement have been understated, Lilly shall pay the balance to Incyte, together with interest in accordance with Section 7.9. Further, if the amount of the understatement is greater than [***] of the amount owed to Incyte with respect to the audited period, then Lilly shall reimburse Incyte for the reasonable cost of the audit. If the audit demonstrates that the payments owed under this Agreement have been overstated, Lilly shall be entitled to credit such amount against payments due to Incyte. All payments owed by Lilly under this Section 7.6 shall be made within [***] after the results of the audit are delivered to the Parties.
- 7.7 Tax Matters. The royalties, milestones and other amounts payable by Lilly to Incyte pursuant to this Agreement shall not be reduced on account of any taxes unless required by Law. Lilly shall inform Incyte of any withholding tax obligation on payments due to Incyte under this Agreement as soon as Lilly becomes aware of the withholding tax obligation. The Parties shall meet promptly thereafter to discuss how best to minimize the amount of such withholding tax obligation in accordance with Law, and Lilly shall take all reasonable and lawful steps to minimize the amount of any such withholding tax obligation. The Parties agree to cooperate in good faith to provide one another with such documents and certifications as are reasonably necessary to enable Lilly and Incyte to minimize and/or recover any withholding tax obligation. Lilly shall provide to Incyte documentation of the payment of any withholding tax that is paid pursuant to this Section 7.7. Notwithstanding the foregoing, Lilly represents that the payments to be paid by Lilly to Incyte pursuant to Sections 7.1, 7.2 and 7.3 hereof shall not be subject to withholding tax under conditions less favorable to Incyte than those applicable to treaty-eligible residents under the income tax treaty between the United States and the country of payment origination in force at the point of time such payments are paid. Payments to Incyte will be made from the United States unless Incyte receives notice from Lilly that payments will be made from either Puerto Rico or Ireland.
- 7.8 <u>Currency Exchange</u>. All payments to be made by Lilly to Incyte shall be made in U.S. Dollars. In the case of sales of Licensed Product outside the United States, royalty payments by Lilly to Incyte shall be converted to U.S. Dollars in accordance with the following: the rate of currency conversion shall be calculated using the average of the daily foreign exchange rates as published by <u>The Wall Street Journal</u>, Eastern Edition, for the Calendar Quarter in which such payments occurred.

7.9 <u>Late Payments</u>. The paying Party shall pay interest to the receiving Party on the aggregate amount of any payments that are not paid on or before the date such payments are due under this Agreement at a rate per annum equal to the lesser of [***], as reported by <u>The Wall Street Journal</u>, Eastern Edition, [***] or the highest rate permitted by applicable Law, calculated on the number of days such payments are paid after the date such payments are due; <u>provided</u>, that with respect to any disputed payments, no interest payment shall be due until such dispute is resolved and the interest which shall be payable thereon shall be based on the finally-resolved amount of such payment, calculated from the original date on which the disputed payment was due through the date on which payment is actually made.

ARTICLE VIII

TERM AND TERMINATION

8.1 <u>Agreement Term.</u> The term of this Agreement shall commence on the Effective Date and shall continue until the earlier of (i) the termination of this Agreement in accordance with Section 8.2; or (ii) following the First Commercial Sale of any Licensed Product, the expiration of the last-to-expire of all Royalty Terms with respect to all Licensed Compounds and Licensed Products (the "<u>Term</u>"). Notwithstanding the above, if there are any ongoing disputes at the end of the Term as set forth above, this Agreement shall remain in full force and effect until all such disputes are resolved.

8.2 Termination.

- (a) <u>Termination for Convenience</u>. Prior to the first anniversary of the Effective Date, Lilly may elect to terminate this Agreement at any time by providing [***] prior written notice to Incyte; <u>provided</u>, that at any time after such notice by Lilly, Incyte may accelerate the effective date of such termination by providing [***] prior written notice to Lilly of such accelerated effective date. After the first anniversary of the Effective Date, Lilly may elect to terminate this Agreement at any time by providing [***] prior written notice to Incyte; <u>provided</u>, that at any time after such notice by Lilly, Incyte may accelerate the effective date of such termination by providing [***] prior written notice to Lilly of such accelerated effective date.
- (b) <u>Termination for Material Breach</u>. If either Party (the "<u>Non-Breaching Party</u>") believes that the other Party (the "<u>Breaching Party</u>") is in material breach of this Agreement, then the Non-Breaching Party may deliver notice of such breach to the Breaching Party. If the Breaching Party fails to cure such breach, or to initiate such steps as would be considered reasonable to effectively cure such breach (and thereafter diligently pursues such cure), within [***] after receipt of such notice of breach, the Non-Breaching Party may terminate this Agreement upon written notice to the Breaching Party. Notwithstanding the foregoing, if a Party disputes the termination, then 8.2(e) shall apply.
- (c) <u>Termination if Lilly Challenges Incyte IP</u>. If Lilly or any of its Affiliates or sublicensees, directly or indirectly, (i) initiates or requests an interference or opposition proceeding with respect to any Incyte Patent Right; (ii) makes, files or maintains any claim,

demand, lawsuit, or cause of action to challenge the validity or enforceability of any Incyte Patent Right; or (iii) opposes any extension of, or the grant of a supplementary protection certificate with respect to, any Incyte Patent Right, Incyte shall have the right to terminate this Agreement upon [***] written notice to Lilly. Any such termination shall only become effective if Lilly or its Affiliate or sublicensee, as applicable, has not withdrawn such action before the end of the above notice period.

- (d) <u>Termination for Lilly's Abandonment of Development or Commercialization</u>. Subject to Section 4.2(b)(iii)A and 5.1(b)(i), if Lilly has Abandoned Development or Abandoned Commercialization in accordance with Section 4.2(a)(iii) or 5.1(b), as applicable, Incyte may elect to terminate this Agreement by providing Lilly written notice of such termination, such termination to be effective immediately. Notwithstanding the foregoing, if Lilly disputes the termination, then 8.2(e) shall apply.
- (e) <u>Termination Disputes</u>. If a Party gives notice of termination under Section 8.2(b), if the Parties dispute whether Lilly has Abandoned Development or Abandoned Commercialization in accordance with Section 4.2(b)(iii) or 5.1(b), as applicable, or Incyte gives notice of termination under 8.2(d), and the other Party disputes whether such notice was proper, then the issue of whether or not Lilly has Abandoned Development, Abandoned Commercialization, or if this Agreement was properly terminated shall be resolved in accordance with ARTICLE XII, and the Agreement shall remain in full force and effect until such dispute is resolved. If as a result of such dispute resolution process it is determined that the notice of termination was proper, then such termination shall be deemed to be effective on the date on which such dispute is resolved. On the other hand, if as a result of the dispute resolution process it is determined that the notice of termination was improper, then no termination shall have occurred and this Agreement shall remain in full force and effect.

8.3 Effects Of Termination.

- (a) Upon termination of this Agreement by Lilly under Section 8.2(a) or by Incyte under Sections 8.2(b), 8.2(c) or 8.2(d):
- (i) all licenses granted by Incyte to Lilly hereunder shall terminate and Lilly shall not have any rights to use or exercise any rights under the Incyte IP;
- (ii) Lilly shall provide to Incyte a fair and accurate summary report of the status of the Development and Commercialization of the Licensed Products in each country in the Territory through the effective date of termination within [***] after such termination;
- (iii) Lilly hereby grants to Incyte, exercisable from and after such termination, an exclusive, worldwide, perpetual, irrevocable, royalty-free, fully-paid license, with the right to grant sublicenses, under Lilly and its Affiliates' interest in the Joint IP and any Know-How or Patent Rights Controlled by Lilly or its Affiliates as of the date of such termination solely to the extent that such licenses are necessary to research, Develop, make, have made, use, offer for sale, sell and import Licensed Products in the Field in the Territory, and Lilly shall retain all other remaining rights;

- (iv) Lilly shall promptly transfer and assign to Incyte all of Lilly's and its Affiliates' rights, title and interests in and to the product trademark(s) (but not any Lilly house marks or any trademark containing the word "Lilly" owned by Lilly and used for the Licensed Products in the Field in the Territory) owned by Lilly and used for the Licensed Products in the Field in the Territory;
- (v) Lilly shall as soon as reasonably practicable transfer and assign to Incyte all Regulatory Documentation, the Global Safety Database and other documented technical and other information or materials Controlled by Lilly which are necessary or useful for the Development, manufacture and Commercialization of the Licensed Compounds or Licensed Products; provided that Lilly may retain a single copy of such items for its records. Within [***] after Incyte's receipt of an invoice therefor, Incyte shall reimburse Lilly for Lilly's and its Affiliates' reasonable Out-of-Pocket Costs incurred in connection with such transfers and assignment (but not the generation, creation or development of such information and materials);
- (vi) Incyte shall have the option, exercisable within [***] following the effective date of such termination, to obtain Lilly inventory of Licensed Products at a price equal to [***] of Lilly's non-auditable "standard cost" that Lilly uses for internal accounting purposes. Lilly's "standard cost" does not include the research and development costs to develop the molecule or costs not associated with Licensed Products. Incyte may exercise such option by written notice to Lilly during such [***] period; provided that in the event Incyte exercises such right to purchase such inventory, Lilly shall grant, and hereby does grant, a royalty-free right and license to any trademarks, names and logos of Lilly contained therein for a period of [***] solely to permit the orderly sale of such inventory, except where Lilly reasonably believes that continued sales would pose an unreasonable safety risk, and any materials having a Lilly logo (a housemark or the word "Lilly") that are released by Lilly must meet the Lilly quality assurance standards:
- (vii) to the extent that Lilly is responsible for manufacturing a Licensed Product prior to termination of this Agreement, Lilly shall:
- A. in exchange for a payment equal to [***] of Lilly's "standard costs", use Commercially Reasonable Efforts to supply Incyte and its Affiliates with comparable quantities of the Licensed Products in the dosage strength, formulation and presentation as were being Commercialized as of the effective date of termination until the earlier of [***] after the effective date of the termination or establishment by Incyte of an alternative supply for such Licensed Product, it being understood that Lilly is not obligated to manufacture itself if Lilly reasonably believes that such manufacture and/or Licensed Product would pose an unreasonable safety risk, and unless Lilly was manufacturing itself immediately prior to termination, and in the event Lilly was utilizing a contract manufacturer, Lilly's obligation is to use Commercially Reasonable Efforts to cooperate with Incyte to obtain Licensed Product from such manufacturer; provided that Incyte shall use its Commercially Reasonable Efforts to establish an alternative supply as promptly as reasonably practicable;
 - B. cooperate with Incyte in reasonable respects to transfer

manufacturing documents and materials which are used (at the time of the termination) by Lilly in the Manufacture of the applicable Licensed Products; and

- C. cooperate with Incyte in reasonable respects to transfer to Incyte, or Incyte's designated contract manufacturer, the manufacturing technologies (including all relevant Know-How) that are used and necessary (at the time of the termination) and Controlled by Lilly in the manufacture of the applicable Licensed Products, <u>provided that</u> Incyte shall reimburse Lilly for Lilly's reasonable Out-of-Pocket Costs to provide such requested assistance;
- (viii) in the event that Incyte terminates this Agreement pursuant to Section 8.2(d) or Lilly terminates pursuant to 8.2(a) and such termination occurs after Lilly has initiated a Phase III Study for a Licensed Product, [***]); and
 - (ix) Section 8.3(d) shall apply.
 - (b) Upon termination of this Agreement by Lilly in accordance with Section 8.2(b):
- (i) the license granted to Lilly pursuant to Section 2.1 and the rights and obligations of the Parties pursuant to Sections 6.2 and 6.3 shall remain in effect and Lilly shall continue to pay to Incyte all royalties due under Section 7.3 and 4.4 and all milestones due under Section 7.2 in accordance with the terms of this Agreement;
- (ii) until the last to expire of all Royalty Terms with respect to Licensed Compounds and Licensed Products, the rights and obligations of the Parties pursuant to Sections 2.6(d), 2.6(e), 2.6(f) shall survive; provided however, that if the First Commercial Sale of a Licensed Product has not occurred at the time of termination, then the rights and obligations of the Parties pursuant to Sections 2.6(d), 2.6(e), 2.6(f) shall survive for [***] after the effective date of such termination provided further that if a First Commercial Sale of a Licensed Product takes place within such [***] period, Sections 2.6(d), 2.6(e), 2.6(f) shall survive until the last to expire of all Royalty Terms; and
 - (iii) Section 8.3(d) shall apply.
- (c) ARTICLE I (Definitions), IX (Indemnification and Limitation of Liability), XI (Confidentiality), XII (Dispute Resolution) and XIII (Miscellaneous) and Sections 6.1 (Inventorship; Ownership), 7.5 (Financial Records), 7.6 (Audits), 8.3 (Effects of Termination), 10.4 (Disclaimer of Warranty) and 10.5 (Standstill) shall survive termination or expiration of this Agreement.
- (d) Termination of this Agreement shall be in addition to, and shall not prejudice, the Parties' remedies at law or in equity, including the Parties' ability to receive legal damages and/or equitable relief with respect to any breach of this Agreement, regardless of whether or not such breach was the reason for the termination.

ARTICLE IX

INDEMNIFICATION; LIMITATION OF LIABILITY

9.1 By Lilly.

- (a) Lilly agrees, at Lilly's cost and expense, to defend, indemnify and hold harmless Incyte and its Affiliates and their respective directors, officers, employees and agents (the "Incyte Indemnified Parties") from and against any losses, costs, damages, fees or expenses arising out of any Third Party claim relating to (i) any breach by Lilly of any of its representations, warranties or obligations pursuant to this Agreement; (ii) the gross negligence or willful misconduct of Lilly; and (iii) the Development, manufacture, Commercialization, use, sale or other disposition by Lilly, its Affiliates or sublicensees of any Licensed Compound or Licensed Product.
- (b) In the event of any such claim against the Incyte Indemnified Parties by any Third Party, Incyte shall promptly notify Lilly in writing of the claim and Lilly shall have the right, exercisable by notice to Incyte within [***] after receipt of notice from Incyte of the claim, to assume direction and control of the defense, litigation, settlement, appeal or other disposition of the claim (including the right to settle the claim solely for monetary consideration) with counsel selected by Lilly and reasonably acceptable to Incyte. The Incyte Indemnified Parties shall cooperate with Lilly and may, at their option and expense, be separately represented in any such action or proceeding. Lilly shall not be liable for any litigation costs or expenses incurred by the Incyte Indemnified Parties without Lilly's prior written authorization. In addition, Lilly shall not be responsible for the indemnification or defense of any Incyte Indemnified Party to the extent arising from any negligent or intentional acts by any Incyte Indemnified Party or the breach by Incyte of any obligation or warranty under this Agreement, or any claims compromised or settled without its prior written consent. Notwithstanding the foregoing, Lilly shall not settle a Third Party claim without the written consent of Incyte, if such settlement would impose any monetary obligation on Incyte or require Incyte to submit to an injunction.
- (c) Notwithstanding anything to the contrary above, in the event of any such claim against the Incyte Indemnified Parties by a governmental or criminal action seeking an injunction against Incyte, Incyte shall have the right to control the defense, litigation, settlement, appeal or other disposition of the claim at Lilly's expense.

9.2 By Incyte.

(a) Incyte agrees, at Incyte's cost and expense, to defend, indemnify and hold harmless Lilly and its Affiliates and their respective directors, officers, employees and agents (the "Lilly Indemnified Parties") from and against any losses, costs, damages, fees or expenses arising out of any Third Party claim relating to (a) any breach by Incyte of any of its representations, warranties or obligations pursuant to this Agreement, or (b) the gross negligence or willful misconduct of Incyte, and (c) the Development, manufacture, Commercialization, use, sale or other disposition by Incyte, its Affiliates or sublicensees of any Licensed Compound or Licensed Product.

- (b) In the event of any such claim against the Lilly Indemnified Parties by any Third Party, Lilly shall promptly notify Incyte in writing of the claim. Incyte shall have the right, exercisable by notice to Lilly within [***] after receipt of notice from Lilly of the claim, to assume direction and control of the defense, litigation, settlement, appeal or other disposition of the claim (including the right to settle the claim solely for monetary consideration) with counsel selected by Incyte and reasonably acceptable to Lilly. The Lilly Indemnified Parties shall cooperate with Incyte and may, at their option and expense, be separately represented in any such action or proceeding. Incyte shall not be liable for any litigation costs or expenses incurred by the Lilly Indemnified Parties without Incyte's prior written authorization. In addition, Incyte shall not be responsible for the indemnification or defense of any Lilly Indemnified Party to the extent arising from any negligent or intentional acts by any Lilly Indemnified Party, or the breach by Lilly of any representation, obligation or warranty under this Agreement, or any claims compromised or settled without its prior written consent. Notwithstanding the foregoing, Incyte shall not settle a Third Party claim without the written consent of Lilly, if such settlement would impose any monetary obligation on Lilly or require Lilly to submit to an injunction.
- (c) Notwithstanding anything to the contrary above, in the event of any such claim against the Lilly Indemnified Parties by a governmental or criminal action seeking an injunction against Lilly, Lilly shall have the right to control the defense, litigation, settlement, appeal or other disposition of the claim at Incyte's expense.
- 9.3 <u>Limitation of Liability</u>. EXCEPT WITH RESPECT TO A BREACH OF ARTICLE XI, OR A PARTY'S LIABILITY PURSUANT TO ARTICLE IX, NEITHER PARTY SHALL BE LIABLE FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL, EXEMPLARY, PUNITIVE, MULTIPLE OR OTHER INDIRECT OR REMOTE DAMAGES, OR, EXCEPT WITH RESPECT TO A BREACH OF SECTION 2.6, FOR LOSS OF PROFITS, LOSS OF DATA OR LOSS OF USE DAMAGES ARISING IN ANY WAY OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, WHETHER BASED UPON WARRANTY, CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OR LOSS.

ARTICLE X

REPRESENTATIONS AND WARRANTIES AND COVENANTS

- 10.1 <u>Representation Of Authority; Consents</u>. Incyte and Lilly each represents and warrants to the other Party that:
 - (a) as of the Effective Date, it has full right, power and authority to enter into this Agreement;
- (b) as of the Effective Date, this Agreement has been duly executed by such Party and constitutes a legal, valid and binding obligation of such Party, enforceable in accordance with its terms, except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other Laws relating to or affecting

creditors' rights generally and by general equitable principles and public policy constraints (including those pertaining to limitations and/or exclusions of liability, competition Laws, penalties and jurisdictional issues including conflicts of Laws); and

- (c) as of the Effective Date, and except as otherwise contemplated in this Agreement, all necessary consents, approvals and authorizations of all government authorities and other persons required to be obtained by such Party in connection with the execution, delivery and performance of this Agreement have been and shall be obtained.
- No Conflict. Each Party represents and warrants to the other Party that the execution and delivery of this Agreement and the performance of such Party's obligations hereunder (a) do not conflict with or violate such Party's corporate charter and bylaws or any requirement of applicable Laws and (b) do not and shall not conflict with, violate or breach or constitute a default or require any consent under, any material oral or written contractual obligation of such Party. Each Party agrees that it shall not during the term of this Agreement grant any right, license, consent or privilege to any Third Party or otherwise undertake any action, either directly or indirectly, that would conflict with the rights granted to the other Party or interfere with any obligations of such Party set forth in this Agreement.
- 10.3 <u>Additional Incyte Representations and Warranties</u>. Incyte represents and warrants that, as of the Effective Date, except as previously disclosed to Lilly:
- (a) Neither it nor any of its Affiliates has received written notice of any claim or litigation which alleges any Intellectual Property Rights of a Third Party are infringed by a Licensed Compound or the Development or Commercialization of any Licensed Compound; to the knowledge of Incyte and its Affiliates, none of Incyte or any of its Affiliates has in the past infringed or is currently infringing any Third Party Intellectual Property Rights through activities related to the Licensed Compounds;
- (b) there are no claims, judgments or settlements against or owed by Incyte or any of its Affiliates, nor, to the knowledge of Incyte or any of its Affiliates, any pending reissue, reexamination, interference, opposition or similar proceedings, with respect to any Licensed Compounds or Incyte IP, and Incyte has not received written notice of any threatened claims or litigation or any reissue, reexamination, interference, opposition or similar proceedings seeking to invalidate or otherwise challenge any Incyte IP;
- (c) to the knowledge of Incyte and its Affiliates, no Third Party is infringing any Incyte Patent Rights;
- (d) (i) Incyte is the legal and beneficial owner or has the right to grant to Lilly the rights granted herein, to all Incyte IP; (ii) no Third Party has any right, interest or claim in or to such rights that would limit the rights granted to Lilly under this Agreement; and (iii) all assignments to Incyte of inventorship rights relating to the Incyte Patent Rights Controlled by Incyte are valid and enforceable;
- (e) all fees due to date that are required to maintain the Incyte IP have been paid in full and to Incyte's knowledge, the Incyte IP is valid and enforceable;

- (f) Incyte has not granted and shall not grant any Third Party rights that are or would be inconsistent with Lilly's rights hereunder and there are no agreements or arrangements to which Incyte or any of its Affiliates is a party relating to Licensed Compound or Incyte IP that would limit the rights granted to Lilly under this Agreement; and
- (g) Incyte has disclosed to Lilly all material information known to it and its Affiliates with respect to the safety and efficacy of each of the Licensed Compounds.
- (h) Neither Incyte nor any of its Affiliates Controls any Patent Rights or Know-How necessary to Develop, manufacture or Commercialize Licensed Products and not included in the licenses granted hereunder to Lilly. Subject to Section 13.3(b)(ii), in the event Incyte subsequently determines that any Patent Rights or Know-How necessary to Develop, manufacture or Commercialize Licensed Products is Controlled by any Affiliate of Incyte, and not Incyte, Incyte shall immediately cause such Affiliate to grant to Incyte, a license (that is sublicenseable to Lilly hereunder) to, or ownership of, such Patent Rights or Know-How in a manner consistent with this Agreement.
- (i) None of the Incyte IP has been licensed or sublicensed from any Third Party, and there are no royalties or other payments that would be due to Third Parties on account of Development or Commercialization of Licensed Compounds or Licensed Products hereunder as a result of any agreement entered into by Incyte or any of its Affiliates.
- 10.4 <u>Disclaimer of Warranty.</u> Nothing in this Agreement shall be construed as a representation made or warranty given by Incyte that Lilly will be successful in obtaining any Patent Rights, that any patents will issue based on pending applications or that any such pending applications or patents issued thereon will be valid. ALL INCYTE IP TRANSFERRED PURSUANT TO THIS AGREEMENT SHALL BE PROVIDED ON AN "AS IS" BASIS. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, EACH PARTY EXPRESSLY DISCLAIMS, WAIVES, RELEASES AND RENOUNCES ANY WARRANTY, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT.

10.5 Standstill.

- (a) Lilly agrees that, for a period commencing on the Effective Date and ending [***] after the Effective Date, unless specifically invited in writing to do so by Incyte, Lilly and each of its Affiliates will not in any manner, directly or indirectly:
- (i) effect, or seek, offer or propose to effect (whether publicly or otherwise) or cause or participate in, (A) any acquisition of (1) any Voting Stock of Incyte or any securities that at such time are convertible or exchangeable into or exercisable for any Voting Stock of Incyte (collectively, "Voting Securities"); (2) any direct or indirect rights or options to acquire any Voting Securities; or (3) any assets or securities of Incyte or any of its subsidiaries; (B) any merger, consolidation, tender or exchange offer, or other business combination involving Incyte or any Affiliate thereof; (C) any restructuring, recapitalization, liquidation, dissolution or similar transaction with respect to Incyte or any Affiliate thereof; (D) any "solicitation" of "proxies" (as such terms are defined or used in Regulation 14A under the Exchange Act) or

consents with respect to any Voting Securities, any "election contest" (as such term is defined or used in Rule 14a-11 of the Exchange Act) with respect to Incyte, or any demand for a copy of Incyte's stock ledger, list of its stockholders, or other books and records; or (E) any action inconsistent with the terms of this Section 10.5;

- (ii) form, join, participate in or encourage the formation of any "group" (within the meaning of Section 13(d)(3) of the Exchange Act) with respect to any Voting Securities;
- (iii) otherwise act, alone or in concert with others (including by providing financing for another party), to seek or offer to control or influence, in any manner, the management, Board of Directors or policies of Incyte;
- (iv) take any action that might force Incyte to make a public announcement regarding any of the types of matters set forth in Section 10.5(a)(i);
- (v) make (publicly or to Incyte, or its directors, officers, employees, agents or security holders, directly or indirectly) any request or proposal to amend, waive or terminate any provision of this Section 10.5 or any inquiry or statement relating thereto; or
 - (vi) instigate, encourage or assist any Third Party to do any of the foregoing.
- (b) Notwithstanding anything in this Section 10.5 to the contrary, the provisions of this Section 10.5 shall immediately cease to be of any effect as to Lilly and its Affiliates and shall be deemed to be waived in the event (i) [***]; or (ii) a person or 13D Group not including Lilly or its Affiliates [***]. In the event that the transactions contemplated by this clause shall have been terminated or abandoned, and such termination or abandonment is demonstrable by objective, written evidence provided by Incyte to Lilly, all of the restrictions in this Section 10.5 shall again be applicable as to the activities Lilly or its Affiliates initiate thereafter for the remainder of the period specified herein.
- (c) Notwithstanding anything in the Section 10.5 to the contrary, Lilly and its Affiliates may acquire an aggregate amount of Voting Securities that would represent less than [***] of the voting power represented by Incyte's Voting Stock solely for the purposes of investment in the ordinary course of business (so long as any decision to make such acquisition is in compliance with United States securities laws). Nothing in this Section 10.5 shall [***].

- (d) This Section 10.5 shall not apply to any of the activities with respect to Licensed Compounds or Licensed Products contemplated by this Agreement.
 - (e) Incyte [***] upon (i) [***]; and (ii) [***].

ARTICLE XI

CONFIDENTIALITY

- 11.1 <u>Confidential Information</u>. All Confidential Information of a Party (the "<u>Disclosing Party</u>") shall not be used by the other Party (the "<u>Receiving Party</u>") except in performing its obligations or exercising rights explicitly granted under this Agreement and shall be maintained in confidence by the Receiving Party and shall not otherwise be disclosed by the Receiving Party to any Third Party, without the prior written consent of the Disclosing Party with respect to such Confidential Information, except to the extent that the Confidential Information:
- (a) was known by the Receiving Party or its Affiliates prior to its date of disclosure to the Receiving Party; or
- (b) is lawfully disclosed to the Receiving Party or its Affiliates by sources other than the Disclosing Party rightfully in possession of the Confidential Information; or
- (c) becomes published or generally known to the public through no fault or omission on the part of the Receiving Party, its Affiliates or its sublicensees; or
- (d) is independently developed by or for the Receiving Party or its Affiliates without reference to or reliance upon such Confidential Information, as established by written records.

Specific information shall not be deemed to be within any of the foregoing exclusions merely because it is embraced by more general information falling within those exclusions.

- 11.2 <u>Permitted Disclosure</u>. The Receiving Party may provide the Disclosing Party's Confidential Information:
- (a) to the Receiving Party's respective employees, consultants and advisors, and to the employees, consultants and advisors of such Party's Affiliates, who have a need to know such information and materials for performing obligations or exercising rights expressly granted under this Agreement and have an obligation to treat such information and materials as confidential;

- (b) to patent offices in order to seek or obtain Patent Rights or to Regulatory Authorities in order to seek or obtain approval to conduct Clinical Trials or to gain Regulatory Approval with respect to the Licensed Product as contemplated by this Agreement; provided, that such disclosure may be made only to the extent reasonably necessary to seek or obtain such Patent Rights or approvals; or
- (c) if such disclosure is required by Law or to defend or prosecute litigation or arbitration; <u>provided that prior</u> to such disclosure, to the extent permitted by Law, the Receiving Party promptly notifies the Disclosing Party of such requirement and furnishes only that portion of the Disclosing Party's Confidential Information that the Receiving Party is legally required to furnish.

11.3 <u>Publicity; Attribution; Terms of this Agreement; Non-Use of Names.</u>

(a) Except as required by judicial order or applicable Law or as set forth below, neither Party shall make any public announcement concerning this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed. The Party preparing any such public announcement shall provide the other Party with a draft thereof at least [***] prior to the date on which such Party would like to make the public announcement. Notwithstanding the foregoing, the Parties shall issue a press release, in the form attached as Exhibit D, within one (1) Business Day after the Effective Date to announce the execution of this Agreement and describe the material financial and operational terms of this Agreement. For purposes of disclosure to the investor community during conference calls, investor presentations, and analyst meetings, the Parties acknowledge that Incyte can disclose the following information, (i) base royalty: tiered, double digit royalty payments on future global sales with rates ranging up to twenty percent, (ii) Development expenditure of thirty percent (30%) of Co-Development costs through Regulatory Approval if Incyte fully participates in co-funding Development, (iii) increased royalties payments on potential future global sales with tiered rates ranging from twenty percent up to the high twenties, (iv) the ability for Incyte to defer Development Costs that exceed a predetermined level against future milestones and royalties, (v) the ability to terminate Co-Development at any time for an incremental royalty commensurate with Incyte's contribution, and (vi) based on the current Co-Development Budget, Incyte's option to fund thirty percent (30%) of Co-Development costs is expected to be primarily funded by the anticipated development and regulatory milestones associated with this collaboration. Neither Party shall use the name, trademark, trade name or logo of the other Party or its employees in any publicity or news release relating to this Agreement or its subject matter, without the prior express written permission of the other Party.

(b) Notwithstanding the terms of this ARTICLE XI,

(i) either Party shall be permitted to disclose the existence and terms of this Agreement to the extent required, based on the advice of such Party's legal counsel, to comply with applicable Laws, including the rules and regulations promulgated by the United States Securities and Exchange Commission (the "SEC") or any other governmental authority, or the rules or regulations of the New York Stock Exchange (the "NYSE"), The NASDAQ Stock Market ("NASDAQ") or any other stock exchange on which securities issued by a Party or a Party's Affiliate are traded. Notwithstanding the foregoing, before disclosing this Agreement or

any of the terms hereof pursuant to this Section 11.3(b), the Parties will coordinate in advance with each other in connection with the redaction of certain provisions of this Agreement with respect to any filings with the SEC, the NYSE, NASDAQ or any other stock exchange on which securities issued by a Party or a Party's Affiliate are traded, and each Party will use Commercially Reasonable Efforts to seek confidential treatment for such terms as may be reasonably requested by the other Party; provided that each Party will ultimately retain control over what information that Party discloses to their relevant exchange, and provided further that the Parties will use their Commercially Reasonable Efforts to file redacted versions with any governing bodies which are consistent with redacted versions previously filed with any other governing bodies. Other than such obligation, neither Party (nor its Affiliates) will be obligated to consult with or obtain approval from the other Party with respect to any filings to the SEC, the NYSE, NASDAQ or any other stock exchange.

- (ii) Either Party may disclose the existence and terms of this Agreement in confidence to its attorneys and advisors, and to potential acquirers (and their respective professional attorneys and advisors), in connection with a potential merger, acquisition or reorganization and to existing and potential investors or lenders of such Party, as a part of their due diligence investigations, or to existing and potential licensees or sublicensees or to permitted assignees, in each case under an agreement to keep the terms of confidentiality and non-use substantially no less rigorous than the terms contained in this Agreement and to use such information solely for the purpose permitted pursuant to this Section 11.3(b).
- (iii) Either Party may issue a press release or make a public disclosure relating to this Agreement or the Parties' activities under this Agreement to the extent that such disclosure describes the commencement and/or "top-line" results of Clinical Trials of the Licensed Product, the achievement of any Development events with respect to the Licensed Product or the filing for or receipt of Regulatory Approval with respect to the Licensed Product, amounts paid to Incyte in respect of the achievement of any milestone events, Incyte's exercise of the co-Development option or the termination of this Agreement; however, the Party responsible for particular Clinical Trials will coordinate press release information and disclosures to protect rights to the Licensed Product and communication strategies relating to the Licensed Product. Prior to making any such disclosure, the Party making the disclosure shall provide the other Party with a draft of such proposed disclosure at least [***] (or, to the extent timely disclosure of a material event is required by Law or stock exchange or stock market rules, such period of time sufficiently in advance of the disclosure so that the other Party will have the opportunity to comment upon the disclosure) prior to making any such disclosure, for the other Party's review and comment.
- (c) For purposes of clarity, either Party may issue a press release or public announcement or make such other disclosure relating to this Agreement if the contents of such press release, public announcement or disclosure (i) has previously been made public other than through a breach of this Agreement by the issuing Party or its Affiliates or (ii) is contained in such Party's financial statements prepared in accordance with Accounting Standards.
- 11.4 <u>Publications</u>. Each Party and its Affiliates shall have the right to make disclosures pertaining to Licensed Compound or Licensed Product to Third Parties in Publications in accordance with the following procedure (provided that Incyte shall abide by such procedure to

the extent possible under any Clinical Trial agreement(s) that Incyte entered into prior to the Effective Date): The publishing Party shall provide the non-publishing Party with an advance copy of the proposed Publication, and each Party shall then have [***] prior to submission for any Publication in which to recommend any changes it reasonably believes are necessary to preserve any Patent Rights or Know-How belonging in whole or in part to the non-publishing Party. If the non-publishing Party informs the publishing Party that such Publication, in the non-publishing Party's reasonable judgment, could be expected to have a material adverse effect on any patentable invention owned by or licensed, in whole or in part, to the non-publishing Party (other than pursuant to a license granted under this Agreement), or on any Know-How which is Confidential Information of the non-publishing Party, the publishing Party shall delay or prevent such Publication as follows: (i) with respect to a patentable invention, such Publication shall be delayed sufficiently long (not to exceed [***]) to permit the timely preparation and filing of a patent application; and (ii) with respect to Know-How which is Confidential Information of such non-publishing Party, such Know-How shall be deleted from the Publication. Following the initiation of Phase III Clinical Trials with respect to a Licensed Product, all Publications relating to such Licensed Product shall be controlled by Lilly, and Incyte shall have no right (other than as required pursuant to any publication provisions contained in any Clinical Trial agreement(s) that Incyte entered into prior to the Effective Date) to publish without Lilly's prior written consent. Notwithstanding the foregoing, Lilly shall be permitted to disclose information on sites such as clinicaltrials gov in accordance with Lilly's normal business practices.

- 11.5 <u>Term.</u> All obligations under this ARTICLE XI shall expire (a) [***] following expiration of this Agreement pursuant to Section 8.1 or (b) [***] following termination of this Agreement pursuant to Sections 8.2(a), 8.2(b), 8.2(c) or 8.2(d).
- Return of Confidential Information. Upon the expiration or termination of this Agreement, upon request, the Receiving Party shall return to the Disclosing Party or destroy all Confidential Information received by the Receiving Party from the Disclosing Party (and all copies and reproductions thereof). In addition, the Receiving Party shall destroy: (a) any notes, reports or other documents prepared by the Receiving Party which contain Confidential Information of the Disclosing Party; and (b) any Confidential Information of the Disclosing Party (and all copies and reproductions thereof) which is in electronic form or cannot otherwise be returned to the Disclosing Party. Nothing in this Section 11.6 shall require the alteration, modification, deletion or destruction of archival tapes or other electronic back-up media made in the ordinary course of business; provided that the Receiving Party shall continue to be bound by its obligations of confidentiality and other obligations under this ARTICLE XI with respect to any Confidential Information contained in such archival tapes or other electronic back-up media. Any requested destruction of Confidential Information shall be certified in writing to the Disclosing Party by an authorized officer of the Receiving Party supervising such destruction. Notwithstanding the foregoing, (i) the Receiving Party may retain one copy of the Disclosing Party's Confidential Information solely for the purpose of determining the Receiving Party's continuing obligations under this ARTICLE XI and (ii) the Receiving Party may retain the Disclosing Party's Confidential Information and its own notes, reports and other documents to the extent reasonably required (x) to exercise the rights and licenses of the Receiving Party expressly surviving expiration or termination of this Agreement; (y) to perform the obligations of the Receiving Party expressly surviving expiration or termination of this Agreement, and for

regulatory or archival purposes. Notwithstanding the return or destruction of the Disclosing Party's Confidential Information, the Receiving Party shall continue to be bound by its obligations of confidentiality and other obligations under this ARTICLE XI.

ARTICLE XII

DISPUTE RESOLUTION

- Dispute Resolution Process. Matters before the JDC and Subcommittees shall be governed by the process specified in Section 3.5. Any controversy, claim or dispute arising out of or relating to this Agreement that is not subject to Section 3.5, shall be settled, if possible, through good faith negotiations between the Parties. If the Parties are unable to settle such dispute within [***], and a Party wishes to pursue the matter, the matter may be referred by either Party to the Executive Officers, who shall meet to attempt to resolve the dispute in good faith. Such resolution, if any, of a referred issue shall be final and binding on the Parties. All negotiations pursuant to this Section 12.1 are confidential and shall be treated as compromise and settlement negotiations for purposes of applicable rules of evidence. If the Executive Officers are unable to settle the dispute within [***] after referral thereto pursuant to Section 12.1, then each Party reserves its right to any and all remedies available under law or equity with respect to the dispute, subject to Section 12.2.
- 12.2 <u>Injunctive Relief.</u> Notwithstanding anything to the contrary in this ARTICLE XII, any Party may seek immediate injunctive or other interim relief from any court of competent jurisdiction as necessary to enforce the provisions of Section 10.5 or ARTICLE XI and to enforce and prevent infringement or misappropriation of the Patent Rights, Know-How or Confidential Information Controlled by such Party.

ARTICLE XIII

MISCELLANEOUS

- 13.1 <u>Governing Law</u>. This Agreement (and any claims or disputes arising out of or related thereto or to the transactions contemplated thereby or to the inducement of any party to enter therein, whether for breach of contract, tortious conduct, or otherwise and whether predicated on common law, statute or otherwise) shall in all respects be governed by and construed in accordance with the laws of the State of New York, including all matters of construction, validity and performance, in each case without reference to any conflict of law rules that might lead to the application of the laws of any other jurisdiction.
- 13.2 <u>Consent to Jurisdiction</u>. Each Party irrevocably submits to the exclusive jurisdiction of the United States District Court for the Southern District of New York or the United States District Court for the District of Delaware, for the purposes of any suit, action or other proceeding arising out of the Transaction. Each Party agrees to commence any such action, suit or proceeding either in the United States District Court for the Southern District of New York or the United States District Court for the District of Delaware or if such suit, action or other proceeding may not be brought in such court for jurisdictional reasons, in the Supreme Court of the State of New York, New York County. Each Party further agrees that service of any

process, summons, notice or document by U.S. registered mail to such Party's respective address set forth in Section 13.5 shall be effective service of process for any action, suit or proceeding in New York or Delaware with respect to any matters to which it has submitted to jurisdiction in this Section 13.2. Each Party irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of this Agreement in (i) the United States District Court for the Southern District of New York or (ii) the United States District Court for the District of Delaware, and hereby and thereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

13.3 <u>Assignment</u>.

- (a) Neither Party may assign its rights and obligations under this Agreement without the prior written consent of the other Party, except that either Party may make such assignment without the prior written consent of the other Party to an Affiliate (so long as such Party shall remain jointly and severally liable with such Affiliate with respect to all obligations so assigned). Any request for consent to assignment shall not be unreasonably withheld or delayed. Any purported assignment in contravention of this Section 13.3 shall, at the option of the non-assigning Party, be null and void and of no effect. No assignment shall release either Party from responsibility for the performance of any accrued obligation of such Party hereunder. This Agreement shall be binding upon and enforceable against the successor to or any permitted assignee from either of the Parties.
 - (b) Each Party agrees that, notwithstanding any provisions of this Agreement to the contrary:
- (i) Either Party may assign this Agreement and the rights, obligations and licenses granted hereunder to a Third Party in connection with a sale or transfer of all or substantially all of the assigning Party's business to which this Agreement relates or if a Party merges or consolidates with a Third Party.
- (ii) In the event that this Agreement is assigned by either Party in connection with a sale or transfer of all or substantially all of the assigning Party's business to which this Agreement relates, such assignment shall not provide (A) the non-assigning Party with rights or access to Intellectual Property Rights of the assignee or acquirer of such Party, nor (B) the assignee or acquirer with rights or access to Intellectual Property Rights of the non-assigning Party.
- 13.4 <u>Entire Agreement; Amendments</u>. This Agreement and the Exhibits and Schedules referred to in this Agreement constitute the entire agreement between the Parties with respect to the subject matter hereof, and supersede all previous arrangements with respect to the subject matter hereof, whether written or oral, including the Prior Confidentiality Agreement. Any amendment or modification to this Agreement shall be made in writing signed by both Parties.
 - 13.5 <u>Notices</u>. Notices to Incyte shall be addressed to:

Incyte Corporation Experimental Station, Route 141 & Henry Clay Road Wilmington, Delaware 19880 Attention: Chief Commercial Officer

Facsimile No.: [***]

with a copy to:

Incyte Corporation
Experimental Station, Route 141 & Henry Clay Road
Building E336
Wilmington, Delaware 19880
Attention: General Counsel
Facsimile No.: [***]

Notices to Lilly shall be addressed to:

Eli Lilly and Company Lilly Corporate Center Indianapolis, Indiana 46285

Attention: Vice President and President, Established Markets

with a copy to:

Eli Lilly and Company Lilly Corporate Center Indianapolis, Indiana 46285

Attention: General Patent Counsel

Facsimile No.: [***]

Either Party may change its address to which notices shall be sent by giving notice to the other Party in the manner herein provided. All reports, approvals, and notices required or permitted by this Agreement to be given to a Party (each a "Notice") shall be given in writing, by personal delivery, telecopy or overnight courier, to the Party concerned at its address as set forth above (or at such other address as a Party may specify by written notice pursuant to this Section 13.5 to the other). All Notices shall be deemed effective, delivered and received (a) if given by personal delivery, or by overnight courier, when actually delivered and signed for; or (b) if given by facsimile, when such facsimile is transmitted to the facsimile number specified above and receipt therefor is confirmed.

- 13.6 <u>Force Majeure</u>. No failure or omission by either Party in the performance of any obligation of this Agreement shall be deemed a breach of this Agreement or create any liability if the same shall arise from a Force Majeure Event; <u>provided that</u> the Party affected by such cause promptly notifies the other Party and uses diligent efforts to cure such failure or omission as soon as is practicable after the occurrence of one or more of the above mentioned causes.
- 13.7 <u>Compliance With Laws</u>. Each Party shall perform its obligations under this Agreement in compliance with all applicable Laws.

- 13.8 <u>Use Of Names, Logos Or Symbols</u>. Subject to Sections 5.3 and 11.3, no Party shall use the name, trademarks, logos, physical likeness, employee names or owner symbol of the other Party for any purpose, including private or public securities placements, without the prior written consent of the affected Party. Nothing contained in this Agreement shall be construed as granting either Party any rights or license to use any of the other Party's trademarks or trade names or the names of any employees thereof, without separate, express written permission of the owner of such trademark or trade name or name.
- 13.9 <u>Independent Contractors</u>. It is understood and agreed that the relationship between the Parties is that of independent contractors and that nothing in this Agreement shall be construed to create a joint venture or any relationship of employment, agency or partnership between the Parties to this Agreement. Neither Party is authorized to make any representations,

commitments, or statements of any kind on behalf of the other Party or to take any action that would bind the other Party except as explicitly provided in this Agreement. Furthermore, none of the transactions contemplated by this Agreement shall be construed as a partnership for any tax purposes.

- 13.10 <u>Headings</u>. The captions or headings of the sections or other subdivisions hereof are inserted only as a matter of convenience or for reference and shall have no effect on the meaning of the provisions hereof.
- 13.11 No Implied Waivers; Rights Cumulative. No failure on the part of Incyte or Lilly to exercise, and no delay by either Party in exercising, any right, power, remedy or privilege under this Agreement, or provided by statute or at law or in equity or otherwise, shall impair, prejudice or constitute a waiver of any such right, power, remedy or privilege by such Party or be construed as a waiver of any breach of this Agreement or as an acquiescence therein by such Party, nor shall any single or partial exercise of any such right, power, remedy or privilege by a Party preclude any other or further exercise thereof or the exercise of any other right, power, remedy or privilege.
- 13.12 <u>Severability</u>. If, under applicable Laws, any provision of this Agreement is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement (such invalid or unenforceable provision, a "<u>Severed Clause</u>"), this Agreement shall endure except for the Severed Clause. The Parties shall consult one another and use good faith efforts to agree upon a valid and enforceable provision that is a reasonable substitute for the Severed Clause in view of the intent of this Agreement.
- 13.13 Execution In Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument. Signatures provided by facsimile transmission or in AdobeTM Portable Document Format (PDF) sent by electronic mail shall be deemed to be original signatures.
- 13.14 <u>No Third Party Beneficiaries</u>. No Person other than Lilly and Incyte (and their respective assignees) shall be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.

- 13.15 <u>Performance by Affiliates</u>. Either Party may use one or more of its Affiliates to perform its obligations and duties hereunder and Affiliates of a Party are expressly granted certain rights herein; <u>provided that</u> each such Affiliate shall be bound by the corresponding obligations of such Party and the Parties shall remain liable hereunder for the prompt payment and performance of all their respective obligations hereunder.
- 13.16 <u>Exhibits</u>. In the event of inconsistencies between this Agreement and any exhibits, schedules or attachments hereto, the terms of this Agreement shall control.

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IN WITNESS WHEREOF, the Parties have caused their duly authorized officers to execute and acknowledge this Agreement as of the date first written above.

ELI LILLY AND COMPANY INCYTE CORPORATION

By: /s/ Steven M. Paul By: /s/ Paul A. Friedman

Name:Steven M. Paul, M.D.Name:Paul A. FriedmanTitle:EVP, Science and TechnologyTitle:President & CEO

Exhibit A

Incyte Patent Rights

Exhibit A-1

Genus Patent Rights

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Exhibit A-2

Selection Patent Rights

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Exhibit B

Initial Information Transfer

Described below are the items to be provided to Lilly by Incyte pursuant to Section 4.1(a) of the Agreement, which include the material documents, information and data listed in this Exhibit B that are recorded in tangible form that are Incyte Know-How, to the extent each of which exists as of the Effective Date and has not already been provided to Lilly. Within sixty (60) days after the Effective Date, Lilly will confirm in writing to Incyte whether Incyte's initial data transfer obligations, as described in Section 4.1(a) of the Agreement, have been achieved.

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Ш	Clinical study related documents, information and data that are recorded in tangible form, including those
	currently possessed by CROs and other third party vendors
	Regulatory Authority submissions, correspondence and all communications, including minutes from
	teleconferences and contact reports (US and ex-US)
	Regulatory Authority meeting briefing documents and related minutes (US and ex-US)
	Pre-IND submissions
	IND submissions
	Annual reports to IND(s)
	CTA/IMPD submissions
	Annual Safety Reports submissions
	Investigator's Brochures and any updates thereto
	Safety reports (CIOMSs and/or Medwatch reports)
	Documents related to serious adverse events ("SAEs")
	Investigator Safety Letters, actions taken for safety reasons, and other relevant safety information
	Safety pharmacology and toxicology study related documents, information and data that are recorded in
	tangible form
	Pharmacology and Absorption, Distribution, Metabolism, and Excretion (ADME) related documents,
	information and data that are recorded in tangible form

Licensed Compound Documents

Incyte may retain (x) originals of all documents, information and data, including regulatory submissions, correspondence, and clinical trial data and (y) originals of regulatory submissions, correspondence, and clinical trial data directly related to Study 201 until fifteen (15) Business Days after responsibility for the relevant regulatory filing or clinical trial has been transferred to Lilly in accordance with the Agreement and this Exhibit B. Incyte will provide both a shared electronic depository and paper copies of all requested documents, information and data where both electronic and paper versions are currently available.

Manufacturing Know-How

Incyte will prepare and compile an inventory of relevant documents and transfer all Incyte Know-How for manufacturing Licensed Products including: laboratory notebook data, batch

records, process data, stability data, summary reports, formulation folders, analytical methods, development reports, quality and regulatory documentation, validation reports and other material data related to the development, manufacturing, and/or distribution of Licensed Compounds and/or Licensed Products. As part of the Know-How transfer, Incyte shall cooperate with Lilly to establish a transfer protocol and make resources available at Incyte's cost to enable the successful execution of the transfer protocol. Additionally, Incyte will disclose and transfer as necessary, any vendor sourcing and/or contracting information that Lilly may reasonably request.

Exhibit C

<u>Initial Development Plans</u>

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[***] Confidential material redacted and filed separately with the Commission.					
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Exhibit D

Press Release





Eli Lilly and Company Lilly Corporate Center Indianapolis, Indiana 46285 U.S.A.

Date: December 21, 2009

For Release: Immediately

Refer to: (317) 276-5795 – Mark E. Taylor (Lilly)

(302) 498-6944 – Pamela Murphy (Incyte)





Eli Lilly and Company Lilly Corporate Center Indianapolis, Indiana 46285

Lilly and Incyte Announce Collaboration for Development and Commercialization of Oral Anti-Inflammatory and Autoimmune Therapies

Lilly Gains Worldwide Rights for Incyte's Novel JAK1/JAK2 Inhibitor, INCB28050, for Inflammatory and Autoimmune Diseases

Incyte to Receive \$90 Million Upfront Payment and up to \$665 Million in Potential Milestones, Plus Royalties on Future Sales

Incyte Retains Co-Development & Co-Promotion Options

INDIANAPOLIS, IN and WILMINGTON, DE -- Eli Lilly and Company (NYSE:LLY) and Incyte Corporation (NASDAQ:INCY) announced today that they have entered into an exclusive worldwide license and collaboration agreement for the development and commercialization of Incyte's oral JAK1/JAK2 inhibitor, INCB28050, and certain follow on compounds, for inflammatory and autoimmune diseases. The lead compound, INCB28050, is currently being studied in a six-month dose-ranging Phase II trial for rheumatoid arthritis.

Under the terms of the agreement, Lilly will receive worldwide rights to develop and commercialize INCB28050 as an oral treatment for all inflammatory conditions. In exchange for these rights, Incyte will receive an initial payment of \$90 million and is eligible for up to \$665 million in additional potential development, regulatory, and commercialization milestones, as well as tiered, double-digit royalty payments on future global sales with rates ranging up to twenty percent if a product is successfully commercialized.





Eli Lilly and Company Lilly Corporate Center Indianapolis, Indiana 46285

"This new alliance with Incyte reinforces Lilly's commitment to expand our presence in inflammation and autoimmunity through the development of a new class of oral anti-inflammatory therapies," said Eiry Roberts, M.D. Lilly vice president for autoimmune product development. "We look forward to continuing the development of INCB28050 in RA and initiating additional clinical studies to help address the unmet patient needs from debilitating autoimmune and inflammatory diseases."

Paul Friedman, Incyte's president and chief executive officer, stated, "Lilly's success in bringing novel therapies to market, their commitment to building a franchise in inflammation and autoimmunity, and their enthusiasm regarding the potential of JAK inhibition gives us confidence that the full therapeutic and commercial potential of INCB28050 in RA as well as other autoimmune and inflammatory conditions can be rapidly and effectively achieved through this agreement. This collaboration leverages the capabilities and strengths of each partner and achieves our objective to retain significant value for Incyte's shareholders."

Incyte will retain the option to co-develop its JAK1/JAK2 inhibitors with Lilly on a compound-by-compound and indication-by-indication basis beginning at the initiation of Phase IIb development. Under the agreement, if Incyte elects to co-develop any compounds and/or indications, Incyte would be responsible for funding thirty percent of the associated future global development costs from the initiation of a Phase IIb trial. Incyte would receive an incremental royalty rate increase across all tiers resulting in effective royalty rates ranging up to the high twenties on potential future global sales for compounds and/or indications that Incyte elects to co-develop. Incyte expects that the earliest it would consider exercising a co-development option would be in the second half of 2010, concurrent with the potential initiation of a Phase IIb trial with INCB28050.





Development of the JAK1/JAK2 inhibitors will be governed by a joint development committee. Incyte also has the option to co-promote products in the US.

As a result of this transaction, Lilly expects to incur a charge to earnings in the fourth quarter of 2009 of approximately \$.05 per share. The company reconfirmed its full-year 2009 earnings-per-share guidance of \$3.90 to \$4.00 per share on a reported basis, or \$4.30 to \$4.40 per share on a pro forma non-GAAP basis.

About Rheumatoid Arthritis (RA)

Rheumatoid arthritis is an autoimmune disease, estimated to affect about 1% of the world's population. The disease is characterized by aberrant immune mechanisms that lead to joint inflammation and swelling with progressive destruction of joints. In addition to affecting the joints, RA can affect connective tissue in the skin and organs of the body. Current treatments include the non-steroidal anti-inflammatory drugs, disease-modifying anti-rheumatic drugs such as methotrexate, and the newer injectable biological response modifiers that target tumor necrosis factor alpha, a pro-inflammatory cytokine implicated in the pathogenesis of rheumatoid arthritis. None of these treatments is curative and RA remains a disease for which there is still a significant unmet clinical need.

About JAK Inhibition

There are four known JAK enzymes: JAK1, 2, 3 and TYK2. These enzymes are critical components of signaling
mechanisms utilized by a number of cytokines and growth factors, including those that are elevated in RA patients.
Cytokines such as interleukin-6, -12, and -23





signal through the JAK pathway and have been clinically validated as therapeutic targets in inflammatory diseases. Additional JAK-dependent cytokines have also been implicated in a number of inflammatory and autoimmune diseases suggesting that JAK inhibitors may be useful for the treatment of a broad range of inflammatory conditions.

About INCB28050

INCB28050 is an orally-available, potent and selective JAK1/JAK2 inhibitor that is currently in Phase II development as a treatment for RA. In previously conducted Phase II studies, Incyte's JAK1/JAK2 inhibitors have demonstrated efficacy and have been well tolerated in clinical studies to date.

About Incyte

Incyte Corporation is a Wilmington, Delaware-based drug discovery and development company focused on developing proprietary small molecule drugs for oncology, inflammation and diabetes. Incyte's most advanced compound, INCB18424, is in Phase III development for myelofibrosis. For additional information on Incyte, visit the Company's web site at www.incyte.com.

About Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers – through medicines and information – for some of the world's most urgent medical needs. Additional information about Lilly is available at www.lilly.com. C-LLY





Lilly Safe Harbor Statement

This press release contains forward-looking statements that are based on management's current expectations, but actual results may differ materially due to various factors. There are significant risks and uncertainties in pharmaceutical research and development. There can be no guarantees with respect to pipeline products (including the compounds discussed in this press release) that the products will receive the necessary clinical and manufacturing regulatory approvals or that they will prove to be commercially successful. The company's results may also be affected by such factors as competitive developments affecting current products; the rate of sales growth of recently launched products; the timing of anticipated regulatory approvals and launches of new products; other regulatory developments and government investigations; patent disputes and other litigation involving current and future products; the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals; business development transactions; changes in tax law; asset impairments and restructuring charges and the impact of exchange rates. For additional information about the factors that affect the company's business, please see the company's latest Form 10-K, filed February 2009, and Form 10-Q filed October 2009. The company undertakes no duty to update forward-looking statements.

Incyte Safe Harbor Statement

Except for the historical information contained herein, the matters set forth in this press release, including statements with respect to with respect to the potential for Incyte to receive up to \$665 million in additional potential milestones, Incyte's expectation for the earliest time for it to consider exercising a co-development option, Incyte's confidence that the full therapeutic and commercial potential of INCB28050 in RA as well as other inflammatory conditions can be rapidly and effectively achieved through the collaboration agreement, and the potential for JAK inhibitors to be useful for the treatment of a broad range of inflammatory conditions, are all forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to risks and uncertainties that may cause the parties not to achieve some or all of the commercial and developmental milestones set forth in the collaboration agreement and that may otherwise cause Incyte's actual results and timing to differ materially, including the high degree of risk and uncertainty associated with drug development and clinical trials, the uncertainty associated with the regulatory approval processes, risks related to the timing of and patient enrollment in clinical trials, risks related to the potential failure of INCB28050 to demonstrate safety and efficacy in clinical testing, risks and uncertainty associated with the therapeutic and commercial value of INCB28050, risks relating to Lilly's and Incyte's abilities to successfully develop and commercialize drug candidates, risks relating to market competition, risks associated with





Incyte's dependence on its relationship with its collaboration partners, and other risks detailed from time to time in Incyte's filings with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the quarter ended September 30, 2009. Incyte disclaims any intent or obligation to update these forward-looking statements.

#

Exhibit E

Hematology Field and Oncology Field (ICD-9CM)

2. NEOPLASMS (140-239)

Content:

This chapter contains the following broad groups:

Malignant neoplasms, stated or presumed to be primary, of specified sites, except of lymphatic and hematopoietic tissue

196-198 Malignant neoplasms, stated or presumed to be secondary, of specified sites

Malignant neoplasms, without specification of site

200-208 Malignant neoplasms, stated or presumed to be primary, of lymphatic and hematopoietic tissue

209 Neuroendocrine tumors
210-229 Benign neoplasms
230-234 Carcinoma in situ

235-238 Neoplasms of uncertain behavior [see Note, at beginning of section 235-238]

Neoplasms of unspecified nature

2. Functional activity

All neoplasms are classified in this chapter, whether or not functionally active. An additional code from Chapter 3 may be used to identify such functional activity associated with any neoplasm, e.g.:

catecholamine-producing malignant pheochromocytoma of adrenal:

code 194.0, additional code 255.6

basophil adenoma of pituitary with Cushing's syndrome:

code 227.3, additional code 255.0

3. Morphology [Histology]

For those wishing to identify the histological type of neoplasms, a comprehensive coded nomenclature, which comprises the morphology rubrics of the ICD-Oncology, is given after the E-code chapter.

4. Malignant neoplasms overlapping site boundaries

Categories 140-195 are for the classification of primary malignant neoplasms according to their point of origin. A malignant neoplasm that overlaps two or more subcategories within a three-digit rubric and whose point of origin cannot be determined should be classified to the subcategory .8 "Other." For example, "carcinoma involving tip and ventral surface of tongue" should be assigned to 141.8. On the other hand, "carcinoma of tip of tongue, extending to involve the ventral surface" should be coded to 141.2, as the point of origin, the tip, is known. Three subcategories (149.8, 159.8, 165.8) have been provided for malignant neoplasms that overlap the boundaries of three-digit rubrics within certain systems. Overlapping malignant neoplasms that cannot be classified as indicated above should be assigned to the appropriate subdivision of category 195 (Malignant neoplasm of other and ill-defined sites).

MALIGNANT NEOPLASM OF LIP, ORAL CAVITY, AND PHARYNX (140-149)

Excludes: carcinoma in situ (230.0)

140 Malignant neoplasm of lip

Excludes: skin of lip (173.0)

140.0 Upper lip, vermilion border

Upper lip: NOS external lipstick area

140.1 Lower lip, vermilion border

Lower lip: NOS external lipstick area

140.3 Upper lip, inner aspect

Upper lip: buccal aspect frenulum mucosa oral aspect

140.4 Lower lip, inner aspect

Lower lip: buccal aspect frenulum mucosa oral aspect

140.5 Lip, unspecified, inner aspect

Lip, not specified whether upper or lower:

buccal aspect frenulum mucosa oral aspect

140.6 Commissure of lip

Labial commissure

140.8 Other sites of lip

Malignant neoplasm of contiguous or overlapping sites of lip whose point of origin cannot be determined

140.9 Lip, unspecified, vermilion border

Lip, not specified as upper or lower:

NOS external lipstick area

141 Malignant neoplasm of tongue

141.0 Base of tongue

Dorsal surface of base of tongue Fixed part of tongue NOS

141.1 Dorsal surface of tongue

Anterior two-thirds of tongue, dorsal surface

Dorsal tongue NOS

Midline of tongue

Excludes: dorsal surface of base of tongue (141.0)

141.2 Tip and lateral border of tongue

141.3 Ventral surface of tongue

Anterior two-thirds of tongue, ventral surface

Frenulum linguae

141.4 Anterior two-thirds of tongue, part unspecified

Mobile part of tongue NOS

141.5 Junctional zone

Border of tongue at junction of fixed and mobile parts at insertion of anterior tonsillar pillar

141.6 Lingual tonsil

141.8 Other sites of tongue

Malignant neoplasm of contiguous or overlapping sites of tongue whose point of origin cannot be determined

141.9 Tongue, unspecified

Tongue NOS

142 Malignant neoplasm of major salivary glands

Includes: salivary ducts

Excludes: malignant neoplasm of minor salivary glands:

NOS (145.9)

buccal mucosa (145.0) soft palate (145.3) tongue (141.0-141.9) tonsil, palatine (146.0)

142.0 Parotid gland

142.1 Submandibular gland

Submaxillary gland

142.2 Sublingual gland

142.8 Other major salivary glands

Malignant neoplasm of contiguous or overlapping sites of salivary glands and ducts whose point of origin cannot be determined

Salivary gland, unspecified

Salivary gland (major) NOS

143 Malignant neoplasm of gum

142.9

Includes: alveolar (ridge) mucosa

gingiva (alveolar) (marginal)

interdental papillae

Excludes: malignant odontogenic neoplasms (170.0-170.1)

143.0 Upper gum143.1 Lower gum

143.8 Other sites of gum

Malignant neoplasm of contiguous or overlapping sites of gum whose point of origin cannot be determined

143.9 Gum, unspecified

144 Malignant neoplasm of floor of mouth

144.0 Anterior portion

Anterior to the premolar-canine junction

144.1 Lateral portion

144.8 Other sites of floor of mouth

Malignant neoplasm of contiguous or overlapping sites of floor of mouth whose point of origin cannot be determined

144.9 Floor of mouth, part unspecified

Malignant neoplasm of other and unspecified parts of mouth

Excludes: mucosa of lips (140.0-140.9)

145.0 Cheek mucosa

Buccal mucosa Cheek, inner aspect

145.1 Vestibule of mouth

Buccal sulcus (upper) (lower) Labial sulcus (upper) (lower)

145.2 Hard palate

145.3 Soft palate

Excludes: nasopharyngeal [posterior] [superior] surface of soft palate (147.3)

145.4 Uvula

145.5 Palate, unspecified

Junction of hard and soft palate

Roof of mouth

145.6 Retromolar area

145.8 Other specified parts of mouth

Malignant neoplasm of contiguous or overlapping sites of mouth whose point of origin cannot be determined

145.9 Mouth, unspecified

Buccal cavity NOS

Minor salivary gland, unspecified site

Oral cavity NOS

146 Malignant neoplasm of oropharynx

146.0 Tonsil

Tonsil:

NOS

faucial

palatine

Excludes: lingual tonsil (141.6)

pharyngeal tonsil (147.1)

146.1 Tonsillar fossa

146.2 Tonsillar pillars (anterior) (posterior)

Faucial pillar Glossopalatine fold Palatoglossal arch Palatopharyngeal arch

146.3 Vallecula

Anterior and medial surface of the pharyngoepiglottic fold

146.4 Anterior aspect of epiglottis

Epiglottis, free border [margin]

Glossoepiglottic fold(s)

Excludes: epiglottis:

NOS (161.1)

suprahyoid portion (161.1)

146.5 Junctional region

Junction of the free margin of the epiglottis, the aryepiglottic fold, and the pharyngoepiglottic fold

146.6 Lateral wall of oropharynx

146.7 Posterior wall of oropharynx

146.8 Other specified sites of oropharynx

Branchial cleft

Malignant neoplasm of contiguous or overlapping sites of oropharynx whose point of origin cannot be

determined

146.9 Oropharynx, unspecified

147 Malignant neoplasm of nasopharynx

147.0 Superior wall

Roof of nasopharynx

147.1 Posterior wall

Adenoid

Pharyngeal tonsil

147.2 Lateral wall

Fossa of Rosenmüller Opening of auditory tube Pharyngeal recess

147.3 Anterior wall

Floor of nasopharynx

Nasopharyngeal [posterior] [superior] surface of soft palate

Posterior margin of nasal septum and choanae

147.8 Other specified sites of nasopharynx

Malignant neoplasm of contiguous or overlapping sites of nasopharynx whose point of origin cannot be determined

147.9 Nasopharynx, unspecified Nasopharyngeal wall NOS

148 Malignant neoplasm of hypopharynx

148.0 Postcricoid region

148.1 Pyriform sinus

Pyriform fossa

148.2 Aryepiglottic fold, hypopharyngeal aspect

Aryepiglottic fold or interarytenoid fold:

NOS

marginal zone

Excludes: aryepiglottic fold or interarytenoid fold, laryngeal aspect (161.1)

148.3 Posterior hypopharyngeal wall

148.8 Other specified sites of hypopharynx

Malignant neoplasm of contiguous or overlapping sites of hypopharynx whose point of origin cannot be

determined

148.9 Hypopharynx, unspecified

Hypopharyngeal wall NOS

Hypopharynx NOS

Malignant neoplasm of other and ill-defined sites within the lip, oral cavity, and pharynx

149.0 Pharynx, unspecified

149.1 Waldeyer's ring

149.8 Other

Malignant neoplasms of lip, oral cavity, and pharynx whose point of origin cannot be assigned to any one of the

categories 140-148

Excludes: "book leaf" neoplasm [ventral surface of tongue and floor of mouth] (145.8)

149.9 Ill-defined

MALIGNANT NEOPLASM OF DIGESTIVE ORGANS AND PERITONEUM (150-159)

Excludes: carcinoma in situ (230.1-230.9)

150 Malignant neoplasm of esophagus

150.0 Cervical esophagus

150.1 Thoracic esophagus

150.2 Abdominal esophagus

Excludes: adenocarcinoma (151.0)

cardio-esophageal junction (151.0)

150.3 Upper third of esophagus

Proximal third of esophagus

150.4 Middle third of esophagus

150.5 Lower third of esophagus

Distal third of esophagus

Excludes: adenocarcinoma (151.0)

cardio-esophageal junction (151.0)

150.8 Other specified part

Malignant neoplasm of contiguous or overlapping sites of esophagus whose point of origin cannot be

determined

150.9 Esophagus, unspecified

151 Malignant neoplasm of stomach

Excludes: benign carcinoid tumor of stomach (209.63)

malignant carcinoid tumor of stomach (209.63)

151.0 Cardia

Cardiac orifice

Cardio-esophageal junction

Excludes: squamous cell carcinoma (150.2, 150.5)

151.1 Pylorus

Prepylorus Pyloric canal

151.2 Pyloric antrum

Antrum of stomach NOS

151.3 Fundus of stomach

151.4 Body of stomach

151.5 Lesser curvature, unspecified

Lesser curvature, not classifiable to 151.1-151.4

151.6 Greater curvature, unspecified

Greater curvature, not classifiable to 151.0-151.4

151.8 Other specified sites of stomach

Anterior wall, not classifiable to 151.0-151.4 Posterior wall, not classifiable to 151.0-151.4

Malignant neoplasm of contiguous or overlapping sites of stomach whose point of origin cannot be determined

151.9 Stomach, unspecified

Carcinoma ventriculi Gastric cancer

Malignant neoplasm of small intestine, including duodenum

Excludes: benign carcinoid tumor of small intestine and duodenum (209.40-209.43)

malignant carcinoid tumor of small intestine and duodenum (209.00-209.03)

152.0 Duodenum

152.1 Jejunum152.2 Ileum

Excludes: ileocecal valve (153.4)

152.3 Meckel's diverticulum

152.8 Other specified sites of small intestine

Duodenojejunal junction

Malignant neoplasm of contiguous or overlapping sites of small intestine whose point of origin cannot be

determined

152.9 Small intestine, unspecified

153 Malignant neoplasm of colon

Excludes: benign carcinoid tumor of colon (209.50-209.56)

malignant carcinoid tumor of colon (209.10-209.16)

153.0 Hepatic flexure

153.1 Transverse colon

153.2 Descending colon

Left colon

153.3 Sigmoid colon

Sigmoid (flexure)

Excludes: rectosigmoid junction (154.0)

153.4 Cecum

lleocecal valve

153.5 Appendix

153.6 Ascending colon

Right colon

153.7 Splenic flexure

153.8 Other specified sites of large intestine

Malignant neoplasm of contiguous or overlapping sites of colon whose point of origin cannot be determined

Excludes: ileocecal valve (153.4)

rectosigmoid junction (154.0)

153.9 Colon, unspecified

Large intestine NOS

154 Malignant neoplasm of rectum, rectosigmoid junction, and anus

Excludes: benign carcinoid tumor of rectum (209.57)

malignant carcinoid tumor of rectum (209.17)

154.0 Rectosigmoid junction

Colon with rectum Rectosigmoid (colon)

154.1 Rectum

Rectal ampulla

154.2 Anal canal

Anal sphincter

Excludes: skin of anus (172.5, 173.5)

> **154**.3 Anus, unspecified anus:

Excludes:

margin (172.5, 173.5) skin (172.5, 173.5)

perianal skin (172.5, 173.5)

154.8 Other

> Anorectum Cloacogenic zone

Malignant neoplasm of contiguous or overlapping sites of rectum, rectosigmoid junction, and anus whose point

of origin cannot be determined

155 Malignant neoplasm of liver and intrahepatic bile ducts

155.0 Liver, primary

Carcinoma:

liver, specified as primary

hepatocellular liver cell Hepatoblastoma

155.1 Intrahepatic bile ducts

> Canaliculi biliferi Interlobular: bile ducts biliary canals Intrahepatic: biliary passages canaliculi gall duct

Excludes: hepatic duct (156.1)

> Liver, not specified as primary or secondary 155.2

156 Malignant neoplasm of gallbladder and extrahepatic bile ducts

156.0 Gallbladder

156.1 Extrahepatic bile ducts

Biliary duct or passage

NOS

Common bile duct Cystic duct Hepatic duct Sphincter of Oddi

156.2 Ampulla of Vater

Other specified sites of gallbladder and extrahepatic bile ducts 156.8

Malignant neoplasm of contiguous or overlapping sites of gallbladder and extrahepatic bile ducts whose point of origin cannot be determined

156.9 Biliary tract, part unspecified

157 Malignant neoplasm of pancreas

157.0 Head of pancreas

157.1 Body of pancreas

157.2 Tail of pancreas

157.3 Pancreatic duct

Duct of:

Santorini

Wirsung

157.4 Islets of Langerhans

Islets of Langerhans, any part of pancreas

Use additional code to identify any functional activity

157.8 Other specified sites of pancreas

Ectopic pancreatic tissue

Malignant neoplasm of contiguous or overlapping sites of pancreas whose point of origin cannot be determined

157.9 Pancreas, part unspecified

Malignant neoplasm of retroperitoneum and peritoneum

158.0 Retroperitoneum

Periadrenal tissue

Perinephric tissue

Perirenal tissue

Retrocecal tissue

158.8 Specified parts of peritoneum

Cul-de-sac (of Douglas)

Mesentery

Mesocolon

Omentum

Peritoneum:

parietal

pelvic

Rectouterine pouch

Malignant neoplasm of contiguous or overlapping sites of retroperitoneum and peritoneum whose point of origin cannot be determined

158.9 Peritoneum, unspecified

Malignant neoplasm of other and ill-defined sites within the digestive organs and peritoneum

159.0 Intestinal tract, part unspecified

Intestine NOS

159.1 Spleen, not elsewhere classified

Angiosarcoma of spleen

Fibrosarcoma of spleen

Excludes: Hodgkin's disease (201.0-201.9)

lymphosarcoma (200.1) reticulosarcoma (200.0)

159.8 Other sites of digestive system and intra-abdominal organs

Malignant neoplasm of digestive organs and peritoneum whose point of origin cannot be assigned to any one of

the categories 150-158

Excludes: anus and rectum (154.8)

cardio-esophageal junction (151.0)

colon and rectum (154.0)

159.9 Ill-defined

Excludes:

Alimentary canal or tract NOS Gastrointestinal tract NOS abdominal NOS (195.2)

intra-abdominal NOS (195.2)

MALIGNANT NEOPLASM OF RESPIRATORY AND INTRATHORACIC ORGANS (160-165)

Excludes: carcinoma in situ (231.0-231.9)

Malignant neoplasm of nasal cavities, middle ear, and accessory sinuses

160.0 Nasal cavities

Cartilage of nose Conchae, nasal Internal nose Septum of nose Vestibule of nose nasal bone (170

Excludes: nasal bone (170.0) nose NOS (195.0)

olfactory bulb (192.0)

posterior margin of septum and choanae (147.3)

skin of nose (172.3, 173.3)

turbinates (170.0)

160.1 Auditory tube, middle ear, and mastoid air cells

Antrum tympanicum Eustachian tube Tympanic cavity

Excludes: auditory canal (external) (172.2, 173.2)

bone of ear (meatus) (170.0) cartilage of ear (171.0) ear (external) (skin) (172.2, 173.2)

160.2 Maxillary sinus

Antrum (Highmore) (maxillary)

160.3 Ethmoidal sinus160.4 Frontal sinus160.5 Sphenoidal sinus

160.8 Other

Malignant neoplasm of contiguous or overlapping sites of nasal cavities, middle ear, and accessory sinuses whose point of origin cannot be determined

160.9 Accessory sinus, unspecified

161 Malignant neoplasm of larynx

161.0 Glottis

Intrinsic larynx

Laryngeal commissure (anterior) (posterior)

True vocal cord Vocal cord NOS

161.1 Supraglottis

Aryepiglottic fold or interarytenoid fold, laryngeal aspect

Epiglottis (suprahyoid portion) NOS

Extrinsic larynx False vocal cords

Posterior (laryngeal) surface of epiglottis

Ventricular bands

Excludes: anterior aspect of epiglottis (146.4)

aryepiglottic fold or interarytenoid fold:

NOS (148.2)

hypopharyngeal aspect (148.2)

marginal zone (148.2)

161.2 Subglottis

161.3 Laryngeal cartilages

Cartilage: arytenoid cricoid cuneiform thyroid

161.8 Other specified sites of larynx

Malignant neoplasm of contiguous or overlapping sites of larynx whose point of origin cannot be determined

161.9 Larvnx, unspecified

Malignant neoplasm of trachea, bronchus, and lung

Excludes: benign carcinoid tumor of bronchus (209.61)

malignant carcinoid tumor of bronchus (209.21)

162.0 Trachea

Cartilage of trachea Mucosa of trachea

162.2 Main bronchus

Carina Hilus of lung

162.3 Upper lobe, bronchus or lung

162.4 Middle lobe, bronchus or lung

162.5 Lower lobe, bronchus or lung162.8 Other parts of bronchus or lung

Malignant neoplasm of contiguous or overlapping sites of bronchus or lung whose point of origin cannot be

determined

162.9 Bronchus and lung, unspecified

163 Malignant neoplasm of pleura

163.0 Parietal pleura

163.1 Visceral pleura

163.8 Other specified sites of pleura

Malignant neoplasm of contiguous or overlapping sites of pleura whose point of origin cannot be determined

163.9 Pleura, unspecified

Malignant neoplasm of thymus, heart, and mediastinum

164.0 Thymus

Excludes: benign carcinoid tumor of the thymus (209.62)

malignant carcinoid tumor of the thymus (209.22)

164.1 Heart

Endocardium Epicardium Myocardium Pericardium

Excludes: great vessels (171.4)

164.2 Anterior mediastinum164.3 Posterior mediastinum

164.8 Other

Malignant neoplasm of contiguous or overlapping sites of thymus, heart, and mediastinum whose point of origin

cannot be determined

164.9 Mediastinum, part unspecified

165 Malignant neoplasm of other and ill-defined sites within the respiratory system and intrathoracic organs

165.0 Upper respiratory tract, part unspecified

165.8 Other

Malignant neoplasm of respiratory and intrathoracic organs whose point of origin cannot be assigned to any one of the categories 160-164

165.9 Ill-defined sites within the respiratory system

Respiratory tract NOS

Excludes: intrathoracic NOS (195.1)

thoracic NOS (195.1)

MALIGNANT NEOPLASM OF BONE, CONNECTIVE TISSUE, SKIN, AND BREAST (170-176)

Excludes: carcinoma in situ:

breast (233.0) skin (232.0-232.9)

170 Malignant neoplasm of bone and articular cartilage

Costal cartilage

```
Includes:
                cartilage (articular) (joint)
           periosteum
                bone marrow NOS (202.9)
Excludes:
           cartilage:
             ear (171.0)
eyelid (171.0)
             larynx (161.3)
             nose (160.0)
           synovia (171.0-171.9)
               Bones of skull and face, except mandible
       170.0
                   ethmoid
                   frontal
                   malar
                   nasal
                   occipital
                   orbital
                   parietal
                   sphenoid
                   temporal
                  zygomatic
                 Maxilla (superior)
                 Turbinate
                 Upper jaw bone
                 Vomer
Excludes:
                carcinoma, any type except intraosseous or odontogenic:
                   maxilla, maxillary (sinus) (160.2)
                   upper jaw bone (143.0)
                  jaw bone (lower) (170.1)
       170.1
               Mandible
                 Inferior maxilla
                 Jaw bone NOS
                Lower jaw bone
Excludes:
                carcinoma, any type except intraosseous or odontogenic:
                   jaw bone NOS (143.9)
                   lower (143.1)
                   upper jaw bone (170.0)
       170.2
               Vertebral column, excluding sacrum and coccyx
                 Spinal column
                 Spine
                 Vertebra
Excludes:
                sacrum and coccyx (170.6)
       170.3
                Ribs, sternum, and clavicle
```

Costovertebral joint

Xiphoid process

170.4 Scapula and long bones of upper limb

Acromion

Bones NOS of upper limb

Humerus Radius Ulna

170.5 Short bones of upper limb

Carpal

Cuneiform, wrist

Metacarpal

Navicular, of hand

Phalanges of hand

Pisiform

Scaphoid (of hand)

Semilunar or lunate

Trapezium

Trapezoid

Unciform

170.6 Pelvic bones, sacrum, and coccyx

Coccygeal vertebra

llium

Ischium Pubic bone

Sacral vertebra

170.7 Long bones of lower limb

Bones NOS of lower limb

Femur Fibula Tibia

170.8 Short bones of lower limb

Astragalus [talus]

Calcaneus

Cuboid

Cuneiform, ankle

Metatarsal

Navicular (of ankle)

Patella

Phalanges of foot

Tarsal

170.9 Bone and articular cartilage, site unspecified

171 Malignant neoplasm of connective and other soft tissue

Includes: blood vessel

bursa fascia fat

ligament, except uterine

peripheral, sympathetic, and parasympathetic nerves and ganglia

```
synovia
           tendon (sheath)
Excludes:
                cartilage (of):
             articular (170.0-170.9)
             larynx (161.3)
             nose (160.0)
           connective tissue:
             breast (174.0-175.9)
             internal organs code to malignant neoplasm of the site [e.g., leiomyosarcoma of stomach, 151.9]
             uterine ligament (183.4)
               Head, face, and neck
                 Cartilage of:
                   ear
                   eyelid
               Upper limb, including shoulder
       171.2
                 Arm
                 Finger
                 Forearm
                 Hand
               Lower limb, including hip
       171.3
                 Foot
                 Leg
                 Popliteal space
                 Thigh
                 Toe
       171.4
               Thorax
                 Axilla
                 Diaphragm
                 Great vessels
Excludes:
                heart (164.1)
                 mediastinum (164.2-164.9)
                 thymus (164.0)
       171.5
               Abdomen
                 Abdominal wall
                 Hypochondrium
Excludes:
                peritoneum (158.8)
                 retroperitoneum (158.0)
       171.6
                Pelvis
                 Buttock
                 Groin
                 Inguinal region
                 Perineum
Excludes:
                pelvic peritoneum (158.8)
                 retroperitoneum (158.0)
                 uterine ligament, any (183.3-183.5)
       171.7
               Trunk, unspecified
                 Back NOS
```

Flank NOS

171.8 Other specified sites of connective and other soft tissue

Malignant neoplasm of contiguous or overlapping sites of connective tissue whose point of origin cannot be determined

171.9 Connective and other soft tissue, site unspecified

172 Malignant melanoma of skin

Includes: melanocarcinoma

melanoma in situ of skin melanoma (skin) NOS

Excludes: skin of genital organs (184.0-184.9, 187.1-187.9)

sites other than skin - code to malignant neoplasm of the site

172.0 Lip

Excludes: vermilion border of lip (140.0-140.1, 140.9)

172.1 Eyelid, including canthus

172.2 Ear and external auditory canal

Auricle (ear)

Auricular canal, external External [acoustic] meatus

Pinna

172.3 Other and unspecified parts of face

Cheek (external)

Chin Eyebrow Forehead Nose, external Temple

172.4 Scalp and neck

172.5 Trunk, except scrotum

Axilla Breast Buttock Groin Perianal s

Perianal skin Perineum Umbilicus

Excludes: anal canal (154.2)

anus NOS (154.3) scrotum (187.7)

172.6 Upper limb, including shoulder

Arm Finger Forearm Hand

172.7 Lower limb, including hip

Ankle Foot Heel Knee Leg

Popliteal area

Thigh

Toe

172.8 Other specified sites of skin

Malignant melanoma of contiguous or overlapping sites of skin whose point of origin cannot be determined

172.9 Melanoma of skin, site unspecified

Other malignant neoplasm of skin

Includes: malignant neoplasm of:

sebaceous glands

sudoriferous, sudoriparous glands

sweat glands

Excludes: Kaposi's sarcoma (176.0-176.9)

malignant melanoma of skin (172.0-172.9) skin of genital organs (184.0-184.9, 187.1-187.9)

173.0 Skin of lip

Excludes: vermilion border of lip (140.0-140.1, 140.9)

173.1 Eyelid, including canthus

Excludes: cartilage of eyelid (171.0)

173.2 Skin of ear and external auditory canal

Auricle (ear)

Auricular canal, external

External meatus

Pinna

Excludes: cartilage of ear (171.0)

173.3 Skin of other and unspecified parts of face

Cheek, external

Chin Eyebrow Forehead Nose, external Temple

173.4 Scalp and skin of neck

173.5 Skin of trunk, except scrotum

Axillary fold Perianal skin Skin of:

abdominal wall

anus back breast buttock chest wall groin perineum Umbilicus

Excludes: anal canal (154.2)

anus NOS (154.3) skin of scrotum (187.7)

173.6 Skin of upper limb, including shoulder

Arm Finger Forearm Hand

173.7 Skin of lower limb, including hip

Ankle Foot Heel Knee Leg

Popliteal area Thigh

Toe

173.8 Other specified sites of skin

Malignant neoplasm of contiguous or overlapping sites of skin whose point of origin cannot be determined

173.9 Skin, site unspecified

174 Malignant neoplasm of female breast

Includes: breast (female)

connective tissue soft parts Paget's disease of: breast

nipple

Use additional code to identify estrogen receptor status (V86.0, V86.1)

Excludes: skin of breast (172.5, 173.5)

174.0 Nipple and areola

174.1 Central portion

174.2 Upper-inner quadrant
174.3 Lower-inner quadrant
174.4 Upper-outer quadrant
174.5 Lower-outer quadrant

174.6 Axillary tail

174.8 Other specified sites of female breast

Ectopic sites Inner breast Lower breast Midline of breast Outer breast Upper breast

Malignant neoplasm of contiguous or overlapping sites of breast whose point of origin cannot be determined

174.9 Breast (female), unspecified

175 Malignant neoplasm of male breast

Use additional code to identify estrogen receptor status (V86.0, V86.1)

Excludes: skin of breast (172.5, 173.5)

175.0 Nipple and areola

175.9 Other and unspecified sites of male breast

Ectopic breast tissue, male

176 Kaposi's sarcoma

176.0 Skin

176.1 Soft tissue

Blood vessel Connective tissue

Fascia Ligament

Lymphatic(s) NEC

Muscle

Excludes: lymph glands and nodes (176.5)

176.2 Palate

176.3 Gastrointestinal sites

176.4 Lung

176.5 Lymph nodes

176.8 Other specified sites

Oral cavity NEC

176.9 Unspecified

Viscera NOS

MALIGNANT NEOPLASM OF GENITOURINARY ORGANS (179-189)

Excludes: carcinoma in situ (233.1-233.9)

179 Malignant neoplasm of uterus, part unspecified

180 Malignant neoplasm of cervix uteri

Includes: invasive malignancy [carcinoma]

Excludes: carcinoma in situ (233.1)

180.0 Endocervix

Cervical canal NOS Endocervical canal Endocervical gland

180.1 Exocervix

180.8 Other specified sites of cervix

Cervical stump

Squamocolumnar junction of cervix

Malignant neoplasm of contiguous or overlapping sites of cervix uteri whose point of origin cannot be determined

180.9 Cervix uteri, unspecified

181 Malignant neoplasm of placenta

Choriocarcinoma NOS Chorioepithelioma NOS

Excludes: chorioadenoma (destruens) (236.1)

hydatidiform mole (630) malignant (236.1) invasive mole (236.1)

male choriocarcinoma NOS (186.0-186.9)

182 Malignant neoplasm of body of uterus

Excludes: carcinoma in situ (233.2)

182.0 Corpus uteri, except isthmus

Cornu Endometrium Fundus Myometrium

182.1 Isthmus

Lower uterine segment

182.8 Other specified sites of body of uterus

Malignant neoplasm of contiguous or overlapping sites of body of uterus whose point of origin cannot be

determined

Excludes: uterus NOS (179)

183 Malignant neoplasm of ovary and other uterine adnexa

Excludes: Douglas' cul-de-sac (158.8)

183.0 Ovary

Use additional code to identify any functional activity

183.2 Fallopian tube

Oviduct Uterine tube

183.3 Broad ligament

Mesovarium

Parovarian region

183.4 Parametrium

Uterine ligament NOS Uterosacral ligament 183.5 Round ligament

183.8 Other specified sites of uterine adnexa

Tubo-ovarian Utero-ovarian

Malignant neoplasm of contiguous or overlapping sites of ovary and other uterine adnexa whose point of origin cannot be determined

183.9 Uterine adnexa, unspecified

Malignant neoplasm of other and unspecified female genital organs

Excludes: carcinoma in situ (233.30-233.39)

184.0 Vagina

Gartner's duct Vaginal vault

184.1 Labia majora

Greater vestibular [Bartholin's] gland

184.2 Labia minora

184.3 Clitoris

184.4 Vulva, unspecified

External female genitalia NOS

Pudendum

184.8 Other specified sites of female genital organs

Malignant neoplasm of contiguous or overlapping sites of female genital organs whose point of origin cannot be determined

184.9 Female genital organ, site unspecified Female genitourinary tract NOS

Malignant neoplasm of prostate

Excludes: seminal vesicles (187.8)

186 Malignant neoplasm of testis

185

Use additional code to identify any functional activity

186.0 Undescended testis

Ectopic testis

Retained testis

186.9 Other and unspecified testis

Testis: NOS descended scrotal

Malignant neoplasm of penis and other male genital organs

187.1 Prepuce

Foreskin

187.2 Glans penis

187.3 Body of penis

Corpus cavernosum

187.4 Penis, part unspecified Skin of penis NOS

187.5 Epididymis

187.6 Spermatic cord

Vas deferens

187.7 Scrotum

Skin of scrotum

187.8 Other specified sites of male genital organs

Seminal vesicle Tunica vaginalis

Malignant neoplasm of contiguous or overlapping sites of penis and other male genital organs whose point of origin cannot be determined

187.9 Male genital organ, site unspecified Male genital organ or tract NOS

188 Malignant neoplasm of bladder

Excludes: carcinoma in situ (233.7)

188.0 Trigone of urinary bladder

188.1 Dome of urinary bladder

188.2 Lateral wall of urinary bladder

188.3 Anterior wall of urinary bladder

188.4 Posterior wall of urinary bladder

188.5 Bladder neck

Internal urethral orifice

188.6 Ureteric orifice

188.7 Urachus

188.8 Other specified sites of bladder

Malignant neoplasm of contiguous or overlapping sites of bladder whose point of origin cannot be determined

188.9 Bladder, part unspecified

Bladder wall NOS

Malignant neoplasm of kidney and other and unspecified urinary organs

Excludes: benign carcinoid tumor of kidney (209.64)

malignant carcinoid tumor of kidney (209.64)

189.0 Kidney, except pelvis

Kidney NOS

Kidney parenchyma

189.1 Renal pelvis

Renal calyces Ureteropelvic junction

189.2 Ureter

Excludes: ureteric orifice of bladder (188.6)

189.3 Urethra

Excludes: urethral orifice of bladder (188.5)

189.4 Paraurethral glands

189.8 Other specified sites of urinary organs

Malignant neoplasm of contiguous or overlapping sites of kidney and other urinary organs whose point of origin

cannot be determined

189.9 Urinary organ, site unspecified

Urinary system NOS

MALIGNANT NEOPLASM OF OTHER AND UNSPECIFIED SITES (190-199)

Excludes: carcinoma in situ (234.0-234.9)

190 Malignant neoplasm of eye

Excludes: carcinoma in situ (234.0)

dark area on retina and choroid (239.81)

eyelid (skin) (172.1, 173.1) cartilage (171.0)

optic nerve (192.0)

orbital bone (170.0) retinal freckle (239.81)

190.0 Eyeball, except conjunctiva, cornea, retina, and choroid

Ciliary body

Crystalline lens Iris Sclera

Uveal tract

190.1 Orbit

Connective tissue of orbit

Extraocular muscle

Retrobulbar

Excludes: bone of orbit (170.0)

190.2 Lacrimal gland

190.3 Conjunctiva

190.4 Cornea

190.5 Retina

190.6 Choroid

190.7 Lacrimal duct

Lacrimal sac

Nasolacrimal duct

190.8 Other specified sites of eye

Malignant neoplasm of contiguous or overlapping sites of eye whose point of origin cannot be determined

190.9 Eye, part unspecified

191 Malignant neoplasm of brain

Excludes: cranial nerves (192.0)

retrobulbar area (190.1)

191.0 Cerebrum, except lobes and ventricles

Basal ganglia Cerebral cortex Corpus striatum Globus pallidus Hypothalamus Thalamus

191.1 Frontal lobe

191.2 Temporal lobe

Hippocampus

Uncus

191.3 Parietal lobe

191.4 Occipital lobe

191.5 Ventricles

Choroid plexus Floor of ventricle

191.6 Cerebellum NOS

Cerebellopontine angle

191.7 Brain stem

Cerebral peduncle

Medulla oblongata

Midbrain

Pons

191.8 Other parts of brain

Corpus callosum

Tapetum

Malignant neoplasm of contiguous or overlapping sites of brain whose point of origin cannot be determined

191.9 Brain, unspecified

Cranial fossa NOS

Malignant neoplasm of other and unspecified parts of nervous system

Excludes: peripheral, sympathetic, and parasympathetic nerves and ganglia (171.0-171.9)

192.0 Cranial nerves

Olfactory bulb

192.1 Cerebral meninges

Dura (mater)

Falx (cerebelli) (cerebri)

Meninges NOS

Tentorium

192.2 Spinal cord

Cauda equina

192.3 Spinal meninges

192.8 Other specified sites of nervous system

Malignant neoplasm of contiguous or overlapping sites of other parts of nervous system whose point of origin

cannot be determined

192.9 Nervous system, part unspecified

Nervous system (central) NOS

Excludes: meninges NOS (192.1)

193 Malignant neoplasm of thyroid gland

Thyroglossal duct

Use additional code to identify any functional activity

Malignant neoplasm of other endocrine glands and related structures

Excludes: islets of Langerhans (157.4)

neuroendocrine tumors (209.00-209.69)

ovary (183.0)

testis (186.0-186.9)

thymus (164.0)

194.0 Adrenal gland

Adrenal cortex Adrenal medulla

Suprarenal gland

194.1 Parathyroid gland

194.3 Pituitary gland and craniopharyngeal duct

Craniobuccal pouch

Hypophysis

Rathke's pouch

Sella turcica

194.4 Pineal gland

194.5 Carotid body

194.6 Aortic body and other paraganglia

Coccygeal body

Glomus jugulare

Para-aortic body

194.8 Other

Pluriglandular involvement NOS

Note: If the sites of multiple involvements are known, they should be coded separately.

195 Malignant neoplasm of other and ill-defined sites

Includes: malignant neoplasms of contiguous sites, not elsewhere classified, whose point of origin cannot be determined

Excludes: malignant neoplasm:

lymphatic and hematopoietic tissue (200.0-208.9)

secondary sites (196.0-198.8) unspecified site (199.0-199.1)

195.0 Head, face, and neck

Cheek NOS Jaw NOS Nose NOS

Supraclavicular region NOS

195.1 Thorax

Axilla

Chest (wall) NOS Intrathoracic NOS

195.2 Abdomen

Intra-abdominal NOS

195.3 Pelvis

Groin

Inguinal region NOS Presacral region Sacrococcygeal region

Sites overlapping systems within pelvis, as:

rectovaginal (septum) rectovesical (septum)

195.4 Upper limb195.5 Lower limb

195.8 Other specified sites

Back NOS Flank NOS Trunk NOS

196 Secondary and unspecified malignant neoplasm of lymph nodes

Excludes: any malignant neoplasm of lymph nodes, specified as primary (200.0-202.9)

Hodgkin's disease (201.0-201.9) lymphosarcoma (200.1)

reticulosarcoma (200.0)

other forms of lymphoma (202.0-202.9)

secondary neuroendocrine tumor of (distant) lymph nodes (209.71)

196.0 Lymph nodes of head, face, and neck

Cervical Cervicofacial Scalene Supraclavicular 196.1 Intrathoracic lymph nodes

Bronchopulmonary

Intercostal

Mediastinal

Tracheobronchial

196.2 Intra-abdominal lymph nodes

Intestinal

Mesenteric

Retroperitoneal

196.3 Lymph nodes of axilla and upper limb

Brachial

Epitrochlear

Infraclavicular

Pectoral

196.5 Lymph nodes of inguinal region and lower limb

Femoral

Groin

Popliteal

Tibial

196.6 Intrapelvic lymph nodes

Hypogastric

Iliac

Obturator

Parametrial

196.8 Lymph nodes of multiple sites

196.9 Site unspecified

Lymph nodes NOS

197 Secondary malignant neoplasm of respiratory and digestive systems

Excludes: lymph node metastasis (196.0-196.9)

secondary neuroendocrine tumor of liver (209.72)

secondary neuroendocrine tumor of respiratory organs (209.79)

197.0 Lung

Bronchus

197.1 Mediastinum

197.2 Pleura

197.3 Other respiratory organs

Trachea

197.4 Small intestine, including duodenum

197.5 Large intestine and rectum

197.6 Retroperitoneum and peritoneum

197.7 Liver, specified as secondary

197.8 Other digestive organs and spleen

198

Excludes: lymph node metastasis (196.0-196.9)

secondary neuroendocrine tumor of other specified sites (209.79)

198.0 Kidney

198.1 Other urinary organs

198.2 Skin

Skin of breast

198.3 Brain and spinal cord

198.4 Other parts of nervous system Meninges (cerebral) (spinal)

198.5 Bone and bone marrow

198.6 Ovary

198.7 Adrenal gland

Suprarenal gland

198.8 Other specified sites

198.81 Breast

Excludes: skin of breast (198.2)

198.82 Genital organs

198.89 Other

Excludes: retroperitoneal lymph nodes (196.2)

199 Malignant neoplasm without specification of site

Excludes: malignant carcinoid tumor of unknown primary site (209.20)

malignant (poorly differentiated) neuroendocrine carcinoma, any site (209.30) malignant (poorly differentiated) neuroendocrine tumor, any site (209.30)

neuroendocrine carcinoma (high grade), any site (209.30)

199.0 Disseminated

Carcinomatosis unspecified site (primary) (secondary)

Generalized:

cancer unspecified site (primary) (secondary) malignancy unspecified site (primary) (secondary) Multiple cancer unspecified site (primary) (secondary)

199.1 Other

Cancer unspecified site (primary) (secondary)
Carcinoma unspecified site (primary) (secondary)
Malignancy unspecified site (primary) (secondary)

199.2 Malignant neoplasm associated with transplanted organ

Code first complication of transplanted organ (996.80-996.89)

Use additional code for specific malignancy

MALIGNANT NEOPLASM OF LYMPHATIC AND HEMATOPOIETIC TISSUE (200-208)

```
secondary neoplasm of:
             bone marrow (198.5)
             spleen (197.8)
           secondary and unspecified neoplasm of lymph nodes (196.0-196.9)
The following fifth-digit subclassification is for use with categories 200-202:
           0 unspecified site, extranodal and solid organ sites
           1 lymph nodes of head, face, and neck
           2 intrathoracic lymph nodes
           3 intra-abdominal lymph nodes
           4 lymph nodes of axilla and upper limb
           5 lymph nodes of inguinal region and lower limb
           6 intrapelvic lymph nodes
           7 spleen
           8 lymph nodes of multiple sites
200
        Lymphosarcoma and reticulosarcoma and other specified malignant tumors of lymphatic tissue
Requires fifth digit. See note before section 200 for codes and definitions.
       200.0
                Reticulosarcoma
       [8-0]
                 Lymphoma (malignant):
                   histiocytic (diffuse):
                     nodular
                     pleomorphic cell type
                   reticulum cell type
                 Reticulum cell sarcoma:
                   NOS
                   pleomorphic cell type
       200.1
                Lymphosarcoma
       [8-0]
                 Lymphoblastoma (diffuse)
                 Lymphoma (malignant):
                   lymphoblastic (diffuse)
                   lymphocytic (cell type) (diffuse)
                   lymphosarcoma type
                 Lymphosarcoma:
                   NOS
                   diffuse NOS
                   lymphoblastic (diffuse)
                   lymphocytic (diffuse)
                   prolymphocytic
Excludes:
                lymphosarcoma:
                   follicular or nodular (202.0)
                   mixed cell type (200.8)
                 lymphosarcoma cell leukemia (207.8)
       200.2
                Burkitt's tumor or lymphoma
       [8-0]
                 Malignant lymphoma, Burkitt's type
       200.3
                Marginal zone lymphoma
       [8-0]
```

autoimmune lymphoproliferative syndrome (279.41)

Excludes:

Extranodal marginal zone B cell lymphoma Mucosa associated lymphoid tissue [MALT] Nodal marginal zone B cell lymphoma Splenic marginal zone B cell lymphoma 200.4 Mantle cell lymphoma [8-0] 200.5 Primary central nervous system lymphoma [8-0] 200.6 Anaplastic large cell lymphoma [8-0] 200.7 Large cell lymphoma [8-0] 200.8 Other named variants [8-0] Lymphoma (malignant): lymphoplasmacytoid type mixed lymphocytic-histiocytic (diffuse) Lymphosarcoma, mixed cell type (diffuse)

201 Hodgkin's disease

Requires fifth digit. See note before section 200 for codes and definitions.

Reticulolymphosarcoma (diffuse)

201.0 Hodgkin's paragranuloma [8-0] 201.1 Hodgkin's granuloma [8-0]201.2 Hodgkin's sarcoma [8-0] 201.4 Lymphocytic-histiocytic predominance [8-0] 201.5 Nodular sclerosis [8-0] Hodgkin's disease, nodular sclerosis: NŎS cellular phase 201.6 Mixed cellularity [8-0] 201.7 Lymphocytic depletion [8-0] Hodgkin's disease, lymphocytic depletion: NÖS diffuse fibrosis reticular type 201.9 Hodgkin's disease, unspecified

[8-0]

Hodgkin's: disease NOS lymphoma NOS Malignant:

lymphogranuloma lymphogranulomatosis

202 Other malignant neoplasms of lymphoid and histiocytic tissue

Requires fifth digit. See note before section 200 for codes and definitions.

202.0 Nodular lymphoma

[8-0]

Brill-Symmers disease

Lymphoma:

follicular (giant) (large cell) lymphocytic, nodular Lymphosarcoma: follicular (giant) nodular

202.1 Mycosis fungoides

[8-0]

Excludes: peripheral T-cell lymphoma (202.7)

> 202.2 Sézary's disease

[8-0]

202.3 Malignant histiocytosis

[8-0]

Histiocytic medullary reticulosis

Malignant:

reticuloendotheliosis

reticulosis

202.4 Leukemic reticuloendotheliosis

[8-0]

Hairy-cell leukemia

202.5 Letterer-Siwe disease

[8-0]

Acute:

differentiated progressive histiocytosis

histiocytosis X (progressive) infantile reticuloendotheliosis

reticulosis of infancy

Excludes: Hand-Schüller-Christian disease (277.89)

histiocytosis (acute) (chronic) (277.89) histiocytosis X (chronic) (277.89)

202.6 Malignant mast cell tumors

[0-8]

Malignant: mastocytoma mastocytosis Mast cell sarcoma Systemic tissue mast cell disease Excludes: mast cell leukemia (207.8)

202.7 Peripheral T cell lymphoma

[8-0]

202.8 Other lymphomas

[8-0]

Lymphoma (malignant):

NOS diffuse

Excludes: benign lymphoma (229.0)

202.9 Other and unspecified malignant neoplasms of lymphoid and histiocytic tissue

[8-0]

Follicular dendritic cell sarcoma Interdigitating dendritic cell sarcoma

Langerhans cell sarcoma

Malignant neoplasm of bone marrow NOS

203 Multiple myeloma and immunoproliferative neoplasms

The following fifth-digit subclassification is for use with category 203:

0 without mention of having achieved remission

failed remission

1 in remission

2 in relapse

203.0 Multiple myeloma

[0-2]

Kahler's disease

Myelomatosis

Excludes: solitary myeloma (238.6)

203.1 Plasma cell leukemia

[0-2]

Plasmacytic leukemia

203.8 Other immunoproliferative neoplasms

[0-2]

204 Lymphoid leukemia

Includes: leukemia:

lymphatic lymphoblastic lymphocytic lymphogenous

The following fifth-digit subclassification is for use with category 204:

0 without mention of having achieved remission

failed remission

1 in remission

2 in relapse

204.0 Acute

[0-2]

```
acute exacerbation of chronic lymphoid leukemia (204.1)
Excludes:
       204.1
               Chronic
       [0-2]
       204.2
               Subacute
       [0-2]
       204.8
               Other lymphoid leukemia
       [0-2]
                Aleukemic leukemia:
                  lymphatic
                  lymphocytic
                  lymphoid
       204.9
               Unspecified lymphoid leukemia
       [0-2]
       Myeloid leukemia
```

205

```
Includes:
                leukemia:
               granulocytic
               myeloblastic
               myelocytic
               myelogenous
               myelomonocytic
               myelosclerotic
           myelosis
The following fifth-digit subclassification is for use with category 205:
           0 without mention of having achieved remission
                   failed remission
           1 in remission
           2 in relapse
       205.0
               Acute
       [0-2]
                 Acute promyelocytic leukemia
Excludes:
                acute exacerbation of chronic myeloid leukemia (205.1)
       205.1
                Chronic
       [0-2]
                 Eosinophilic leukemia
                 Neutrophilic leukemia
       205.2
                Subacute
       [0-2]
                Myeloid sarcoma
       205.3
       [0-2]
                 Chloroma
                 Granulocytic sarcoma
       205.8
                Other myeloid leukemia
       [0-2]
                 Aleukemic leukemia:
                   granulocytic
                   myelogenous
```

myeloid Aleukemic myelosis

205.9 Unspecified myeloid leukemia

[0-2]

206 Monocytic leukemia

Includes: leukemia:

histiocytic monoblastic monocytoid

The following fifth-digit subclassification is for use with category 206:

0 without mention of having achieved remission

failed remission

1 in remission 2 in relapse

206.0 Acute

[0-2]

Excludes: acute exacerbation of chronic monocytic leukemia (206.1)

206.1 Chronic

[0-2]

206.2 Subacute

[0-2]

206.8 Other monocytic leukemia

[0-2]

Aleukemic:

monocytic leukemia monocytoid leukemia

206.9 Unspecified monocytic leukemia

[0-2]

207 Other specified leukemia

Excludes: leukemic reticuloendotheliosis (202.4)

plasma cell leukemia (203.1)

The following fifth-digit subclassification is for use with category 207:

0 without mention of having achieved remission

failed remission

1 in remission

2 in relapse

207.0 Acute erythremia and erythroleukemia

[0-2]

Acute erythremic myelosis Di Guglielmo's disease Erythremic myelosis

207.1 Chronic erythremia

[0-2]

Heilmeyer-Schöner disease

207.2 Megakaryocytic leukemia

[0-2] Megakaryocytic myelosis
Thrombocytic leukemia

207.8 Other specified leukemia

[0-2] Lymphosarcoma cell leukemia

208 Leukemia of unspecified cell type

The following fifth-digit subclassification is for use with category 208:

0 without mention of having achieved remission

failed remission

1 in remission 2 in relapse

208.0 Acute

[0-2]

Acute leukemia NOS Blast cell leukemia Stem cell leukemia

Excludes: acute exacerbation of chronic unspecified leukemia (208.1)

208.1 Chronic

[0-2]

Chronic leukemia NOS

208.2 Subacute

[0-2]

Subacute leukemia NOS

208.8 Other leukemia of unspecified cell type

[0-2]

208.9 Unspecified leukemia

[0-2]

Leukemia NOS

NEUROENDOCRINE TUMORS (209)

209 Neuroendocrine tumors

Code first any associated multiple endocrine neoplasia syndrome (258.01-258.03)

Use additional code to identify associated endocrine syndrome, such as:

carcinoid syndrome (259.2)

Excludes: benign pancreatic islet cell tumors (211.7)

malignant pancreatic islet cell tumors (157.4)

 $209.0 \qquad \text{Malignant carcinoid tumors of the small intestine} \\$

209.00 Malignant carcinoid tumor of the small intestine, unspecified portion

209.01 Malignant carcinoid tumor of the duodenum209.02 Malignant carcinoid tumor of the jejunum

	209 .03	Malignant carcinoid tumor of the ileum	
209.1	Malignant carcinoid tumors of the appendix, large intestine, and rectum		
	209.10	Malignant carcinoid tumor of the large intestine, unspecified portion Malignant carcinoid tumor of the colon NOS	
	209.11	Malignant carcinoid tumor of the appendix	
	209.12	Malignant carcinoid tumor of the cecum	
	209.13	Malignant carcinoid tumor of the ascending colon	
	209.14	Malignant carcinoid tumor of the transverse colon	
	209.15	Malignant carcinoid tumor of the descending colon	
	209.16	Malignant carcinoid tumor of the sigmoid colon	
	209.17	Malignant carcinoid tumor of the rectum	
209.2	Malignant carcinoid tumors of other and unspecified sites		
	209.20	Malignant carcinoid tumor of unknown primary site	
	209.21	Malignant carcinoid tumor of the bronchus and lung	
	209.22	Malignant carcinoid tumor of the thymus	
	209.23	Malignant carcinoid tumor of the stomach	
	209.24	Malignant carcinoid tumor of the kidney	
	209.25	Malignant carcinoid tumor of the foregut NOS	
	209.26	Malignant carcinoid tumor of the midgut NOS	
	209.27	Malignant carcinoid tumor of the hindgut NOS	
	209.29	Malignant carcinoid tumors of other sites	
209.3	Malignant poorly differentiated neuroendocrine tumors		
Excludes:	209.30 Merk	Malignant poorly differentiated neuroendocrine carcinoma, any site High grade neuroendocrine carcinoma, any site Malignant poorly differentiated neuroendocrine tumor NOS el cell carcinoma (209.31-209.36)	
Excludes.	209.31	Merkel cell carcinoma of the face	
	203.31	Merkel cell carcinoma of the ear Merkel cell carcinoma of the eyelid, including canthus Merkel cell carcinoma of the lip	
	209.32	Merkel cell carcinoma of the scalp and neck	
	209.33	Merkel cell carcinoma of the upper limb	
	209.34	Merkel cell carcinoma of the lower limb	
	209.35	Merkel cell carcinoma of the trunk	

	209.36	Merkel cell carcinoma of other sites Merkel cell carcinoma of the buttock Merkel cell carcinoma of the genitals Merkel cell carcinoma NOS		
209.4	Benign carcinoid tumors of the small intestine			
	209.40	Benign carcinoid tumor of the small intestine, unspecified portion		
	209.41	Benign carcinoid tumor of the duodenum		
	209.42	Benign carcinoid tumor of the jejunum		
	209.43	Benign carcinoid tumor of the ileum		
209.5	Benign carcinoid tumors of the appendix, large intestine, and rectum			
	209.50	Benign carcinoid tumor of the large intestine, unspecified portion Benign carcinoid tumor of the colon NOS		
	209.51	Benign carcinoid tumor of the appendix		
	209.52	Benign carcinoid tumor of the cecum		
	209.53	Benign carcinoid tumor of the ascending colon		
	209.54	Benign carcinoid tumor of the transverse colon		
	209.55	Benign carcinoid tumor of the descending colon		
	209.56	Benign carcinoid tumor of the sigmoid colon		
	209.57	Benign carcinoid tumor of the rectum		
209.6	Benign carcinoid tumors of other and unspecified sites			
	209.60	Benign carcinoid tumor of unknown primary site Carcinoid tumor NOS Neuroendocrine tumor NOS		
	209.61	Benign carcinoid tumor of the bronchus and lung		
	209.62	Benign carcinoid tumor of the thymus		
	209.63	Benign carcinoid tumor of the stomach		
	209.64	Benign carcinoid tumor of the kidney		
	209.65	Benign carcinoid tumor of the foregut NOS		
	209.66	Benign carcinoid tumor of the midgut NOS		
	209.67	Benign carcinoid tumor of the hindgut NOS		
	209.69	Benign carcinoid tumors of other sites		
209.7	Secondary neuroendocrine tumors Secondary carcinoid tumors			
	209.70	Secondary neuroendocrine tumor, unspecified site		
	209.71	Secondary neuroendocrine tumor of distant lymph nodes		

Mesentery metastasis of neuroendocrine tumor

209.72 Secondary neuroendocrine tumor of liver

209.73 Secondary neuroendocrine tumor of bone

209.74 Secondary neuroendocrine tumor of peritoneum

209.75 Secondary Merkel cell carcinoma

Merkel cell carcinoma nodal presentation

Merkel cell carcinoma visceral metastatic presentation

Secondary Merkel cell carcinoma, any site

209.79 Secondary neuroendocrine tumor of other sites

BENIGN NEOPLASMS (210-229)

210 Benign neoplasm of lip, oral cavity, and pharynx

Excludes: cyst (of):

jaw (526.0-526.2, 526.89) oral soft tissue (528.4) radicular (522.8)

210.0 Lip

Frenulum labii

Lip (inner aspect) (mucosa) (vermilion border)

Excludes: labial commissure (210.4)

skin of lip (216.0)

210.1 Tongue

Lingual tonsil

210.2 Major salivary glands

Gland: parotid sublingual submandibular

Excludes: benign neoplasms of minor salivary glands:

NOS (210.4)

buccal mucosa (210.4)

lips (210.0)

palate (hard) (soft) (210.4)

tongue (210.1) tonsil, palatine (210.5)

210.3 Floor of mouth

210.4 Other and unspecified parts of mouth

Gingiva

Gum (upper) (lower) Labial commissure Oral cavity NOS Oral mucosa Palate (hard) (soft)

Uvula

Excludes: benign odontogenic neoplasms of bone (213.0-213.1)

developmental odontogenic cysts (526.0)

mucosa of lips (210.0)

nasopharyngeal [posterior] [superior] surface of soft palate (210.7)

210.5 Tonsil

Tonsil (faucial) (palatine)

Excludes: lingual tonsil (210.1)

pharyngeal tonsil (210.7)

tonsillar: fossa (210.6) pillars (210.6)

210.6 Other parts of oropharynx

Branchial cleft or vestiges Epiglottis, anterior aspect

Fauces NOS Mesopharynx NOS Tonsillar:

fossa pillars Vallecula

Excludes: epiglottis:

NOS (212.1)

suprahyoid portion (212.1)

210.7 Nasopharynx

Adenoid tissue Lymphadenoid tissue Pharyngeal tonsil Posterior nasal septum

210.8 Hypopharynx

Arytenoid fold Laryngopharynx Postcricoid region Pyriform fossa

210.9 Pharynx, unspecified

Throat NOS

211 Benign neoplasm of other parts of digestive system

Excludes: benign stromal tumors of digestive system (215.5)

211.0 Esophagus211.1 Stomach

Body of stomach Cardia of stomach Fundus of stomach Cardiac orifice

Pylorus

Excludes: benign carcinoid tumors of the stomach (209.63)

211.2 Duodenum, jejunum, and ileum

Small intestine NOS

Excludes: ampulla of Vater (211.5)

benign carcinoid tumors of the small intestine (209.40-209.43)

ileocecal valve (211.3)

211.3 Colon

Appendix Cecum Ileocecal valve Large intestine NOS

Excludes: benign carcinoid tumors of the large intestine (209.50-209.56)

rectosigmoid junction (211.4)

211.4 Rectum and anal canal

Anal canal or sphincter

Anus NOS

Rectosigmoid junction

Excludes: anus:

margin (216.5) skin (216.5) perianal skin (216.5)

benign carcinoid tumors of the rectum (209.57)

211.5 Liver and biliary passages

Ampulla of Vater Common bile duct Cystic duct Gallbladder Hepatic duct Sphincter of Oddi

211.6 Pancreas, except islets of Langerhans

211.7 Islets of Langerhans Islet cell tumor

Use additional code to identify any functional activity

211.8 Retroperitoneum and peritoneum

Mesentery Mesocolon Omentum

Retroperitoneal tissue

211.9 Other and unspecified site

Alimentary tract NOS Digestive system NOS Gastrointestinal tract NOS Intestinal tract NOS

Intestine NOS

Spleen, not elsewhere classified

Benign neoplasm of respiratory and intrathoracic organs

212.0 Nasal cavities, middle ear, and accessory sinuses

Cartilage of nose Eustachian tube

Nares

Septum of nose

Sinus:

ethmoidal frontal maxillary sphenoidal auditory cal

Excludes: auditory canal (external) (216.2)

bone of: ear (213.0)

nose [turbinates] (213.0) cartilage of ear (215.0) ear (external) (skin) (216.2)

nose NOS (229.8) skin (216.3) olfactory bulb (225.1) polyp of:

accessory sinus (471.8) ear (385.30-385.35) nasal cavity (471.0)

posterior margin of septum and choanae (210.7)

212.1 Larynx

Cartilage: arytenoid cricoid cuneiform thyroid

Epiglottis (suprahyoid portion) NOS

Glottis

Vocal cords (false) (true)

Excludes: epiglottis, anterior aspect (210.6)

polyp of vocal cord or larynx (478.4)

212.2 Trachea

212.3 Bronchus and lung

Carina Hilus of lung

Excludes: benign carcinoid tumors of bronchus and lung (209.61)

212.4 Pleura212.5 Mediastinum212.6 Thymus

Excludes: benign carcinoid tumors of thymus (209.62)

212.7 Heart

Excludes:

Excludes: great vessels (215.4)

212.8 Other specified sites212.9 Site unspecified

Respiratory organ NOS Upper respiratory tract NOS intrathoracic NOS (229.8)

thoracic NOS (229.8)

Includes: cartilage (articular) (joint) periosteum Excludes: cartilage of: ear (215.0) eyelid (215.0) larynx (212.1) nose (212.0) exostosis NOS (726.91) synovia (215.0-215.9)

- 213.0 Bones of skull and face
 Excludes: lower jaw bone (213.1)
 - 213.1 Lower jaw bone
 - 213.2 Vertebral column, excluding sacrum and coccyx
 - 213.3 Ribs, sternum, and clavicle
 - 213.4 Scapula and long bones of upper limb
 - 213.5 Short bones of upper limb
 - 213.6 Pelvic bones, sacrum, and coccyx
 - 213.7 Long bones of lower limb213.8 Short bones of lower limb
 - 213.9 Bone and articular cartilage, site unspecified

214 Lipoma

Includes: angiolipoma

fibrolipoma hibernoma

lipoma (fetal) (infiltrating) (intramuscular)

myelolipoma myxolipoma

- 214.0 Skin and subcutaneous tissue of face214.1 Other skin and subcutaneous tissue
- 214.2 Intrathoracic organs
- 214.3 Intra-abdominal organs
- 214.4 Spermatic cord
- 214.8 Other specified sites
- 214.9 Lipoma, unspecified site

Other benign neoplasm of connective and other soft tissue

Includes: blood vessel

bursa

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fascia
           ligament
           muscle
           peripheral, sympathetic, and parasympathetic nerves and ganglia
           synovia
           tendon (sheath)
Excludes:
                 cartilage:
             articular (213.0-213.9)
             larynx (212.1)
             nose (212.0)
           connective tissue of:
             breast (217)
             internal organ, except lipoma and hemangioma - code to benign neoplasm of the site
             lipoma (214.0-214.9)
       215.0
                Head, face, and neck
       215.2
                Upper limb, including shoulder
       215.3
                Lower limb, including hip
       215.4
                Thorax
Excludes:
                heart (212.7)
                 mediastinum (212.5)
                 thymus (212.6)
       215.5
                Abdomen
                 Abdominal wall
                 Benign stromal tumors of abdomen
                 Hypochondrium
       215.6
                Pelvis
                 Buttock
                 Groin
                 Inguinal region
                 Perineum
Excludes:
                uterine:
```

leiomyoma (218.0-218.9) ligament, any (221.0)

Trunk, unspecified 215.7

> **Back NOS** Flank NOS

Other specified sites 215.8 215.9 Site unspecified

Benign neoplasm of skin 216

Includes: blue nevus

> dermatofibroma hydrocystoma pigmented nevus syringoadenoma syringoma

Excludes: skin of genital organs (221.0-222.9) 216.0 Skin of lip

Excludes: vermilion border of lip (210.0)

216.1 Eyelid, including canthus Excludes: cartilage of eyelid (215.0)

216.2 Ear and external auditory canal

Auricle (ear)

Auricular canal, external

External meatus

Pinna

Excludes: cartilage of ear (215.0)

216.3 Skin of other and unspecified parts of face

Cheek, external Eyebrow Nose, external Temple

216.4 Scalp and skin of neck

216.5 Skin of trunk, except scrotum

Axillary fold Perianal skin Skin of:

abdominal wall

anus
back
breast
buttock
chest wall
groin
perineum
Umbilicus

Excludes: anal canal (211.4)

anus NOS (211.4) skin of scrotum (222.4)

216.6 Skin of upper limb, including shoulder216.7 Skin of lower limb, including hip

216.8 Other specified sites of skin

216.9 Skin, site unspecified

217 Benign neoplasm of breast

Breast (male) (female) connective tissue glandular tissue soft parts

Excludes: adenofibrosis (610.2)

benign cyst of breast (610.0) fibrocystic disease (610.1) skin of breast (216.5)

218 Uterine leiomyoma

Includes: fibroid (bleeding) (uterine)

uterine:

fibromyoma myoma

218.0 Submucous leiomyoma of uterus218.1 Intramural leiomyoma of uterus

Interstitial leiomyoma of uterus

218.2 Subserous leiomyoma of uterus

Subperitoneal leiomyoma of uterus

218.9 Leiomyoma of uterus, unspecified

Other benign neoplasm of uterus

219.0 Cervix uteri

219.1 Corpus uteri

Endometrium Fundus Myometrium

219.8 Other specified parts of uterus

219.9 Uterus, part unspecified

220 Benign neoplasm of ovary

Use additional code to identify any functional activity (256.0-256.1)

Excludes: cy

cyst:

corpus albicans (620.2) corpus luteum (620.1) endometrial (617.1) follicular (atretic) (620.0) graafian follicle (620.0) ovarian NOS (620.2) retention (620.2)

Benign neoplasm of other female genital organs

Includes: adenomatous polyp

benign teratoma

Excludes: cyst:

epoophoron (752.11) fimbrial (752.11) Gartner's duct (752.11) parovarian (752.11)

221.0 Fallopian tube and uterine ligaments

Oviduct Parametrium

Uterine ligament (broad) (round) (uterosacral)

Uterine tube

221.1 Vagina

221.2 Vulva

Clitoris External female genitalia NOS

Greater vestibular [Bartholin's] gland

Labia (majora) (minora)

Pudendum

Excludes: Bartholin's (duct) (gland) cyst (616.2)

221.8 Other specified sites of female genital organs

221.9 Female genital organ, site unspecified

Female genitourinary tract NOS

222 Benign neoplasm of male genital organs

222.0 Testis

Use additional code to identify any functional activity

222.1 Penis

Corpus cavernosum

Glans penis Prepuce

222.2 Prostate

Excludes: adenomatous hyperplasia of prostate (600.20-600.21)

prostatic:

adenoma (600.20-600.21) enlargement (600.00-600.01) hypertrophy (600.00-600.01)

222.3 Epididymis222.4 Scrotum

Skin of scrotum

222.8 Other specified sites of male genital organs

Seminal vesicle Spermatic cord

222.9 Male genital organ, site unspecified

Male genitourinary tract NOS

Benign neoplasm of kidney and other urinary organs

223.0 Kidney, except pelvis

Kidney NOS

Excludes: benign carcinoid tumors of kidney (209.64)

renal:

calyces (223.1) pelvis (223.1)

223.1 Renal pelvis

223.2 Ureter

Excludes: ureteric orifice of bladder (223.3)

223.3 Bladder

223.8 Other specified sites of urinary organs

223.81 Urethra

Excludes: urethral orifice of bladder (223.3)

223.89 Other

Paraurethral glands 223.9 Urinary organ, site unspecified

Urinary system NOS

224 Benign neoplasm of eye

Excludes: cartilage of eyelid (215.0)

eyelid (skin) (216.1) optic nerve (225.1) orbital bone (213.0)

224.0 Eyeball, except conjunctiva, cornea, retina, and choroid

Ciliary body Iris Sclera Uveal tract

224.1 Orbit

Excludes: bone of orbit (213.0)

224.2 Lacrimal gland224.3 Conjunctiva224.4 Cornea224.5 Retina

Excludes: hemangioma of retina (228.03)

224.6 Choroid
224.7 Lacrimal duct
Lacrimal sac
Nasolacrimal duct

224.8 Other specified parts of eye

224.9 Eye, part unspecified

225 Benign neoplasm of brain and other parts of nervous system

Excludes: hemangioma (228.02)

neurofibromatosis (237.7) peripheral, sympathetic, and parasympathetic nerves and ganglia (215.0-215.9) retrobulbar (224.1)

225.0 Brain

225.1 Cranial nerves225.2 Cerebral meninges

Meninges NOS Meningioma (cerebral)

225.3 Spinal cord

Cauda equina

225.4 Spinal meninges

Spinal meningioma

225.8 Other specified sites of nervous system

225.9 Nervous system, part unspecified

Nervous system (central) NOS

Excludes: meninges NOS (225.2)

226 Benign neoplasm of thyroid glands

Use additional code to identify any functional activity

Benign neoplasm of other endocrine glands and related structures

Use additional code to identify any functional activity

Excludes: ovary (220)

pancreas (211.6) testis (222.0)

227.0 Adrenal gland

Suprarenal gland

227.1 Parathyroid gland

227.3 Pituitary gland and craniopharyngeal duct (pouch)

Craniobuccal pouch Hypophysis Rathke's pouch Sella turcica

227.4 Pineal gland

Pineal body

227.5 Carotid body

227.6 Aortic body and other paraganglia

Coccygeal body Glomus jugulare

Para-aortic body

227.8 Other

227.9 Endocrine gland, site unspecified

Hemangioma and lymphangioma, any site

Includes: angioma (benign) (cavernous) (congenital) NOS

cavernous nevus glomus tumor

hemangioma (benign) (congenital)

Excludes: benign neoplasm of spleen, except hemangioma and lymphangioma (211.9)

glomus jugulare (227.6)

nevus:

NOS (216.0-216.9)

blue or pigmented (216.0-216.9)

vascular (757.32)

228.0 Hemangioma, any site

228.00 Of unspecified site

228.01 Of skin and subcutaneous tissue

228.02 Of intracranial structures

228.03 Of retina

228.04 Of intra-abdominal structures

Peritoneum

Retroperitoneal tissue

228.09 Of other sites

Systemic angiomatosis

228.1 Lymphangioma, any site

Congenital lymphangioma

Lymphatic nevus

229 Benign neoplasm of other and unspecified sites

229.0 Lymph nodes

Excludes: lymphangioma (228.1)

229.8 Other specified sites

Intrathoracic NOS Thoracic NOS

229.9 Site unspecified

CARCINOMA IN SITU (230-234)

Includes: Bowen's disease

erythroplasia

Queyrat's erythroplasia

Excludes: leukoplakia - see Alphabetic Index

230 Carcinoma in situ of digestive organs

230.0 Lip, oral cavity, and pharynx

Gingiva Hypopharynx Mouth [any part] Nasopharynx Oropharynx

Salivary gland or duct

Tongue

Excludes: aryepiglottic fold or interarytenoid fold, laryngeal aspect (231.0)

epiglottis:

NOS (231.0)

suprahyoid portion (231.0)

skin of lip (232.0)

230.1 Esophagus

230.2 Stomach

Body of stomach Cardia of stomach Fundus of stomach Cardiac orifice Pylorus

230.3 Colon

Appendix Cecum Ileocecal valve Large intestine NOS

Excludes: rectosigmoid junction (230.4)

230.4 Rectum

Rectosigmoid junction

230.5 Anal canal

Anal sphincter

230.6 Anus, unspecified

Excludes: anus:

margin (232.5) skin (232.5) perianal skin (233

perianal skin (232.5)

230.7 Other and unspecified parts of intestine

Duodenum Ileum Jejunum

Small intestine NOS

Excludes: ampulla of Vater (230.8)

230.8 Liver and biliary system

Ampulla of Vater Common bile duct Cystic duct Gallbladder Hepatic duct Sphincter of Oddi

230.9 Other and unspecified digestive organs

Digestive organ NOS Gastrointestinal tract NOS

Pancreas Spleen

231 Carcinoma in situ of respiratory system

231.0 Larynx

Cartilage:
arytenoid
cricoid
cuneiform
thyroid
Epiglottis:
NOS

posterior surface suprahyoid portion Vocal cords (false) (true)

Excludes:

aryepiglottic fold or interarytenoid fold:

NOS (230.0)

hypopharyngeal aspect (230.0)

marginal zone (230.0)

231.1 Trachea

231.2 Bronchus and lung

Carina Hilus of lung

231.8 Other specified parts of respiratory system

Accessory sinuses Middle ear Nasal cavities

Pleura

Excludes: ear (external) (skin) (232.2)

nose NOS (234.8) skin (232.3)

231.9 Respiratory system, part unspecified

Respiratory organ NOS

232 Carcinoma in situ of skin

Includes: pigment cells

Excludes: melanoma in situ of skin (172.0-172.9)

232.0 Skin of lip

Excludes: vermilion border of lip (230.0)

232.1 Eyelid, including canthus232.2 Ear and external auditory canal

232.3 Skin of other and unspecified parts of face

232.4 Scalp and skin of neck

232.5 Skin of trunk, except scrotum

Anus, margin Axillary fold Perianal skin Skin of:

abdominal wall

anus back breast buttock chest wall groin perineum Umbilicus

Excludes: anal canal (230.5)

anus NOS (230.6)

skin of genital organs (233.30-233.39, 233.5-233.6)

232.6 Skin of upper limb, including shoulder
232.7 Skin of lower limb, including hip
232.8 Other specified sites of skin
232.9 Skin, site unspecified

233 Carcinoma in situ of breast and genitourinary system

233.0 Breast

Excludes: Paget's disease (174.0-174.9)

skin of breast (232.5)

233.1 Cervix uteri

Adenocarcinoma in situ of cervix

Cervical intraepithelial glandular neoplasia, grade III

Cervical intraepithelial neoplasia III [CIN III]

Severe dysplasia of cervix

Excludes: cervical intraepithelial neoplasia II [CIN II] (622.12)

cytologic evidence of malignancy without histologic confirmation (795.06)

high grade squamous intraepithelial lesion (HGSIL) (795.04)

moderate dysplasia of cervix (622.12)

233.2 Other and unspecified parts of uterus

233.3 Other and unspecified female genital organs

233.30 Unspecified female genital organ

233.31 Vagina

Severe dysplasia of vagina

Vaginal intraepithelial neoplasia [VAIN III]

233.32 Vulva

Severe dysplasia of vulva

Vulvar intraepithelial neoplasia [VIN III]

233.39 Other female genital organ

233.4 Prostate

233.5 Penis

233.6 Other and unspecified male genital organs

233.7 Bladder

233.9 Other and unspecified urinary organs

234 Carcinoma in situ of other and unspecified sites

234.0 Eye

Excludes: cartilage of eyelid (234.8)

eyelid (skin) (232.1) optic nerve (234.8) orbital bone (234.8)

234.8 Other specified sites

Endocrine gland [any]

234.9 Site unspecified

Carcinoma in situ NOS

NEOPLASMS OF UNCERTAIN BEHAVIOR (235-238)

Note: Categories 235-238 classify by site certain histo-morphologically well-defined neoplasms, the subsequent behavior of which cannot be predicted from the present appearance.

Neoplasm of uncertain behavior of digestive and respiratory systems

Excludes: stromal tumors of uncertain behavior of digestive system (238.1)

235.0 Major salivary glands

Gland: parotid sublingual submandibular

Excludes: minor salivary glands (235.1)

235.1 Lip, oral cavity, and pharynx

Gingiva Hypopharynx Minor salivary glands Mouth

Nasopharynx Oropharynx Tongue

Excludes: aryepiglottic fold or interarytenoid fold, laryngeal aspect (235.6)

epiglottis: NOS (235.6)

suprahyoid portion (235.6)

skin of lip (238.2)

235.2 Stomach, intestines, and rectum

235.3 Liver and biliary passages

Ampulla of Vater Bile ducts [any] Gallbladder Liver

235.4 Retroperitoneum and peritoneum

235.5 Other and unspecified digestive organs

Anal: canal

sphincter Anus NOS Esophagus Pancreas Spleen

Excludes:

anus:

margin (238.2) skin (238.2) perianal skin (238.2)

235.6 Larynx

Excludes:

aryepiglottic fold or interarytenoid fold:

NOS (235.1)

hypopharyngeal aspect (235.1)

marginal zone (235.1)

235.7 Trachea, bronchus, and lung

235.8 Pleura, thymus, and mediastinum

235.9 Other and unspecified respiratory organs

Accessory sinuses Middle ear Nasal cavities

Respiratory organ NOS

Excludes: ear (external) (skin) (238.2)

nose (238.8) skin (238.2)

Neoplasm of uncertain behavior of genitourinary organs

236.0 Uterus

236.1 Placenta

Chorioadenoma (destruens)

Invasive mole

Malignant hydatid(iform) mole

236.2 Ovary

Use additional code to identify any functional activity

236.3 Other and unspecified female genital organs

236.4 Testis

Use additional code to identify any functional activity

236.5 Prostate

236.6 Other and unspecified male genital organs

236.7 Bladder

236.9 Other and unspecified urinary organs

236.90 Urinary organ, unspecified

236.91 Kidney and ureter

Neoplasm of uncertain behavior of endocrine glands and nervous system

237.0 Pituitary gland and craniopharyngeal duct

Use additional code to identify any functional activity

237.1 Pineal gland

237.2 Adrenal gland

Suprarenal gland

Use additional code to identify any functional activity

237.3 Paraganglia

Aortic body Carotid body Coccygeal body

Glomus jugulare

237.4 Other and unspecified endocrine glands

Parathyroid gland Thyroid gland

237.5 Brain and spinal cord

237.6 Meninges

Meninges: NOS

cerebral spinal

237.7 Neurofibromatosis

von Recklinghausen's disease

237.70 Neurofibromatosis, unspecified

237.71 Neurofibromatosis, type 1 [von Recklinghausen's disease]

237.72 Neurofibromatosis, type 2 [acoustic neurofibromatosis]

237.9 Other and unspecified parts of nervous system

Cranial nerves

Excludes: peripheral, sympathetic, and parasympathetic nerves and ganglia (238.1)

Neoplasm of uncertain behavior of other and unspecified sites and tissues

238.0 Bone and articular cartilage

Excludes:

cartilage: ear (238.1)

eyelid (238.1) larynx (235.6) nose (235.9)

synovia (238.1)

238.1 Connective and other soft tissue

Peripheral, sympathetic, and parasympathetic nerves and ganglia

Stromal tumors of digestive system

Excludes: cartilage (of):

articular (238.0) larynx (235.6) nose (235.9)

connective tissue of breast (238.3)

238.2 Skin

Excludes: anus NOS (235.5)

skin of genital organs (236.3, 236.6) vermilion border of lip (235.1)

238.3 Breast

Excludes: skin of breast (238.2)

238.4 Polycythemia vera

238.5 Histiocytic and mast cells

Mast cell tumor NOS Mastocytoma NOS

238.6 Plasma cells

Plasmacytoma NOS Solitary myeloma

238.7 Other lymphatic and hematopoietic tissues

Excludes: acute myelogenous leukemia (205.0)

chronic myelomonocytic leukemia (205.1) myelosclerosis NOS (289.89)

myelosis:

NOS (205.9)

megakaryocytic (207.2)

238.71 Essential thrombocythemia

Essential hemorrhagic thrombocythemia

Essential thrombocytosis

Idiopathic (hemorrhagic) thrombocythemia

Primary thrombocytosis

238.72 Low grade myelodysplastic syndrome lesions

Refractory anemia (RA)

Refractory anemia with excess blasts-1 (RAEB-1) Refractory anemia with ringed sideroblasts (RARS) Refractory cytopenia with multilineage dysplasia (RCMD)

Refractory cytopenia with multilineage dysplasia and ringed sideroblasts (RCMD-RS)

238.73 High grade myelodysplastic syndrome lesions

Refractory anemia with excess blasts-2 (RAEB-2)

238.74 Myelodysplastic syndrome with 5g deletion

5q minus syndrome NOS

Excludes: constitutional 5q deletion (758.39)

high grade myelodysplastic syndrome with 5q deletion (238.73)

238.75 Myelodysplastic syndrome, unspecified

238.76 Myelofibrosis with myeloid metaplasia

Agnogenic myeloid metaplasia Idiopathic myelofibrosis (chronic) Myelosclerosis with myeloid metaplasia

Primary myelofibrosis

Excludes: myelofibrosis NOS (289.83)

myelophthisic anemia (284.2)

myelophthisis (284.2)

secondary myelofibrosis (289.83)

238.77 Post-transplant lymphoproliferative disorder (PTLD)

Code first complications of transplant (996.80-996.89)

238.79 Other lymphatic and hematopoietic tissues

Lymphoproliferative disease (chronic) NOS

Megakaryocytic myelosclerosis

Myeloproliferative disease (chronic) NOS

Panmyelosis (acute)

238.8 Other specified sites

Eye Heart

Excludes: eyelid (skin) (238.2)

cartilage (238.1)

238.9 Site unspecified

NEOPLASMS OF UNSPECIFIED NATURE (239)

Neoplasms of unspecified nature

Note: Category 239 classifies by site neoplasms of unspecified morphology and behavior. The term "mass," unless otherwise stated, is not to be regarded as a neoplastic growth.

Includes: "growth" NOS

neoplasm NOS new growth NOS tumor NOS

239.0 Digestive system

Excludes: anus:

margin (239.2) skin (239.2) perianal skin (239.2)

239.1 Respiratory system

239.2 Bone, soft tissue, and skin

Excludes: anal canal (239.0)

anus NOS (239.0) bone marrow (202.9)

cartilage: larynx (239.1) nose (239.1)

connective tissue of breast (239.3) skin of genital organs (239.5) vermilion border of lip (239.0)

239.3 Breast

Excludes: skin of breast (239.2)

239.4 Bladder

239.5 Other genitourinary organs

239.6 Brain

Excludes: cerebral meninges (239.7)

cranial nerves (239.7)

239.7 Endocrine glands and other parts of nervous system

Excludes: peripheral, sympathetic, and parasympathetic nerves and ganglia (239.2)

239.8 Other specified sites Excludes: eyelid (skin) (239.2)

cartilage (239.2) great vessels (239.2) optic nerve (239.7)

239.81 Retina and choroid Dark area on retina

Retinal freckle

239.89 Other specified sites

239.9 Site unspecified

4. DISEASES OF THE BLOOD AND BLOOD-FORMING ORGANS (280-289)

280 Iron deficiency anemias

Includes: anemia:

asiderotic

hypochromic-microcytic

sideropenic

Excludes: familial microcytic anemia (282.49)

280.0 Secondary to blood loss (chronic)

Normocytic anemia due to blood loss

Excludes: acute posthemorrhagic anemia (285.1)

280.1 Secondary to inadequate dietary iron intake

280.8 Other specified iron deficiency anemias

Paterson-Kelly syndrome Plummer-Vinson syndrome Sideropenic dysphagia

280.9 Iron deficiency anemia, unspecified

Anemia: achlorhydric chlorotic

idiopathic hypochromic iron [Fe] deficiency NOS

281 Other deficiency anemias

281.0 Pernicious anemia

Anemia: Addison's Biermer's

congenital pernicious

Congenital intrinsic factor [Castle's] deficiency

Excludes: combined system disease without mention of anemia (266.2)

subacute degeneration of spinal cord without mention of anemia (266.2)

281.1 Other vitamin B12 deficiency anemia

Anemia: vegan's

vitamin B12 deficiency (dietary)

due to selective vitamin B12 malabsorption with proteinuria

Syndrome: Imerslund's

Imerslund-Gräsbeck

Excludes: combined system disease without mention of anemia (266.2)

subacute degeneration of spinal cord without mention of anemia (266.2)

281.2 Folate-deficiency anemia

Congenital folate malabsorption Folate or folic acid deficiency anemia:

NOS dietary drug-induced Goat's milk anemia

Nutritional megaloblastic anemia (of infancy)

Use additional E code to identify drug

281.3 Other specified megaloblastic anemias, not elsewhere classified

Combined B12 and folate-deficiency anemia

281.4 Protein-deficiency anemia

Amino-acid-deficiency anemia

281.8 Anemia associated with other specified nutritional deficiency

Scorbutic anemia

281.9 Unspecified deficiency anemia

Anemia:
dimorphic
macrocytic
megaloblastic NOS
nutritional NOS
simple chronic

282 Hereditary hemolytic anemias

282.0 Hereditary spherocytosis

Acholuric (familial) jaundice

Congenital hemolytic anemia (spherocytic)

Congenital spherocytosis

Minkowski-Chauffard syndrome

Spherocytosis (familial)

Excludes: hemolytic anemia of newborn (773.0-773.5)

282.1 Hereditary elliptocytosis

Elliptocytosis (congenital)

Ovalocytosis (congenital) (hereditary)

282.2 Anemias due to disorders of glutathione metabolism

Anemia:

6-phosphogluconic dehydrogenase deficiency

enzyme deficiency, drug-induced erythrocytic glutathione deficiency

glucose-6-phosphate dehydrogenase [G-6-PD] deficiency

glutathione-reductase deficiency

hemolytic nonspherocytic (hereditary), type I Disorder of pentose phosphate pathway

Favism

282.3 Other hemolytic anemias due to enzyme deficiency

Anemia:

hemolytic nonspherocytic (hereditary), type II

hexokinase deficiency

pyruvate kinase [PK] deficiency triosephosphate isomerase deficiency

282.4 Thalassemias

Excludes: sickle-cell:

disease (282.60-282.69)

trait (282.5)

282.41 Sickle-cell thalassemia without crisis

Sickle-cell thalassemia NOS

Thalassemia Hb-S disease without crisis

282.42 Sickle-cell thalassemia with crisis

Sickle-cell thalassemia with vaso-occlusive pain

Thalassemia Hb-S disease with crisis

Use additional code for type of crisis, such as:

Acute chest syndrome (517.3) Splenic sequestration (289.52)

282.49 Other thalassemia

Cooley's anemia Hb-Bart's disease Hereditary leptocytosis

Mediterranean anemia (with other hemoglobinopathy)

Microdrepanocytosis

Thalassemia (alpha) (beta) (intermedia) (major) (minima) (minor) (mixed) (trait) (with other

hemoglobinopathy)

Thalassemia NOS

282.5 Sickle-cell trait

Hb-AS genotype

Hemoglobin S [Hb-S] trait

Heterozygous:

hemoglobin S

Hb-S

Excludes: that with other hemoglobinopathy (282.60-282.69)

that with thalassemia (282.49)

282.6 Sickle-cell disease

Sickle-cell anemia

Excludes: sickle-cell thalassemia (282.41-282.42)

sickle-cell trait (282.5)

282.60 Sickle-cell disease, unspecified

Sickle-cell anemia NOS

282.61 Hb-SS disease without crisis

282.62 Hb-SS disease with crisis

Hb-SS disease with vaso-occlusive pain

Sickle-cell crisis NOS

Use additional code for type of crisis, such as:

Acute chest syndrome (517.3) Splenic sequestration (289.52)

282.63 Sickle-cell/Hb-C disease without crisis

Hb-S/Hb-C disease without crisis

282.64 Sickle-cell/HB-C disease with crisis

Hb-S/Hb-C disease with crisis

Sickle-cell/Hb-C disease with vaso-occlusive pain

Use additional code for types of crisis, such as:

Acute chest syndrome (517.3) Splenic sequestration (289.52)

282.68 Other sickle-cell disease without crisis

Hb-S/Hb-D disease without crisis Hb-S/Hb-E disease without crisis Sickle-cell/Hb-D disease without crisis Sickle-cell/Hb-E disease without crisis

282.69 Other sickle-cell disease with crisis

Hb-S/Hb-D disease with crisis Hb-S/Hb-E disease with crisis Sickle-cell/Hb-D disease with crisis Sickle-cell/Hb-E disease with crisis

Other sickle-cell disease with vaso-occlusive pain

Use additional code for type of crisis, such as:

Acute chest syndrome (517.3) Splenic sequestration (289.52)

282.7 Other hemoglobinopathies

Abnormal hemoglobin NOS Congenital Heinz-body anemia

Disease:

hemoglobin C [Hb-C] hemoglobin D [Hb-D] hemoglobin E [Hb-E] hemoglobin Zurich [Hb-Zurich]

Hemoglobinopathy NOS

Hereditary persistence of fetal hemoglobin [HPFH]

Unstable hemoglobin hemolytic disease

Excludes: fai

familial polycythemia (289.6) hemoglobin M [Hb-M] disease (289.7) high-oxygen-affinity hemoglobin (289.0)

282.8 Other specified hereditary hemolytic anemias

Stomatocytosis

282.9 Hereditary hemolytic anemia, unspecified

Hereditary hemolytic anemia NOS

283 Acquired hemolytic anemias

283.0 Autoimmune hemolytic anemias

Autoimmune hemolytic disease (cold type) (warm type)

Chronic cold hemagglutinin disease Cold agglutinin disease or hemoglobinuria Hemolytic anemia:

cold type (secondary) (symptomatic)

drug-induced

warm type (secondary) (symptomatic)

Use additional E code to identify cause, if drug-induced

Excludes: Evans' syndrome (287.32)

hemolytic disease of newborn (773.0-773.5)

283.1 Non-autoimmune hemolytic anemias

283.10 Non-autoimmune hemolytic anemia, unspecified

283.11 Hemolytic-uremic syndrome

283.19 Other non-autoimmune hemolytic anemias

Hemolytic anemia: mechanical microangiopathic toxic

Use additional E code to identify cause

283.2 Hemoglobinuria due to hemolysis from external causes

Acute intravascular hemolysis

Hemoglobinuria: from exertion march

paroxysmal (cold) (nocturnal)

due to other hemolysis

Marchiafava-Micheli syndrome

Use additional E code to identify cause

283.9 Acquired hemolytic anemia, unspecified

Acquired hemolytic anemia NOS Chronic idiopathic hemolytic anemia

284.0 Constitutional aplastic anemia

284.01 Constitutional red blood cell aplasia

Aplasia, (pure) red cell:

congenital of infants primary

Blackfan-Diamond syndrome Familial hypoplastic anemia

284.09 Other constitutional aplastic anemia

Fanconi's anemia

Pancytopenia with malformations

284.1 Pancytopenia

Excludes: pancytopenia (due to) (with):

aplastic anemia NOS (284.9) bone marrow infiltration (284.2)

constitutional red blood cell aplasia (284.01)

drug induced (284.89)

hairy cell leukemia (202.4)

human immunodeficiency virus disease (042)

leukoerythroblastic anemia (284.2)

malformations (284.09)

myelodysplastic syndromes (238.72-238.75)

myeloproliferative disease (238.79)

other constitutional aplastic anemia (284.09)

284.2 Myelophthisis

Leukoerythroblastic anemia

Myelophthisic anemia

Code first the underlying disorder, such as:

malignant neoplasm of breast (174.0-174.9, 175.0-175.9)

tuberculosis (015.0-015.9)

Excludes: idiopathic myelofibrosis (238.76)

myelofibrosis NOS (289.83)

myelofibrosis with myeloid metaplasia (238.76)

primary myelofibrosis (238.76) secondary myelofibrosis (289.83)

284.8 Other specified aplastic anemias

284.81 Red cell aplasia (acquired) (adult) (with thymoma)

Red cell aplasia NOS

284.89 Other specified aplastic anemias

Aplastic anemia (due to):

chronic systemic disease

drugs infection radiation toxic (paralytic)

Use additional E code to identify cause

284.9 Aplastic anemia, unspecified

Anemia:

aplastic (idiopathic) NOS

aregenerative hypoplastic NOS nonregenerative Medullary hypoplasia

Excludes: refractory anemia (238.72)

Other and unspecified anemias

285.0 Sideroblastic anemia

Anemia:

hypochromic with iron loading

sideroachrestic sideroblastic: acquired congenital hereditary primary

secondary (drug-induced) (due to disease)

sex-linked hypochromic vitamin B6-responsive

Pyridoxine-responsive (hypochromic) anemia

Excludes: refractory sideroblastic anemia (238.72)

Use additional E code to identify cause, if drug-induced

285.1 Acute posthemorrhagic anemia

Anemia due to acute blood loss

Excludes: anemia due to chronic blood loss (280.0)

blood loss anemia NOS (280.0)

285.2 Anemia of chronic disease

Anemia in (due to) (with) chronic illness
285.21 Anemia in chronic kidney disease
Anemia in end-stage renal disease

Erythropoietin-resistant anemia (EPO resistant anemia)

285.22 Anemia in neoplastic disease

Excludes: anemia due to antineoplastic chemotherapy (285.3)

285.29 Anemia of other chronic disease Anemia in other chronic illness

285.3 Antineoplastic chemotherapy induced anemia Anemia due to antineoplastic chemotherapy

Excludes: anemia due to drug NEC - code to type of anemia

anemia in neoplastic disease (285.22)

aplastic anemia due to antineoplastic chemotherapy (284.89)

285.8 Other specified anemias

Anemia:

dyserythropoietic (congenital) dyshematopoietic (congenital)

```
von Jaksch's
                 Infantile pseudoleukemia
       285.9
                Anemia, unspecified
                 Anemia:
                   NOS
                   essential
                   normocytic, not due to blood loss
                   profound
                   progressive
                   secondary
                 Oligocythemia
Excludes:
                 anemia (due to):
                   blood loss:
                       acute (285.1)
                       chronic or unspecified (280.0)
                   iron deficiency (280.0-280.9)
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286 Coagulation defects

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286.0
                Congenital factor VIII disorder
                  Antihemophilic globulin [AHG] deficiency
                  Factor VIII (functional) deficiency
                  Hemophilia:
                    NOS
                    Α
                    classical
                    familial
                    hereditary
                  Subhemophilia
Excludes:
                 factor VIII deficiency with vascular defect (286.4)
                Congenital factor IX disorder
        286.1
                  Christmas disease
                  Deficiency:
                    factor IX (functional)
                    plasma thromboplastin component [PTC]
                  Hemophilia B
                Congenital factor XI deficiency
        286.2
                  Hemophilia C
                  Plasma thromboplastin antecedent [PTA] deficiency
                  Rosenthal's disease
        286.3
                Congenital deficiency of other clotting factors
                  Congenital afibrinogenemia
                  Deficiency:
                    AC globulin
                    factor:
                      I [fibrinogen]
                      II [prothrombin]
                      V [labile]
                      VII [stable]
                      X [Stuart-Prower]
                      XII [Hageman]
                      XIII [fibrin stabilizing]
```

Laki-Lorand factor proaccelerin
Disease:

Owren's Stuart-Prower

Dysfibrinogenemia (congenital) Dysprothrombinemia (constitutional)

Hypoproconvertinemia

Hypoprothrombinemia (hereditary)

Parahemophilia

286.4 von Willebrand's disease

Angiohemophilia (A) (B) Constitutional thrombopathy

Factor VIII deficiency with vascular defect

Pseudohemophilia type B Vascular hemophilia

von Willebrand's (-Jürgens') disease

Excludes: factor VIII deficiency:

NOS (286.0)

with functional defect (286.0) hereditary capillary fragility (287.8)

286.5 Hemorrhagic disorder due to intrinsic circulating anticoagulants

Antithrombinemia Antithromboplastinemia Antithromboplastino-genemia

Hyperheparinemia Increase in: anti-VIIIa anti-IXa anti-Xa anti-XIa antithrombin

Secondary hemophilia

Systemic lupus erythematosus [SLE] inhibitor

286.6 Defibrination syndrome

Afibrinogenemia, acquired Consumption coagulopathy

Diffuse or disseminated intravascular coagulation [DIC syndrome]

Fibrinolytic hemorrhage, acquired Hemorrhagic fibrinogenolysis Pathologic fibrinolysis Purpura:

fibrinolytic fulminans

Excludes: that complicating:

abortion (634-638 with .1, 639.1)

pregnancy or the puerperium (641.3, 666.3)

disseminated intravascular coagulation in newborn (776.2)

286.7 Acquired coagulation factor deficiency

Deficiency of coagulation factor due to:

liver disease vitamin K deficiency

Hypoprothrombinemia, acquired

Excludes: vitamin K deficiency of newborn (776.0)

Use additional E-code to identify cause, if drug-induced

286.9 Other and unspecified coagulation defects

Defective coagulation NOS

Deficiency, coagulation factor NOS

Delay, coagulation

Disorder: coagulation hemostasis

Excludes: abnormal coagulation profile (790.92)

hemorrhagic disease of newborn (776.0)

that complicating:

abortion (634-638 with .1, 639.1)

pregnancy or the puerperium (641.3, 666.3)

287 Purpura and other hemorrhagic conditions

Excludes: hemorrhagic thrombocythemia (238.79)

purpura fulminans (286.6)

287.0 Allergic purpura

Peliosis rheumatica Purpura:

anaphylactoid autoimmune

Henoch's

nonthrombocytopenic:

hemorrhagic idiopathic rheumatica Schönlein-Henoch

vascular

Vasculitis, allergic

Excludes: hemorrhagic purpura (287.39)

purpura annularis telangiectodes (709.1)

287.1 Qualitative platelet defects

Thrombasthenia (hemorrhagic) (hereditary)

Thrombocytasthenia

Thrombocytopathy (dystrophic) Thrombopathy (Bernard-Soulier)

Excludes: von Willebrand's disease (286.4)

287.2 Other nonthrombocytopenic purpuras

Purpura: NOS senile simplex

287.3 Primary thrombocytopenia

Excludes: thrombotic thrombocytopenic purpura (446.6)

transient thrombocytopenia of newborn (776.1)

287.30 Primary thrombocytopenia unspecified

Megakaryocytic hypoplasia

287.31 Immune thrombocytopenic purpura

Idiopathic thrombocytopenic purpura

Tidal platelet dysgenesis

287.32 Evans' syndrome

287.33 Congenital and hereditary thrombocytopenic purpura

Congenital and hereditary thrombocytopenia

Thrombocytopenia with absent radii (TAR) syndrome

Excludes: Wiskott-Aldrich syndrome (279.12)

287.39 Other primary thrombocytopenia

287.4 Secondary thrombocytopenia

Posttransfusion purpura Thrombocytopenia (due to):

dilutional drugs

extracorporeal circulation of blood

massive blood transfusion platelet alloimmunization

Use additional E code to identify cause

Excludes: heparin-induced thrombocytopenia (HIT) (289.84)

transient thrombocytopenia of newborn (776.1)

287.5 Thrombocytopenia, unspecified

287.8 Other specified hemorrhagic conditions

Capillary fragility (hereditary) Vascular pseudohemophilia

287.9 Unspecified hemorrhagic conditions

Hemorrhagic diathesis (familial)

288 Diseases of white blood cells

Excludes: leukemia (204.0-208.9)

288.0 Neutropenia

Decreased Absolute Neutrophil Count (ANC)

Use additional code for any associated:

fever (780.61)

mucositis (478.11, 528.00-528.09, 538, 616.81)

Excludes: neutropenic splenomegaly (289.53)

transitory neonatal neutropenia (776.7)

288.00 Neutropenia, unspecified

288.01 Congenital neutropenia

Congenital agranulocytosis Infantile genetic agranulocytosis

Kostmann's syndrome

288.02 Cyclic neutropenia

Cyclic hematopoiesis

Periodic neutropenia

288.03 Drug induced neutropenia

Use additional E code to identify drug

288.04 Neutropenia due to infection

288.09 Other neutropenia

Agranulocytosis Neutropenia:

immune toxic

288.1 Functional disorders of polymorphonuclear neutrophils

Chronic (childhood) granulomatous disease

Congenital dysphagocytosis

Job's syndrome

Lipochrome histiocytosis (familial)

Progressive septic granulomatosis

288.2 Genetic anomalies of leukocytes

Anomaly (granulation) (granulocyte) or syndrome:

Alder's (-Reilly)

Chédiak-Steinbrinck (-Higashi)

Jordan's May-Hegglin Pelger-Huet Hereditary:

hypersegmentation hyposegmentation leukomelanopathy

288.3 Eosinophilia

Eosinophilia allergic hereditary idiopathic secondary

Eosinophilic leukocytosis

Excludes: Löffler's syndrome (518.3)

pulmonary eosinophilia (518.3)

288.4 Hemophagocytic syndromes

Familial hemophagocytic lymphohistiocytosis

Familial hemophagocytic reticulosis

Hemophagocytic syndrome, infection-associated

Histiocytic syndromes

Macrophage activation syndrome

288.5 Decreased white blood cell count Excludes: neutropenia (288.01-288.09)

288.50 Leukocytopenia, unspecified

Decreased leukocytes, unspecified

Decreased white blood cell count, unspecified

Leukopenia NOS

288.51 Lymphocytopenia

Decreased lymphocytes

288.59 Other decreased white blood cell count

Basophilic leukopenia Eosinophilic leukopenia Monocytopenia Plasmacytopenia

288.6 Elevated white blood cell count

Excludes: eosinophilia (288.3)

288.60 Leukocytosis, unspecified

Elevated leukocytes, unspecified

Elevated white blood cell count, unspecified

288.61 Lymphocytosis (symptomatic) Elevated lymphocytes

288.62 Leukemoid reaction

Basophilic leukemoid reaction Lymphocytic leukemoid reaction Monocytic leukemoid reaction Myelocytic leukemoid reaction Neutrophilic leukemoid reaction

288.63 Monocytosis (symptomatic)

Excludes: infectious mononucleosis (075)

288.64 Plasmacytosis288.65 Basophilia288.66 Bandemia

Bandemia without diagnosis of specific infection

Excludes: confirmed infection - code to infection

leukemia (204.00-208.9)

288.69 Other elevated white blood cell count

288.8 Other specified disease of white blood cells

Excludes: decreased white blood cell counts (288.50-288.59)

elevated white blood cell counts (288.60-288.69)

immunity disorders (279.0-279.9)

288.9 Unspecified disease of white blood cells

Other diseases of blood and blood-forming organs

289.0 Polycythemia, secondary

High-oxygen-affinity hemoglobin

Polycythemia: acquired benign due to:

fall in plasma volume

high altitude

emotional erythropoietin hypoxemic nephrogenous relative spurious stress Excludes: polycythemia: neonatal (776.4) primary (238.4) vera (238.4) 289.1 Chronic lymphadenitis Chronic: adenitis any lymph node, except mesenteric lymphadenitis any lymph node, except mesenteric Excludes: acute lymphadenitis (683) mesenteric (289.2) enlarged glands NOS (785.6) 289.2 Nonspecific mesenteric lymphadenitis Mesenteric lymphadenitis (acute) (chronic) 289.3 Lymphadenitis, unspecified, except mesenteric 289.4 Hypersplenism "Big spleen" syndrome Dyssplenism Hypersplenia Excludes: primary splenic neutropenia (289.53) 289.5 Other diseases of spleen 289.50 Disease of spleen, unspecified 289.51 Chronic congestive splenomegaly 289.52 Splenic sequestration Code first sickle-cell disease in crisis (282.42, 282.62, 282.64, 282.69) 289.53 Neutropenic splenomegaly 289.59 Other Lien migrans Perisplenitis Splenic: abscess atrophy cyst fibrosis infarction rupture, nontraumatic Splenitis Wandering spleen bilharzial splenic fibrosis (120.0-120.9) Excludes: hepatolienal fibrosis (571.5)

splenomegaly NOS (789.2)

289.6 Familial polycythemia Familial: benign polycythemia erythrocytosis Methemoglobinemia 289.7 Congenital NADH [DPNH]-methemoglobin-reductase deficiency Hemoglobin M [Hb-M] disease Methemoglobinemia: NOS acquired (with sulfhemoglobinemia) hereditary toxic Stokvis' disease Sulfhemoglobinemia Use additional E code to identify cause Other specified diseases of blood and blood-forming organs 289.81 Primary hypercoagulable state Activated protein C resistance Antithrombin III deficiency Factor V Leiden mutation

289.82 Secondary hypercoagulable state

Lupus anticoagulant Protein C deficiency Protein S deficiency Prothrombin gene mutation

Excludes: heparin-induced thrombocytopenia (HIT) (289.84)

289.83 Myelofibrosis

Myelofibrosis NOS Secondary myelofibrosis

Code first the underlying disorder, such as:

malignant neoplasm of breast (174.0-174.9, 175.0-175.9)

Use additional code for associated therapy-related myelodysplastic syndrome, if applicable (238.72, 238.73)

Use additional external cause code if due to anti-neoplastic chemotherapy (E933.1)

Excludes: idiopathic myelofibrosis (238.76) leukoerythroblastic anemia (284.2)

myelofibrosis with myeloid metaplasia (238.76)

myelophthisic anemia (284.2)

myelophthisis (284.2)

primary myelofibrosis (238.76)

289.84 Heparin-induced thrombocytopenia (HIT)

289.89 Other specified diseases of blood and blood-forming organs

Hypergammaglobulinemia Pseudocholinesterase deficiency

289.9 Unspecified diseases of blood and blood-forming organs

Blood dyscrasia NOS Erythroid hyperplasia

Schedule 1.43

[***]

[***]

-74-

[***]

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Schedule 1.48

Initial Licensed Back-Up Compounds

[***] [***] [***] EXTENSION OF CONFIDENTIAL TREATMENT REQUESTED: Certain identified information, marked by [***], has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company, if publicly disclosed. An extension of confidential treatment for such information has been requested. An unredacted version of this document has been filed separately with the Securities and Exchange Commission (the "Commission").

AMENDMENT

This Amendment ("Amendment") is entered into effective June 22, 2010 (the "Amendment Effective Date") by and between Incyte Corporation, a Delaware Corporation having an office at Experimental Station, Route 141 & Henry Clay Road, Wilmington, Delaware ("Incyte"), and Eli Lilly and Company ("Lilly"), an Indiana corporation having an office at Lilly Corporate Center, Indianapolis, Indiana 46285.

RECITALS

- A. Incyte and Lilly are parties to a License, Development and Commercialization Agreement ("Agreement"), effective December 18, 2010 ("Effective Date") pursuant to which Incyte has granted Lilly an exclusive license to develop and commercialize Licensed Compounds and Licensed Products in the Field.
- B. The parties now desire to amend the Agreement to [***].
- C. Unless otherwise defined herein, all capitalized terms appearing in this Amendment shall have the meaning as set forth in the Agreement.

AGREEMENT

The parties hereby agree as follows:

1. Section 4.2(b)(ii) of the Agreement is hereby amended and restated to read in its entirety as follows:

"Within [***], Lilly shall complete the first patient visit for the first patient in a Phase IIb Study of the Initial Lead Compound for rheumatoid arthritis; provided that (1) the [***] study results from the Phase IIa Study INCB28050-201 supports initiation; (2) the clinical trial protocol is approved and does not require any specialized equipment, testing, or site preparation; (3) the clinical trial material is acceptable; (4) there are no delays caused by a Regulatory Authority; (5) there are no delays caused by a contract research organization that could not have been reasonably avoided by Lilly; and (6) there are no other factors that cause a delay that could not have been reasonably avoided by Lilly. If any of the factors set forth in items (2) through (6) prevent Lilly from completing the first patient

visit as set forth above within [***], Lilly shall complete such first patient visit within a reasonable time after the relevant factors are addressed.

- 2. Sections 4.4(general statement), 4.4(a) and 4.4(b) of the Agreement are hereby amended and restated to read in their entirety as follows:
 - "4.4 <u>Licensed Product Co-Development Option</u>.
 - (a) Generally

On a Licensed Product-by-Licensed Product basis, for each Indication for which (x) Lilly anticipates initiating a Phase IIb Study and (y) there is a means to separately track the Annual Net Sales of such Licensed Product for such Indication (each a "Co-Development Indication") based on a new formulation or a new targeted prescribing specialist group [***], and provided that Incyte has not exercised the Incyte Development Opt Out in accordance with Section 4.4(c)(ii) for any Licensed Product, Incyte shall have the option to co-fund Development of such Co-Development Indication (the "Co-Development Option") as follows:

- (i) <u>Licensed Product containing Initial Lead Compound for Rheumatoid Arthritis</u>: Within [***] of Lilly's receipt of the [***] study results generated in the Phase IIa Study INCB28050-201, Lilly shall provide to Incyte Lilly's then current Development Plan, including the then current estimated total global Development Budget (including the overall estimated costs for each study, annualized over the course of each such study) for the development of the Initial Lead Compound for rheumatoid arthritis (the "RA Co-Development Budget"). Incyte shall have the option to co-fund Development of such Co-Development Indication under this paragraph, exercisable by (i) providing Lilly written notice within [***] after receipt of such information and (ii) co-funding thirty percent (30%) of Lilly's total global Development Costs for such Co-Development Indication incurred after the date of such notice through the Regulatory Approval of such Co-Development Indication on a country by country basis ("Incyte Target Global Funding"). As used herein in this Section 4.4, Regulatory Approval costs include costs for any post-launch studies required by a Regulatory Authority.
- (ii) <u>Licensed Product containing Licensed Back Up Compound or Licensed Product containing Initial Lead</u>
 <u>Compound for Indication other than Rheumatoid Arthritis</u>

Not later than [***] prior to the anticipated initiation of a Phase IIb Study for (1) a Licensed Product containing the Initial Lead Compound for a Co-Development Indication other than rheumatoid arthritis; or (2) a Licensed Product containing a Licensed Back Up Compound for a Co-Development Indication, Lilly shall notify Incyte of such anticipated initiation and shall provide Incyte with the following information to the extent not already provided: all material pre-clinical and clinical data and related analysis and regulatory

information submitted to any Regulatory Authorities prior to the applicable time-period mentioned above with respect to such Co-Development Indication, and Lilly's then current Development Plans and then current estimated total global Development Budget (including the overall estimated costs for each study, annualized over the course of each such study) with respect to any such Co-Development Indication (each an "Additional Co-Development Indication Budget"). Incyte shall have the option to co-fund Development of such Co-Development Indication under this paragraph, exercisable by (i) providing Lilly written notice within [***] after receipt of such information and (ii) co-funding thirty percent (30%) of Lilly's total global Development Costs for such Co-Development Indication incurred after the date of such notice through the Regulatory Approval of such Co-Development Indication on a country by country basis ("Incyte Target Global Funding"). As used herein in this Section 4.4, Regulatory Approval costs include costs for any post-launch studies required by a Regulatory Authority. As used in this Agreement, the term "Co-Development Indication Budget" means the RA Co-Development Indication Budget or each Additional Co-Development Indication Budget, as appropriate.

- (b) If Incyte timely delivers such notice of such exercise as provided in paragraphs (a)(i) or (a)(ii), within [***] following the end of each Calendar Quarter after Incyte has delivered such notice, Lilly shall prepare and deliver to Incyte a quarterly report detailing its Development Costs incurred during such period with respect to such Co-Development Indication. Lilly shall submit any supporting information reasonably requested by Incyte related to such Development Costs included in its report within [***] after its receipt of such request. Lilly shall issue an invoice to Incyte for thirty percent (30%) of the Development Costs identified in such report. Incyte shall pay all amounts payable under any such invoice within [***] after its receipt of such invoice, subject to Section 4.4(c). Incyte shall have the right to audit the records of Lilly with respect to any purported Development Costs included in such reports, in accordance with Section 7.6."
- 3. [***] of the Agreement is hereby amended to include [***] as follows:

Milestone Event	[***]	[***]	[***]
[***] Completion of first	US \$19,000,000		
patient visit in a Phase IIb			
Study with Initial Lead			
Compound for Rheumatoid			
Arthritis			

- 4. The Parties hereby acknowledge that [***] the date of this Amendment.
- 5. All other terms and conditions of the Agreement shall remain in full force and effect. Section 13.1 (Governing Law), 13.2 (Consent to Jurisdiction), and 13.13 (Execution in Counterparts) of the Agreement shall apply to this Amendment.
- 6. This Amendment shall be effective as of the Amendment Effective Date.

Title: Executive Vice President and President Lilly Bio-Medicines

IN WITNESS WHEREOF, the parties by their respective authorized representatives, have executed this Agreement as of the date first written above.

ncyte Corporation	
sy: /s/ Patricia S. Andrews_	
Jame: Patricia S. Andrews_	
itle: EVP and Chief Commercial Officer	
li Lilly and Company	
sy: /s/ Bryce Carmine	
Jame: Bryce Carmine	

EXTENSION OF CONFIDENTIAL TREATMENT REQUESTED: Certain identified information, marked by [***], has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company, if publicly disclosed. An extension of confidential treatment for such information has been requested. An unreducted version of this document has been filed separately with the Securities and Exchange Commission (the "Commission").

THIRD AMENDMENT

This Third Amendment ("Third Amendment") is entered into effective March 31, 2016 (the "Third Amendment Effective Date") by and between Incyte Corporation ("Incyte"), a Delaware corporation having an office at 1801 Augustine Cut-off, Wilmington, DE 19803, and Eli Lilly and Company ("Lilly"), an Indiana corporation having an office at Lilly Corporate Center, Indianapolis, IN 46285.

RECITALS

- A. Incyte and Lilly are parties to (i) a License, Development and Commercialization Agreement, effective December 18, 2009, (ii) an Amendment, effective June 22, 2010, and (iii) a Second Amendment, effective August 1, 2011, pursuant to which Incyte has granted Lilly an exclusive License to develop and commercialize Licensed Compounds and Licensed Products in the Field (such Agreement, as so amended, the "Agreement").
- B. The Parties now desire to further amend the Agreement by excluding Ruxolitinib (as defined below) for use in the Graft-Versus-Host Disease Field (as defined below) from the prohibition in Section 2.6 against Incyte Developing or Commercializing JAK2 Inhibitor Compounds in the Field in exchange for certain payments by Incyte and the waiver by Incyte of its Co-Promotion Option.
- C. Unless otherwise defined herein, all capitalized terms appearing in this Third Amendment shall have the meaning set forth in the Agreement.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

- 1. "Graft-Versus-Host Disease Field" means the treatment, control, management, mitigation, prevention or cure of all graft-versus-host disease Indications as defined in subsections 279.50 through 279.53 of the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) as set forth in Exhibit A to this Third Amendment. [***]
- 2. "Ruxolitinib" means Incyte's proprietary JAK2 Inhibitor known as ruxolitinib.

- 3. Section 2.6(a) (LICENSES; Non-Compete) and Section 2.6(b) (LICENSES; Non-Compete) of the Agreement shall not apply to Development or Commercialization of Ruxolitinib by Incyte, its Affiliates, licensees or sublicensees for use in the Graft-Versus-Host Disease Field.
- 4. Incyte shall pay to Lilly the following payments:
 - a. A one-time, non-creditable, non-refundable payment of \$35,000,000 within [***];
 - b. A one-time, non-creditable, non-refundable milestone payment of \$20,000,000 within [***] after Incyte, [***] Regulatory Approval from the FDA of Ruxolitinib in the Graft-Versus-Host Disease Field; and
 - c. A one-time, non-creditable, non-refundable milestone payment of [***].
- 5. In no event may Lilly hold back any amount of any triggered and owing Lilly milestone or royalty payment under the Agreement as an escrow or otherwise in anticipation of any of the payments due and owing or to become due and owing from Incyte under this Third Amendment. Similarly, in no event may Incyte hold back any amount of any triggered and owing Incyte upfront or milestone payment under this Third Amendment as an escrow or otherwise in anticipation of any of the payments due and owing or to become due and owing from Lilly under the Agreement.
- 6. For clarity, the Parties acknowledge that the Graft-Versus-Host Disease Field is within the Inflammatory Disease Field and the Licensed Field, and that this Third Amendment does not alter this fact or restrict Lilly from Development or Commercialization of any Licensed Compound for use in the Graft-Versus-Host Disease Field.
- 7. Section 5.4 (COMMERCIALIZATION; Co-Promotion) of the Agreement is hereby deleted and replaced in its entirety with "[RESERVED]". The Table of Contents of the Agreement is hereby appropriately revised to reflect such deletion, the reference to "Co-Promotion Option" in the "Additional Definitions" section of the Agreement is deleted, and Section 2.6(g)(iii) (LICENSES; Non-Compete) (relating to termination of the Co-Promotion Option) of the Agreement is hereby deleted.
- 8. The provision for notices to Incyte in Section 13.5 of the Agreement is hereby amended and restated to read in its entirety as follows:

"Notices to Incyte shall be addressed to:

Incyte Corporation 1801 Augustine Cut-Off Wilmington, DE 19803 Attn: President and CEO Facsimile No.: [***]

[***] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

With a copy to:

Incyte Corporation 1801 Augustine Cut-Off Wilmington, DE 19803 Attn: General Counsel Facsimile No.: [***]"

- 9. All other terms and conditions of the Agreement shall remain in full force and effect.
- 10. Any disputes regarding this Third Amendment shall be dealt with in accordance the provisions of ARTICLE XII (Dispute Resolution) of the Agreement. The provisions of ARTICLE XIII (Miscellaneous) of the Agreement shall apply to this Third Amendment as if repeated herein.

[remainder of page intentionally left blank]

[***] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

IN WITNESS WHEREOF, the parties by their respective authorized representatives have executed this Third Amendment as of the Effective Date.

ELI LILLY AND COMPANY INCYTE CORPORATION

/s/ David A. Ricks By: Name: David A. Ricks

/s/ Hervé Hoppenot Name: Hervé Hoppenot Title: President and Chief Executive Title: President, Lilly Bio-Medicines

Officer

Exhibit A

Graft-Versus-Host Disease Field (ICD-9-CM)

279.50 Graft-versus-host disease, unspecified (including prophylaxis of Graft-versus-host disease)
279.51 Acute graft-versus-host disease
279.52 Chronic graft-versus-host disease
279.53 Acute on chronic graft-versus-host disease

EMPLOYMENT AGREEMENT

THIS AMENDED AND RESTATED EMPLOYMENT AGREEMENT (the "Agreement") by and between INCYTE CORPORATION, a Delaware corporation (the "Company"), and Hervé Hoppenot (the "Executive"), dated as of the 25th day of October, 2019.

The Board of Directors of the Company (the "Board"), has determined that it is in the best interests of the Company and its stockholders to assure that the Company will have the continued dedication of the Executive, notwithstanding the possibility, threat or occurrence of a Change in Control (as defined below) of the Company. The Board believes it is imperative to diminish the inevitable distraction of the Executive by virtue of the personal uncertainties and risks created by a pending or threatened Change in Control and to encourage the Executive's full attention and dedication to the Company currently and in the event of any threatened or pending Change in Control, and to provide the Executive with compensation and benefits arrangements upon a Change in Control and an event of Change in Control Good Reason that ensure that the compensation and benefits expectations of the Executive will be satisfied and that are competitive with those of other comparable corporations. In addition, as an inducement to the agreement by Executive to be employed by the Company prior to a Change in Control on an "at will" basis, the Company desires to provide Executive with certain benefits upon termination of Executive's employment under certain circumstances as set forth herein.

In order to accomplish these objectives, the Board caused the Company to enter into the employment agreement with the Executive dated as of January 11, 2014, and to amend such agreement as of April 13, 2015 and February 28, 2019. The Board has caused the Company to enter into this amended and restated Agreement in furtherance of the same objectives and to provide additional incentives for the Executive to remain employed by the Company at least through his retirement after December 31, 2024 (or such later date after December 31, 2024 as shall be mutually agreed upon by the parties), specifically, in the form of continued vesting and exercisability of outstanding equity awards following his retirement.

NOW, THEREFORE, IT IS HEREBY AGREED AS FOLLOWS:

SECTION 1. DEFINITIONS

- (a) "Annual Base Salary" shall mean the highest rate of annual base salary paid or payable, including any base salary that has been earned but deferred, to the Executive by the Company and its affiliated companies in respect of the 12-month period immediately preceding the month in which the Change in Control or, in the case of termination other than on account of a Change in Control, the Date of Termination occurs.
- (b) "Business Unit" shall mean a Subsidiary or a business division of the Company or Subsidiary in which the Executive is primarily employed.
 - (c) "Cause" shall mean, during the Change in Control Employment Period:

- (i) The willful and continued failure of the Executive to perform substantially the Executive's duties with the Company or one of its affiliates (other than any such failure resulting from incapacity due to physical or mental illness or impairment), after a written demand for substantial performance is delivered to the Executive by the Board of the Company which specifically identifies the manner in which the Board believes that the Executive has not substantially performed the Executive's duties; or
- (ii) The willful engaging by the Executive in illegal conduct, gross misconduct or dishonesty which is materially and demonstrably injurious to the Company; or
- (iii) Unauthorized and prejudicial disclosure or misuse of the Company's secret, confidential or proprietary information, knowledge or data relating to the Company or its affiliates.

Notwithstanding the foregoing, "Cause" during the Change in Control Employment Period shall not include any act, or failure to act, based upon authority given pursuant to a resolution duly adopted by the Board or based upon the advice of counsel for the Company. The cessation of employment of the Executive shall not be deemed to be for Cause unless and until there shall have been delivered to the Executive a copy of a resolution duly adopted by the affirmative vote of not less than three-quarters of the entire membership of the Board at a meeting of the Board called and held for such purpose (after reasonable notice is provided to the Executive and the Executive is given an opportunity, together with counsel, to be heard before the Board), finding that, in the good faith opinion of the Board, the Executive is guilty of the conduct described in subparagraph (i), (ii) or (iii) above, and specifying the particulars thereof in detail.

"Cause" shall mean, during the Employment Period:

- (i) The continued failure of the Executive to perform the Executive's duties with the Company or one of its affiliates, other than any such failure resulting from incapacity due to Disability, which incapacity has been recognized as such by the Board, after a written demand for substantial performance is delivered to the Executive by the Board that specifically identifies the manner in which the Board believes that the Executive has not substantially performed the Executive's duties; or
- (ii) The engaging by the Executive in illegal conduct, gross misconduct or dishonesty which is injurious to the Company; or
- (iii) Unauthorized disclosure or misuse of the Company's secret, confidential or proprietary information, knowledge or data relating to the Company or its affiliates; or
- (iv) A material breach by the Executive of Section 7 of this Agreement which, if curable (as reasonably determined by the Board), the Executive has failed to remedy after the Board has given the Executive written notice of, and a reasonable opportunity to cure, such breach.

Notwithstanding the foregoing, "Cause" during the Employment Period shall not include any act, or failure to act, based upon authority given pursuant to a resolution duly adopted by the Board or based upon the advice of counsel for the Company. The cessation of employment of the Executive shall not be deemed to be for Cause unless and until there shall have been delivered to the Executive a copy of a resolution duly adopted by the affirmative vote of not less than two-thirds of the members of the Board then in office excluding, for this purpose, the Executive, at a meeting of the Board called and held for such purpose (after reasonable notice is provided to the Executive and the Executive is given an opportunity, together with counsel, to be heard before the Board), finding that, in the good faith opinion of the Board, the Executive is guilty of the conduct described in subparagraph (i), (ii), (iii), (iv) or (v) above, and specifying the particulars thereof in detail.

- (d) "Change in Control" shall mean the occurrence of any of the following events:
- (i) A change in the composition of the Board, as a result of which fewer than one-half of the incumbent directors are directors who either:
 - (A) Had been directors of the Company 24 months prior to such change; or
 - (B) Were elected, or nominated for election, to the Board with the affirmative votes of at least a majority of the directors who had been directors of the Company 24 months prior to such change and who were still in office at the time of the election or nomination;
- (ii) Any "person" (as such term is used in Sections 13(d) and 14(d) of the Exchange Act) by the acquisition or aggregation of securities is or becomes the beneficial owner, directly or indirectly, of securities of the Company representing 50% or more of the combined voting power of the Company's then outstanding securities ordinarily (and apart from rights accruing under special circumstances) having the right to vote at elections of directors (the "Base Capital Stock"); except that any change in the relative beneficial ownership of the Company's securities by any person resulting solely from a reduction in the aggregate number of outstanding shares of Base Capital Stock, and any decrease thereafter in such person's ownership of securities, shall be disregarded until such person increases in any manner, directly or indirectly, such person's beneficial ownership of any securities of the Company;
- (iii) The stockholders of the Company approve a plan of complete liquidation or dissolution of the Company;
- (iv) There is consummated an agreement for the sale or disposition by the Company of all or substantially all of the Company's assets, other than a sale or disposition by the Company to a Subsidiary or to an entity, the voting securities of which are owned by stockholders of the Company in substantially the same proportions as their ownership of the Company immediately prior to such sale; or

(v) The sale, transfer or other disposition of a substantial portion of the stock or assets of the Company or a Business Unit or a similar transaction as the Board, in each case, in its sole discretion, may determine to be a Change in Control.

The term "Change in Control" shall not include a transaction, the sole purpose of which is to change the state of the Company's incorporation or the initial public offering of the stock of a Business Unit.

- (e) "Change in Control Employment Period" shall mean the 24-month period following the occurrence of a Change in Control.
 - (f) "Change in Control Good Reason" shall mean:
 - (i) The assignment to Executive of any duties inconsistent with Executive's position (including status, offices, titles and reporting requirements), authority, duties or responsibilities as in effect immediately prior to a Change in Control or any other action by the Company that results in a diminishment in such position, authority, duties or responsibilities; or
 - (ii) (A) Except as required by law, the failure by the Company to continue to provide to Executive benefits substantially equivalent or more beneficial (including in terms of the amount of benefits provided and the level of participation of Executive relative to other participants), in the aggregate, to those enjoyed by Executive under the Company's employee benefit plans (including, without limitation, any pension, deferred compensation, split-dollar life insurance, supplemental retirement, retirement or savings plan(s) or program(s)) and Welfare Benefits in which Executive was eligible to participate immediately prior to the Change in Control; or (B) the taking of any action by the Company that would, directly or indirectly, materially reduce or deprive Executive of any other benefit, perquisite or privilege enjoyed by Executive immediately prior to the Change in Control, other than an isolated, insubstantial and inadvertent failure not occurring in bad faith and that is remedied by the Company promptly after receipt of notice thereof given by the Executive; or
 - (iii) The Company's requiring the Executive to be based at any office or location more than 35 miles from the office or location where the Executive is based immediately prior to the Change in Control; or
 - (iv) Any reduction in the Executive's Base Salary or Target Bonus opportunity; or
 - (v) A material breach by the Company of Sections 2, 3 or 4 of the Offer Letter or this Agreement.
 - (g) "Code" shall mean the Internal Revenue Code of 1986, as amended.
- (h) "Disability" shall mean the absence of the Executive from the Executive's duties with the Company on a full-time basis for 180 consecutive business days as a result of incapacity due to mental or physical illness or impairment which is determined to be total and permanent by a

physician selected by the Company or its insurers and acceptable to the Executive or the Executive's legal representative.

(i) "Employment Period" means the period the Executive is employed by the Company prior to the Change in Control Employment Period and the period the Executive is employed by the Company after the end of a Change in Control Employment Period.

(i) "Good Reason" shall mean:

- (i) The assignment to Executive of any duties substantially and materially inconsistent with Executive's position (including status, offices, titles and reporting requirements), authority, duties or responsibilities as in effect prior to the Date of Termination or any other action by the Company that results in a substantial and material diminishment in such position, authority, duties or responsibilities; or
- (ii) Any material reduction in the Executive's Base Salary, Target Bonus opportunity or Welfare Benefits, unless such reductions are made proportionally for all executives of the Company at the same time; or
- (iii) A material breach by the Company of this Agreement or of Sections 2, 3 or 4 of the Offer Letter.
- (k) "Offer Letter" shall mean the letter agreement between the Company and the Executive dated December 24, 2013.
- (l) "Performance Shares" shall mean awards under the Company's Amended and Restated 2010 Stock Incentive Plan or any other stock-based incentive plan which entitle Executive to receive shares of common stock of the Company upon achievement of certain performance goals set forth in the applicable award agreements.
- (m) "Retirement" shall mean the Executive's voluntary termination of employment with the Company after December 31, 2024 (or such later date after December 31, 2024 as shall have been mutually agreed upon by Executive and the Company through amendment of this Agreement), provided that he has remained in continuous employment with the Company through such date.
- (n) "RSUs" shall mean the restricted stock units which entitle Executive to receive shares of common stock of the Company, as described in the Offer Letter, or, as the case may be, other restricted stock units awarded under the Company's Amended and Restated 2010 Stock Incentive Plan or any other stock-based incentive plan which entitle Executive to receive shares of common stock of the Company.
- (o) "Signing Bonus" shall mean the signing bonus payable to the Executive pursuant to Section 2 of the Offer Letter.
- (p) "Subsidiary" shall mean any other entity, whether incorporated or unincorporated, in which the Company or any one or more of its Subsidiaries directly owns or controls (i) 50% or more of the securities or other ownership interests, including profits, equity or beneficial

interests, or (ii) securities or other interests having by their terms ordinary voting power to elect more than 50% of the board of directors or others performing similar function with respect to such other entity that is not a corporation.

- (q) "Target Bonus" shall mean the Executive's target bonus under the Company's annual bonus program, or any comparable bonus under any predecessor or successor plan for the year prior to the year in which the Change in Control or, in the case of a termination other than on account of a Change in Control, the Date of Termination occurs.
- (r) "Welfare Benefits" shall mean welfare benefit plans, practices, policies and programs provided by the Company and its affiliated companies (including, without limitation, medical, prescription, dental, disability, employee life, and group life plans and programs) (i) in effect for the Executive at any time during the 120-day period immediately preceding (A) the Change in Control or (B) the Date of Termination (as defined below) or (ii) which are provided at any time after the Change in Control to peer executives of the Company and its affiliated companies, whichever of (i)(A), (i)(B) or (ii) provides the most favorable benefit to the Executive, as determined separately for each such benefit.

SECTION 2. TERMINATION OF EMPLOYMENT.

- (a) <u>Death or Disability</u>. The Executive's employment shall terminate automatically upon the Executive's death during the Employment Period or Change in Control Employment Period. If the Company determines in good faith that the Disability of the Executive has occurred during the Employment Period or Change in Control Employment Period, it may give to the Executive written notice in accordance with Section 9(b) of this Agreement of its intention to terminate the Executive's employment. In such event, the Executive's employment with the Company shall terminate effective on the 30th day after receipt of such notice by the Executive (the "Disability Effective Date"), provided that, within the 30 days after such receipt, the Executive shall not have returned to full-time performance of the Executive's duties.
- (b) <u>Cause</u>. The Company may terminate the Executive's employment for Cause during the Employment Period or Change in Control Employment Period.
- (c) <u>Good Reason</u>. The Executive's employment may be terminated by the Executive for Good Reason during the Employment Period. For purposes of this Section 2(c), any good faith determination of "Good Reason" made by the Executive shall be conclusive.
- (d) <u>Change in Control Good Reason</u>. The Executive's employment may be terminated by the Executive for Change in Control Good Reason during the Change in Control Employment Period. For purposes of this Section 2(d), any good faith determination of "Change in Control Good Reason" made by the Executive shall be conclusive. The termination of the Executive's employment with the Company prior to, but in anticipation of or in connection with, a Change in Control shall be deemed to be a termination by the Executive for Change in Control Good Reason during the Change in Control Employment Period if the Board so determines in its good faith judgment.
- (e) <u>Notice of Termination</u>. Any termination by the Company for Cause, or by the Executive for Good Reason during the Employment Period or for Change in Control Good

Reason during the Change in Control Employment Period, shall be communicated by Notice of Termination to the other party hereto given in accordance with Section 9(b) of this Agreement. For purposes of this Agreement, a "Notice of Termination" means a written notice which (i) indicates the specific termination provision in this Agreement relied upon, (ii) to the extent applicable, sets forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of the Executive's employment under the provision so indicated and (iii) if the Date of Termination (as defined below) is other than the date of receipt of such notice, specifies the termination date (which date shall be not more than 30 days after the giving of such notice or such later date as provided under this Section 2(e)). The failure by the Executive or the Company to set forth in the Notice of Termination any fact or circumstance which contributes to a showing of Good Reason, Change in Control Good Reason or Cause shall not waive any right of the Executive or the Company, respectively, hereunder or preclude the Executive or the Company, respectively, from asserting such fact or circumstance in enforcing the Executive's or the Company's rights hereunder. Notwithstanding the foregoing, a termination shall not be treated as a termination for Good Reason unless (i) the Executive provides a Notice of Termination or a supplemental written notice asserting existence of the condition constituting Change in Control Good Reason within 60 days following the initial existence of the condition, (ii) the Company shall have 60 days from the date of receiving such notice to remedy the condition (the "Cure Period"), and (iii) if the Company fails to remedy the condition during the Cure Period, the Executive terminates employment no later than 60 days after the end of the Cure Period.

(f) <u>Date of Termination</u>. "Date of Termination" means (i) if the Executive's employment is terminated by the Company for Cause, by the Executive for Good Reason during the Employment Period, or by the Executive for Change in Control Good Reason during the Change in Control Employment Period, the date of receipt of the Notice of Termination or any later date specified therein or otherwise required by Section 2(e) above, as the case may be, (ii) if the Executive's employment is terminated by the Company other than for Cause or Disability or by the Executive other than for Good Reason or Change in Control Good Reason, the Date of Termination shall be the date on which the Company or the Executive, as the case may be, notifies the other of such termination, and (iii) if the Executive's employment is terminated by reason of death or Disability, the Date of Termination shall be the date of death of the Executive or the Disability Effective Date, as the case may be.

SECTION 3. OBLIGATIONS OF THE COMPANY UPON TERMINATION

- (a) <u>Termination Other Than for Death or Disability During the Change in Control Employment Period (i)</u> <u>Other Than for Cause or (ii) for Change in Control Good Reason</u>. If, during the Change in Control Employment Period, the Company shall terminate the Executive's employment other than for Cause or the Executive shall terminate employment for Change in Control Good Reason (and the Executive's employment is not terminated by reason of death or Disability):
 - (i) The Company shall pay to the Executive the aggregate of the following amounts:
 - (A) the sum of (1) the Executive's Annual Base Salary through the Date of Termination to the extent not theretofore paid, (2) the product of (x) the

Target Bonus and (y) a fraction, the numerator of which is the number of days in the current fiscal year through the Date of Termination, and the denominator of which is 365 and (3) any compensation previously deferred by the Executive (together with any accrued interest or earnings thereon) and any accrued vacation pay, in each case to the extent not theretofore paid (the sum of the amounts described in clauses (1), (2), and (3) shall be hereinafter referred to as the "Accrued Obligations");

- (B) the amount equal to the product of (1) three and (2) the sum of (x) the Executive's Annual Base Salary and (y) the Target Bonus or, if greater, the bonus pursuant to the Company's management bonus plan in the most recently completed fiscal year; and
 - (C) the Signing Bonus, to the extent not theretofore paid.

Subject to Section 10(c), the payments described in this Section 3(a)(i) shall be paid to the Executive in a lump sum payment within 30 days after the Date of Termination.

- (ii) For 36 months after the Executive's Date of Termination or such longer period as may be provided by the terms of the appropriate plan, program, practice or policy, the Company shall continue Welfare Benefits to the Executive and/or the Executive's family; *provided*, *however*, that if the Executive becomes reemployed with another employer and is eligible to receive medical or other welfare benefits under another employer provided plan, the medical and other welfare benefits described herein shall be secondary to those provided under such other plan during such applicable period of eligibility. Notwithstanding the foregoing, if and to the extent providing such continued Welfare Benefits would result in imposition on the Company of the tax under Section 4980D of the Code or otherwise violate applicable law, the Company shall provide cash payments to the Executive sufficient, on an after-tax basis, to enable the Executive to purchase the affected coverage. For purposes of determining eligibility (but not the time of commencement of benefits) of the Executive for retiree benefits pursuant to such plans, practices, programs and policies, the Executive shall be considered to have remained employed until 36 months after the Executive's Date of Termination and to have retired on the last day of such period;
- (iii) All options acquired under the Company's Amended and Restated 2010 Stock Incentive Plan or any other stock-based incentive plan of or agreement with the Company that have not vested in accordance with the terms and conditions of the grant, award or purchase, shall become 100% vested and all options shall continue to be exercisable for 12 months following the Date of Termination; all Performance Shares shall become 100% vested and shall be settled assuming the target level of performance has been achieved, with the resulting shares of common stock of the Company delivered to the Executive within 30 days after the Date of Termination; and all RSUs, including, without limitation, the RSUs granted pursuant to Section 4 of the Offer Letter, shall become 100% vested and the shares of common stock of the Company shall be delivered to the Executive within 30 days after the Date of Termination;

- (iv) The Company shall, at its sole expense as incurred, provide the Executive with outplacement services for a period of 12 months following the Date of Termination, the scope and provider of which shall be selected by the Executive in his sole discretion(the "Outplacement Benefits"); and
- (v) To the extent not theretofore paid or provided, the Company shall timely pay or provide to the Executive any other amounts or benefits required to be paid or provided or which the Executive is eligible to receive under any plan, program, policy or practice or contract or agreement of the Company and its affiliated companies (such other amounts and benefits shall be hereinafter referred to as the "Other Benefits").
- (b) <u>Termination Other Than for Death or Disability During the Employment Period (i) Other Than for Cause or (ii) for Good Reason</u>. If, during the Employment Period, the Company shall terminate the Executive's employment other than for Cause or the Executive shall terminate employment for Good Reason (and the Executive's employment is not terminated by reason of death or Disability):
 - (i) The Company shall pay to the Executive the aggregate of the following amounts:
 - (A) The Accrued Obligations;
 - (B) the amount equal to the product of (1) 1.5 and (2) the sum of (x) the Executive's Annual Base Salary and (y) the Target Bonus or, if greater, the bonus pursuant to the Company's management bonus plan in the most recently completed fiscal year; and
 - (C) the Signing Bonus, to the extent not theretofore paid.

Subject to Section 10(c), the payments described in this Section 3(b)(i) shall be paid to the Executive in a lump sum payment within 30 days after the Date of Termination.

(ii) For 12 months after the Executive's Date of Termination, if the Executive properly elects to continue the Company's group health plan coverage as is the Executive's right under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), the Company shall pay the portion of the COBRA premiums for Executive and/or the Executive's family equal to the percentage share of medical premiums the Company paid for the Executive and/or the Executive's family prior to the Date of Termination; *provided*, *however*, that if the Executive becomes reemployed with another employer and is eligible to receive medical or other welfare benefits under an other employer provided plan, the medical and other welfare benefits described herein shall be secondary to those provided under such other plan during such applicable period of eligibility. Notwithstanding the foregoing, if and to the extent providing such COBRA premium payments would result in imposition on the Company of the tax under Section 4980D of the Code or otherwise violate applicable law, the Company shall provide cash payments to the Executive sufficient, on an after-tax basis, to enable the Executive to purchase the affected coverage. For purposes of determining eligibility (but not the time

of commencement of benefits) of the Executive for retiree benefits pursuant to such plans, practices, programs and policies, the Executive shall be considered to have remained employed until 12 months after the Executive's Date of Termination and to have retired on the last day of such period;

- An additional portion of options acquired under the Company's Amended and Restated 2010 Stock Incentive Plan or any other stock-based incentive plan of or agreement with the Company that have not vested in accordance with the terms and conditions of the grant, award or purchase, shall become vested equal to the amount of vesting that would have occurred if the Executive had continued working for the Company for an additional 18 months after the Date of Termination and all options shall continue to be exercisable for 180 days following the Date of Termination; an additional portion of the RSUs other than the RSUs granted pursuant to Section 4 of the Offer Letter that have not vested in accordance with the terms and conditions of such grant shall become vested equal to the amount of vesting that would have occurred if the Executive had continued working for the Company for an additional 18 months after the Date of Termination and the shares of common stock of the Company shall be delivered to the Executive within 30 days after the Date of Termination; and an additional portion of the RSUs granted pursuant to Section 4 of the Offer Letter that have not vested in accordance with the terms and conditions of such grant shall become vested equal to the 100% of the amount of vesting that would have occurred if the Executive had continued working for the Company for an additional 12 months after the Date of Termination and 50% of the amount of vesting that would have occurred if the Executive had continued working for the Company for an additional 12 months subsequent to the initial 12 months after the Date of Termination and the shares of common stock of the Company shall be delivered to the Executive within 30 days after the Date of Termination; and
- (iv) The Company shall provide to the Executive the Outplacement Benefits and the Other Benefits.
- (c) <u>Termination for Cause</u>. If the Executive's employment shall be terminated for Cause during the Employment Period or the Change in Control Employment Period, this Agreement shall terminate without further obligations to the Executive other than the obligation to pay to the Executive (x) the Executive's Annual Base Salary through the Date of Termination, (y) the amount of any compensation previously deferred by the Executive, including vested RSUs, and (z) Other Benefits, in each case to the extent theretofore unpaid. In such case, all amounts due and owing to the Executive pursuant to this Section 3(c) shall be paid to the Executive in a lump sum in cash or, in the case of RSUs, in shares of common stock of the Company, within 30 days of the Date of Termination.
- (d) <u>Voluntary Termination</u>. If the Executive voluntarily terminates employment during the Employment Period, other than for Good Reason, or during the Change in Control Employment Period, other than for Change in Control Good Reason, this Agreement shall terminate without further obligations to the Executive other than for Accrued Obligations and the timely payment or provision of Other Benefits; provided that if such termination occurs during the Employment Period, the Executive shall not receive a prorated Target Bonus. In such case, all amounts due and owing to the Executive pursuant to this Section 3(d) shall be paid to the Executive in a lump sum in cash or, in the case of RSUs, in shares of common stock of the

Company, within 30 days of the Date of Termination. Notwithstanding the foregoing, in the event of the Executive's Retirement,

- (i) The Executive shall be entitled to continued vesting in all of his outstanding unvested awards that are granted after July 15, 2019 and before December 31, 2024 (or such later date after December 31, 2024 as shall have been mutually agreed upon by Executive and the Company through amendment of this Agreement) under the Company's Amended and Restated 2010 Stock Incentive Plan and any other stock-based incentive plan of the Company (including but not limited to stock option, restricted stock unit and performance share awards), with such awards to become vested, exercisable and/or payable at the same time or times and under the same conditions as are provided in the applicable award agreements as if the Executive continued to be employed by the Company following the date of his Retirement; and
- (ii) Any outstanding stock option awards that are granted after July 15, 2019 and before December 31, 2024 (or such later date after December 31, 2024 as shall have been mutually agreed upon by Executive and the Company through amendment of this Agreement) and that are either vested as of the date of the Executive's Retirement or become vested after such date pursuant to clause (i) above shall be exercisable at any time during the remainder of the original term of the stock options as set forth in the applicable award agreements;

<u>provided</u>, <u>however</u>, that the benefits under clauses (i) and (ii) of this sentence shall be subject in each case to the Executive's continued compliance after his Retirement with the covenants in Section 7 of this Agreement.

(e) <u>Death or Disability</u>. If the Executive's employment is terminated during the Employment Period or the Change in Control Employment Period due to the death or Disability of the Executive, this Agreement shall terminate without further obligations to the Executive other than for (i) Accrued Obligations and the timely payment or provision of Other Benefits; and (ii) the Signing Bonus, to the extent not theretofore paid. In such case, all amounts due and owing to the Executive or the Executive's estate, as the case may be, pursuant to this Section 3(e) shall be paid to the Executive or the Executive's estate in a lump sum in cash within 30 days of the receipt by the Company of written notice of the Executive's death from the executor of the Executive's estate or the Disability Effective Date.

SECTION 4. SECTION 280G

(a) <u>Basic Rule</u>. Notwithstanding anything in this Agreement to the contrary, in the event that the independent auditors most recently selected by the Board (the "Auditors") determine that any payment or distribution of any type to or for the benefit of the Executive by the Company under this Agreement or any other plan of or agreement with the Company (each a "Payment") is or will be subject to the excise tax imposed under Section 4999 of the Code (the "Excise Tax"), then the Payments shall be reduced (but not below zero) if and to the extent that a reduction in the Payments would result in the Executive retaining a larger amount, on an after-tax basis (taking into account federal, state and local income taxes and the Excise Tax) than if the Executive received the entire amount of such Payments. The determination of which of the

Payments are to be reduced shall be made in a manner consistent with the provisions of Section 4(b).

- (b) Reduction of Payments. If the Auditors determine that any Payments would be subject to the Excise Tax, which calculation shall occur at the time of the Change in Control, then the Company shall promptly give the Executive notice to that effect and a copy of the detailed calculation thereof and of any reduction in Payments needed to comply with Section 4(a), and the Executive may then elect, in the Executive's sole discretion, which and how much of such Payments shall be eliminated or reduced and shall advise the Company in writing of the Executive's election within 10 days of receipt of notice. If no such election is made by the Executive within such 10-day period, then the Company may decide which and how much of such Payments shall be eliminated or reduced in order to comply with Section 4(a) and shall notify the Executive promptly of such decision. For purposes of this Section 4, present value shall be determined in accordance with section 280G(d)(4) of the Code. All determinations made by the Auditors under this Section 4 shall be binding upon the Company and the Executive and shall be made within 60 days of the date when a Payment becomes payable or transferable. As promptly as practicable following such determination and the elections hereunder, the Company shall pay or transfer to or for the benefit of the Executive such amounts as are then due to the Executive under this Agreement and shall promptly pay or transfer to or for the benefit of the Executive in the future such amounts as become due to the Executive under this Agreement.
- (c) Overpayments and Underpayments. As a result of uncertainty in the application of section 280G of the Code at the time of an initial determination by the Auditors hereunder, it is possible that Payments will have been made by the Company that should not have been made (an "Overpayment") or that additional Payments that will not have been made by the Company could have been made (an "Underpayment"), consistent in each case with the calculation of the maximum amount permitted to be paid under Section 4(a). In the event that the Auditors, based upon the assertion of a deficiency by the Internal Revenue Service against the Company or the Executive that the Auditors believe has a high probability of success, determine that an Overpayment has been made, such Overpayment shall be treated for all purposes as a loan to the Executive which he or she shall repay to the Company, together with interest at the applicable federal rate provided in section 7872(f)(2) of the Code; provided, however, that no amount shall be payable by the Executive to the Company if and to the extent that such payment would not reduce the Company's Federal income tax liability under section 280G of the Code. In the event that the Auditors determine that an Underpayment has occurred, such Underpayment shall promptly be paid or transferred by the Company to or for the benefit of the Executive, together with interest at the applicable federal rate provided in section 7872(f)(2) of the Code.
- (d) <u>Waiver of Limitation</u>. At any time, and in its sole discretion, the Company's Compensation Committee of the Board may elect to waive, in whole or in part, the reduction of a Payment to be made pursuant to this Agreement, notwithstanding the determination that such Payment will be nondeductible by the Company for federal income tax purposes because of section 280G of the Code.
- (e) <u>Related Corporations</u>. For purposes of this Section 4, the term "Company" shall include affiliated corporations to the extent determined by the Auditors in accordance with section 280G(d)(5) of the Code.

SECTION 5. NON-EXCLUSIVITY OF RIGHTS.

Nothing in this Agreement shall prevent or limit the Executive's continuing or future participation in any plan, program, policy or practice provided by the Company or any of its affiliated companies and for which the Executive may qualify, nor, subject to Section 9(f), shall anything herein limit or otherwise affect such rights as the Executive may have under any contract or agreement with the Company or any of its affiliated companies. Amounts which are vested benefits or which the Executive is otherwise entitled to receive under any plan, policy, practice or program of or any contract or agreement with the Company or any of its affiliated companies at or subsequent to the Date of Termination shall be payable in accordance with such plan, policy, practice or program or contract or agreement except as explicitly modified by this Agreement.

SECTION 6. FULL SETTLEMENT.

The Company's obligation to make the payments provided for in this Agreement and otherwise to perform its obligations hereunder shall not be affected by any set-off, counterclaim, recoupment, defense or other claim, right or action which the Company may have against the Executive or others (other than pursuant to Section 7(d) of this Agreement). In no event shall the Executive be obligated to seek other employment or take any other action by way of mitigation of the amounts payable to the Executive under any of the provisions of this Agreement and such amounts shall not be reduced whether or not the Executive obtains other employment. The Company agrees to pay as incurred, to the full extent permitted by law, all legal fees and expenses which the Executive may reasonably incur as a result of any contest (regardless of the outcome thereof) by the Company, the Executive or others of the validity or enforceability of, or liability under, any provision of this Agreement or any guarantee of performance thereof (including as a result of any contest by the Executive about the amount of any payment pursuant to this Agreement), plus in each case interest on any delayed payment at the applicable Federal rate provided for in section 7872(f)(2)(A) of the Code. Notwithstanding the foregoing, the Company will not pay any legal fees or expenses which the Executive may incur as a direct result of any contest or dispute regarding Sections 7(a), 7(b) or 7(d) of this Agreement; provided, however, that (i) this sentence shall not apply if (A) after a Change in Control the Executive's employment with the Company is terminated by the Company without Cause or by the Executive for Change in Control Good Reason and (B) the Executive has not, in the good faith determination of the Board, blatantly and willfully breached Sections 7(a), 7(b) or 7(c) of this Agreement and (ii) if this sentence applies and there is a contest or dispute regarding Sections 7(a), 7(b) or 7(d) of this Agreement and the Executive is found to have not violated Section 7 of this Agreement, then the Company will reimburse all such legal fees and expenses reasonably incurred as a result of such contest or dispute.

SECTION 7. COVENANTS.

(a) The Executive represents and warrants to the Company that the performance of the Executive's duties will not violate any agreements with or trade secrets of any other person or entity or previous employers, including without limitation agreements containing provisions against solicitation or competition. The Executive has provided the Company with a copy of the Employment Agreement, dated April 15, 2010, between Novartis Pharmaceuticals Corporation and the Executive and any other agreements that could restrict the Executive's activities in the

course of the Executive's employment with the Company. The Executive represents and warrants to the Company that there is no other agreement that could restrict his activities in the course of his employment with the Company, it being understood that Executive may execute any document re-affirming Executive's confidentiality obligations to Novartis. The Company's offer of employment is based on the accuracy of the Executive's representation and warranty and a violation of this Section 7(a) shall be grounds for termination with Cause.

- (b) During the Executive's employment with the Company and for two (2) years after the termination of the Executive's employment for any reason (and in the event of the Executive's Retirement, for any additional period during which the Executive's equity awards continue to vest after his Retirement pursuant to Section 3(d) hereof), the Executive agrees that, without the prior express written consent of the Company, the Executive shall not, anywhere in the world, for his own benefit or for, with or through any other person, firm, partnership, corporation or other entity or individual (other than the Company or its affiliates) as or in the capacity of an owner, shareholder, employee, consultant, director, officer, trustee, partner, agent, independent contractor and/or in any other representative capacity or otherwise:
 - (i) personally (or personally direct another to) solicit or hire (A) any employee of the Company or its affiliates at the time of such solicitation or hiring or (B) any former employee of the Company or its affiliates who had such relationship within six (6) months prior to the date of such solicitation or hiring, including but not limited to attempting to induce any such employee of the Company or its affiliates to leave the employ of the Company; or
 - (ii) personally (or personally direct another to) disparage the Company, any of its products or practices, or any of its directors, officers, agents, representatives, owners or employees, either orally or in writing; <u>provided</u>, that the Executive may confer in confidence with his legal representatives and make truthful statements as required by law.

For purposes of this Section 7(b), the term "solicit" means any communication of any kind whatsoever, regardless of by whom initiated, inviting, encouraging or requesting any person or entity to take or refrain from taking any action.

(c) The Executive shall hold in a fiduciary capacity for the benefit of the Company all secret or confidential information, knowledge or data relating to the Company or any of its affiliated companies, and their respective businesses, which shall have been obtained by the Executive during the Executive's employment by the Company or any of its affiliated companies and which shall not be or become public knowledge (other than by acts by the Executive or representatives of the Executive in violation of this Agreement). After termination of the Executive's employment with the Company, the Executive shall not, without the prior written consent of the Company or as may otherwise be required by law or legal process, communicate or divulge any such information, knowledge or data to anyone other than the Company and those designated by it. In no event shall an asserted violation of the provisions of this Section 7 constitute a basis for deferring or withholding any amounts otherwise payable to the Executive under this Agreement. The Executive also agrees to comply with the terms set forth in the Confidential Information and Invention Assignment Agreement.

- (d) If at any time prior to the date that is 365 days after the Executive's Date of Termination or, in the event of the Executive's Retirement, any time after such Retirement and prior to the date on which the Executive's equity awards have become fully vested in accordance with Section 3(d) hereof, the Executive breaches any provision of Sections 7(a), 7(b) or 7(c) of this Agreement in more than a minor, de minimis or trivial manner, then (i) the Executive shall forfeit all of his unexercised Company stock options or stock appreciation rights, unvested Company restricted stock, unvested Company restricted stock units (including unvested RSUs) and unvested Performance Shares, and (ii) the gain or income realized within the twenty-four (24) months prior to such breach from (A) the exercise of any Company stock options or stock appreciation rights, (B) the vesting of any Company restricted stock or other Company equity based awards, (C) the vesting and settlement of any Performance Shares, or (D) the vesting of restricted stock units, by the Executive from such event shall be paid by the Executive to the Company upon notice from the Company (for purposes of this Section 7(d), the exercise of incentive stock options and the vesting of restricted stock units shall be treated as a realization event). Such gain shall be determined on a gross basis, without reduction for any taxes incurred, as of the date of such event, and without regard to any subsequent change in the Fair Market Value (as defined below) of a share of Company common stock. The Company shall have the right to offset such gain against any amounts otherwise owed to the Executive by the Company (whether as wages, vacation pay, or pursuant to any benefit plan or other compensatory arrangement). For purposes of this Section 7(d), the "Fair Market Value" of a share of Company common stock on any date shall be (i) the closing sale price per share of Company common stock during normal trading hours on the national securities exchange on which the Company common stock is principally traded for such date or the last preceding date on which there was a sale of such Company common stock on such exchange or (ii) if the shares of Company common stock are then traded on any over-the-counter market, the average of the closing bid and asked prices for the shares of Company common stock during normal trading hours in such over-the-counter market for such date or the last preceding date on which there was a sale of such Company common stock in such market, or (iii) if the shares of Company common stock are not then listed on a national securities exchange or traded in an over-the-counter market, such value as the Compensation Committee shall determine in good faith. Notwithstanding the foregoing, this Section 7(d) shall not apply in the event that after a Change in Control the Executive's employment with the Company is terminated either (i) by the Company without Cause or (ii) by the Executive for Change in Control Good Reason.
- (e) Any termination of the Executive's employment or of this Agreement shall have no effect on the continuing operation of this Section 7.
- (f) The Executive acknowledges and agrees that the Company will have no adequate remedy at law, and could be irreparably harmed, if the Executive breaches or threaten to breach any of the provisions of this Section 7. The Executive agrees that the Company shall be entitled to equitable and/or injunctive relief to prevent any breach or threatened breach of this Section 7, and to specific performance of each of the terms hereof in addition to any other legal or equitable remedies that the Company may have. The Executive further agrees that he shall not, in any equity proceeding relating to the enforcement of the terms of this Section 7, raise the defense that the Company has an adequate remedy at law.

- (g) The terms and provisions of this Section 7 are intended to be separate and divisible provisions and if, for any reason, any one or more of them is held to be invalid or unenforceable, neither the validity nor the enforceability of any other provision of this Agreement shall thereby be affected. The parties hereto acknowledge that the potential restrictions on the Executive's future employment imposed by this Section 7 are reasonable in both duration and geographic scope and in all other respects. If for any reason any court of competent jurisdiction shall find any provisions of this Section 7 unreasonable in duration or geographic scope or otherwise, the Executive and the Company agree that the restrictions and prohibitions contained herein shall be effective to the fullest extent allowed under applicable law in such jurisdiction.
- (h) The parties acknowledge that the Offer Letter and this Agreement would not have been entered into and the benefits described herein and therein would not have been promised in the absence of the Executive's promises under this Section 7.

SECTION 8. SUCCESSORS.

- (a) This Agreement is personal to the Executive and without the prior written consent of the Company shall not be assignable by the Executive otherwise than by will or the laws of descent and distribution. This Agreement shall inure to the benefit of and be enforceable by the Executive's legal representatives.
- (b) This Agreement shall inure to the benefit of and be binding upon the Company and its successors and assigns.
- (c) The Company will require any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business and/or assets of the Company or the relevant Business Unit to assume expressly and agree to perform this Agreement in the same manner and to the same extent that the Company or such Business Unit would be required to perform it if no such succession had taken place. As used in this Agreement, "Company" shall mean the Company as hereinbefore defined and any successor to its business and/or assets as aforesaid which assumes and agrees to perform this Agreement by operation of law, or otherwise.

SECTION 9. MISCELLANEOUS.

- (a) This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware without reference to principles of conflict of laws. The captions of this Agreement are not part of the provisions hereof and shall have no force or effect. This Agreement may not be amended or modified otherwise than by a written agreement executed by the parties hereto or their respective successors and legal representatives.
- (b) All notices and other communications hereunder shall be in writing and shall be given by hand delivery to the other party or by registered or certified mail, return receipt requested, postage prepaid, addressed as follows:

If to the Executive:

at the Executive's current address as shown on the records of the Company.

If to the Company: Incyte Corporation 1801 Augustine Cut-Off Wilmington, DE 19803 Attention: General Counsel

or to such other address as either party shall have furnished to the other in writing in accordance herewith. Notice and communications shall be effective when actually received by the addressee.

- (c) The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement.
- (d) The Company may withhold from any amounts payable under this Agreement such Federal, state, local or foreign taxes as shall be required to be withheld pursuant to any applicable law or regulation.
- (e) The Executive's or the Company's failure to insist upon strict compliance with any provision of this Agreement or the failure to assert any right the Executive or the Company may have hereunder, including, without limitation, the right of the Executive to terminate employment for Good Reason pursuant to Section 2(c) or Change in Control Good Reason pursuant to Section 2(d) of this Agreement, shall not be deemed to be a waiver of such provision or right or any other provision or right of this Agreement.
- (f) The Executive and the Company acknowledge that, except as may otherwise be provided under any other written agreement between the Executive and the Company, the employment of the Executive by the Company is "at will" and, prior to the Change in Control, the Executive's employment and/or this Agreement may be terminated by either the Executive or the Company at any time, in which case the Executive shall have no further rights under this Agreement except as expressly set forth in Section 3 hereof. From and after the closing of a Change in Control transaction, this Agreement shall supersede any other agreement between the parties with respect to the subject matter hereof (provided that it shall not supersede the Company's obligations in the Offer Letter or the Executive's obligations under the Confidential Information and Invention Assignment Agreement).
- (g) Should any disputes, claims, complaints, or causes of action occur between Executive and the Company (the "Parties") which arise out of, are related to, or connected with, either or directly or indirectly, the interpretation, application, or alleged violation of this Agreement, or which arise out of any other professional, personal or business dealings or relationships between the Parties, they shall all be resolved in arbitration in accordance with the rules and procedures of JAMS (Judicial Arbitration and Mediation Services), New York Times Building, 620 8th Avenue, New York, NY 10018 (212-751-2700). The Parties voluntarily and knowingly acknowledge their understanding that under this provision for arbitration they are waiving (*i.e.*, giving up) their right to bring a law suit in a court of law and to have a judge and a trial by jury to resolve any of these claims/disputes/causes of action between them. If any arbitration is brought by any Party under this Agreement and under the Offer Letter, then both arbitrations shall be consolidated into one and shall be heard by one arbitrator in a single arbitration proceeding. Any arbitration proceeding shall be held in Wilmington, Delaware. Any decision as

to the scope and nature of Executive's duties shall be made by the Board, in its sole discretion, and shall not be subject to any dispute resolution.

SECTION 10. CODE SECTION 409A COMPLIANCE.

- (a) To the fullest extent applicable, amounts and other benefits payable under this Agreement are intended to be exempt from the definition of "nonqualified deferred compensation" under section 409A of the Code ("Section 409A") in accordance with one or more of the exemptions available under the final Treasury regulations promulgated under Section 409A and, to the extent that any such amount or benefit is or becomes subject to Section 409A due to a failure to qualify for an exemption from the definition of nonqualified deferred compensation in accordance with such final Treasury regulations, this Agreement is intended to comply with the applicable requirements of Section 409A with respect to such amounts or benefits. This Agreement shall be interpreted and administered to the extent possible in a manner consistent with the foregoing statement of intent.
- (b) Notwithstanding anything in this Agreement or elsewhere to the contrary, for purposes of determining the payment date of any amounts that are treated as nonqualified deferred compensation under Section 409A of the Code that become payable under this Agreement in connection with a termination of employment, the Date of Termination shall be the date on which the Executive has incurred a "separation from service" within the meaning of Treasury Regulation section 1.409A-1(h), or in subsequent IRS guidance under Code section 409A.
- (c) Notwithstanding anything in this Agreement or elsewhere to the contrary, if the Company reasonably determines that (A) the Executive is a "specified employee" (within the meaning of Treasury Regulation Section 1.409A-1(i)) on the Executive's Date of Termination and (B) commencement of any payments or other benefits payable under this Agreement in connection with the Executive's separation from service, including without limitation, payment of any of the payments on the scheduled payment dates specified in Section 3, will subject the Executive to an "additional tax" under Section 409A(a)(1)(B) (together with any interest or penalties imposed with respect to, or in connection with, such tax, a "Section 409A Tax"), then the Company shall withhold payment of any such payments or benefits until the first business day of the seventh month following the date of the Executive's Date of Termination or, if earlier, the date of the Executive's death (the "Delayed Payment Date"). In the event that this Section 10(c) requires any payments to be withheld, such withheld payments shall be accumulated and paid in a single lump sum, with interest at the applicable federal rate provided in section 7872(f)(2) of the Code, on the Delayed Payment Date.
- (d) In each case where this Agreement provides for the payment of an amount that constitutes nonqualified deferred compensation under Section 409A to be made to the Executive within a designated period (e.g., within 30 days after the Date of Termination) and such period begins and ends in different calendar years, the exact payment date within such range shall be determined by the Company, in its sole discretion, and the Executive shall have no right to designate the year in which the payment shall be made.

(e) The Company and the Executive may agree to take other actions to avoid the imposition of a Section
409A Tax at such time and in such manner as permitted under Section 409A.
This Agreement may be executed in counterparts, each of which is deemed an original, but all of which
constitute one and the same agreement.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Executive and the Company, through its duly authorized Officer, have executed this Agreement as of the day and year first above written.

EXECUTIVE

/s/ Hervé Hoppenot

COMPANY

By /s/ Paula J. Swain

Its Executive Vice President, Human Resources

CERTIFICATION

- I, Hervé Hoppenot, certify that:
- 1. I have reviewed this quarterly report on Form 10-Q of Incyte Corporation;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 29, 2019

/s/ HERVÉ HOPPENOT

Hervé Hoppenot Chief Executive Officer

CERTIFICATION

- I, Christiana Stamoulis, certify that:
- 1. I have reviewed this quarterly report on Form 10-Q of Incyte Corporation;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 29, 2019

/s/ CHRISTIANA STAMOULIS

Christiana Stamoulis Chief Financial Officer

STATEMENT PURSUANT TO 18 U.S.C. SECTION 1350

With reference to the Quarterly Report of Incyte Corporation (the "Company") on Form 10-Q for the quarter ended September 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Hervé Hoppenot, Chief Executive Officer of the Company, certify, for the purposes of 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ HERVÉ HOPPENOT

Hervé Hoppenot Chief Executive Officer October 29, 2019

STATEMENT PURSUANT TO 18 U.S.C. SECTION 1350

With reference to the Quarterly Report of Incyte Corporation (the "Company") on Form 10-Q for the quarter ended September 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Christiana Stamoulis, Chief Financial Officer of the Company, certify, for the purposes of 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ CHRISTIANA STAMOULIS

Christiana Stamoulis Chief Financial Officer October 29, 2019