
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549
FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2021

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission File Number: 001-12400

INCYTE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

94-3136539
(IRS Employer
Identification No.)

**1801 Augustine Cut-Off
Wilmington, DE 19803**
(Address of principal executive offices)

19803
(Zip Code)

(302) 498-6700

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of exchange on which registered</u>
Common Stock, \$.001 par value per share	INCY	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The number of outstanding shares of the registrant's Common Stock, \$.001 par value, was 219,923,477 as of April 27, 2021.

INCYTE CORPORATION

INDEX

<u>PART I: FINANCIAL INFORMATION</u>	3
<u>Item 1. Financial Statements</u>	3
<u>Condensed Consolidated Balance Sheets</u>	3
<u>Condensed Consolidated Statements of Operations</u>	4
<u>Condensed Consolidated Statements of Comprehensive Income (Loss)</u>	5
<u>Condensed Consolidated Statements of Stockholders' Equity</u>	6
<u>Condensed Consolidated Statements of Cash Flows</u>	7
<u>Notes to Condensed Consolidated Financial Statements</u>	8
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	37
<u>Forward-Looking Statements</u>	37
<u>Summary Risk Factors</u>	40
<u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u>	64
<u>Item 4. Controls and Procedures</u>	64
<u>PART II: OTHER INFORMATION</u>	
<u>Item 1A. Risk Factors</u>	64
<u>Item 6. Exhibits</u>	90
<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)

	March 31, 2021	December 31, 2020*
	<u>(unaudited)</u>	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 1,669,968	\$ 1,513,008
Marketable securities—available-for-sale (amortized cost \$292,278; allowance for credit losses \$0)	292,425	288,369
Accounts receivable	397,357	481,994
Inventory	16,700	16,425
Prepaid expenses and other current assets	73,519	60,098
Total current assets	<u>2,449,969</u>	<u>2,359,894</u>
Restricted cash and investments	1,643	1,757
Long term investments	202,174	222,301
Inventory	23,679	19,548
Property and equipment, net	594,670	559,625
Finance lease right-of-use assets, net	27,987	28,451
Other intangible assets, net	166,907	172,291
Goodwill	155,593	155,593
Other assets, net	38,814	41,458
Total assets	<u>\$ 3,661,436</u>	<u>\$ 3,560,918</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 85,058	\$ 98,767
Accrued compensation	75,718	113,340
Accrued and other current liabilities	420,882	378,404
Finance lease liabilities	2,317	2,284
Acquisition-related contingent consideration	39,906	38,400
Total current liabilities	<u>623,881</u>	<u>631,195</u>
Acquisition-related contingent consideration	223,094	227,600
Finance lease liabilities	32,154	32,573
Other liabilities	54,463	58,282
Total liabilities	<u>933,592</u>	<u>949,650</u>
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; none issued or outstanding as of March 31, 2021 and December 31, 2020	—	—
Common stock, \$0.001 par value; 400,000,000 shares authorized; 219,880,198 and 219,489,329 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	220	219
Additional paid-in capital	4,420,902	4,352,864
Accumulated other comprehensive loss	(20,358)	(15,360)
Accumulated deficit	(1,672,920)	(1,726,455)
Total stockholders' equity	<u>2,727,844</u>	<u>2,611,268</u>
Total liabilities and stockholders' equity	<u>\$ 3,661,436</u>	<u>\$ 3,560,918</u>

* The condensed consolidated balance sheet at December 31, 2020 has been derived from the audited consolidated financial statements at that date.

See accompanying notes.

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

	Three Months Ended March 31,	
	2021	2020
Revenues:		
Product revenues, net	\$ 504,811	\$ 486,727
Product royalty revenues	99,907	81,780
Total revenues	<u>604,718</u>	<u>568,507</u>
Costs and expenses:		
Cost of product revenues (including definite-lived intangible amortization)	29,220	27,319
Research and development	306,896	1,085,287
Selling, general and administrative	153,795	111,148
Change in fair value of acquisition-related contingent consideration	5,526	6,627
Collaboration loss sharing	10,484	2,130
Total costs and expenses	<u>505,921</u>	<u>1,232,511</u>
Income (loss) from operations	98,797	(664,004)
Other income (expense), net	(1,407)	8,662
Interest expense	(359)	(602)
Unrealized loss on long term investments	(27,709)	(48,132)
Income (loss) before provision for income taxes	69,322	(704,076)
Provision for income taxes	15,787	16,566
Net income (loss)	<u>\$ 53,535</u>	<u>\$ (720,642)</u>
Net income (loss) per share:		
Basic	\$ 0.24	\$ (3.33)
Diluted	\$ 0.24	\$ (3.33)
Shares used in computing net income (loss) per share:		
Basic	219,801	216,721
Diluted	221,867	216,721

See accompanying notes.

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

	Three Months Ended	
	March 31,	
	2021	2020
Net income (loss)	\$ 53,535	\$ (720,642)
Other comprehensive income (loss):		
Foreign currency translation	(5,308)	1,560
Unrealized (loss) gain on marketable securities, net of tax	(32)	654
Defined benefit pension obligations, net of tax	342	221
Other comprehensive income (loss)	(4,998)	2,435
Comprehensive income (loss)	<u>\$ 48,537</u>	<u>\$ (718,207)</u>

See accompanying notes.

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

	For the Three Months Ended March 31, 2020				
	Common Stock	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
Balances at January 1, 2020	\$ 216	\$ 4,044,490	\$ (15,542)	\$ (1,430,758)	\$ 2,598,406
Issuance of 772,538 shares of Common Stock upon exercise of stock options and settlement of employee restricted stock units	1	14,618	—	—	14,619
Issuance of 1,957 shares of Common Stock for services rendered	—	145	—	—	145
Stock compensation	—	42,758	—	—	42,758
Other comprehensive income	—	—	2,435	—	2,435
Net loss	—	—	—	(720,642)	(720,642)
Balances at March 31, 2020	\$ 217	\$ 4,102,011	\$ (13,107)	\$ (2,151,400)	\$ 1,937,721

	For the Three Months Ended March 31, 2021				
	Common Stock	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
Balances at January 1, 2021	\$ 219	\$ 4,352,864	\$ (15,360)	\$ (1,726,455)	\$ 2,611,268
Issuance of 389,512 shares of Common Stock upon exercise of stock options and settlement of employee restricted stock units	1	20,027	—	—	20,028
Issuance of 1,357 shares of Common Stock for services rendered	—	108	—	—	108
Stock compensation	—	47,903	—	—	47,903
Other comprehensive loss	—	—	(4,998)	—	(4,998)
Net income	—	—	—	53,535	53,535
Balances at March 31, 2021	\$ 220	\$ 4,420,902	\$ (20,358)	\$ (1,672,920)	\$ 2,727,844

See accompanying notes.

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

	Three Months Ended	
	March 31,	
	2021	2020
Cash flows from operating activities:		
Net income (loss)	\$ 53,535	\$ (720,642)
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	13,838	13,098
Stock-based compensation	47,358	42,513
Other, net	4,622	145
Unrealized loss on long term investments	27,709	48,132
Change in fair value of acquisition-related contingent consideration	5,526	6,627
Changes in operating assets and liabilities:		
Accounts receivable	84,637	(42,713)
Prepaid expenses and other assets	(10,777)	(16,701)
Inventory	(4,406)	(5,712)
Accounts payable	(13,709)	(22,710)
Accrued and other liabilities	(2,238)	14,546
Net cash provided by (used in) operating activities	<u>206,095</u>	<u>(683,417)</u>
Cash flows from investing activities:		
Purchase of long term investment	(8,662)	(95,468)
Sale of long term investment	1,080	—
Capital expenditures	(48,083)	(39,265)
Purchases of marketable securities	(39,301)	(147,403)
Sale and maturities of marketable securities	35,213	173,576
Net cash (used in) investing activities	<u>(59,753)</u>	<u>(108,560)</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock under stock plans	20,028	14,619
Payment of finance lease liabilities	(573)	(187)
Payment of contingent consideration	(6,620)	(11,933)
Net cash provided by financing activities	<u>12,835</u>	<u>2,499</u>
Effect of exchange rates on cash, cash equivalents, restricted cash and investments	(2,331)	1,560
Net increase (decrease) in cash, cash equivalents, restricted cash and investments	156,846	(787,918)
Cash, cash equivalents, restricted cash and investments at beginning of period	1,514,765	1,833,707
Cash, cash equivalents, restricted cash and investments at end of period	<u>\$ 1,671,611</u>	<u>\$ 1,045,789</u>
Supplemental Schedule of Cash Flow Information		
Income taxes paid	\$ 339	\$ 855
Unpaid purchases of property and equipment	\$ 21,262	\$ 13,582
Leased assets obtained in exchange for new operating lease liabilities	\$ 1,898	\$ 1,984
Leased assets obtained in exchange for new finance lease liabilities	\$ 68	\$ —

See accompanying notes.

INCYTE CORPORATION
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2021
(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), ICLUSIG® (ponatinib), PEMAZYRE® (pemigatinib) and MONJUVI® (tafasitamab-cxix), which is co-commercialized. 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 March 31, 2021, the condensed consolidated statements of operations, comprehensive income (loss), stockholders’ equity, and cash flows for the three months ended March 31, 2021 and 2020, 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, 2020 has been derived from our audited consolidated 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, 2020.

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. By policy, we invest our excess available funds

primarily in U.S. government debt securities which are securities issued or guaranteed by the U.S. government and money market funds that meet certain guidelines, which limits exposure to potential credit losses. Our receivables mainly relate to our product sales 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.

Current Expected Credit Losses. Financial assets measured at amortized cost are assessed for future expected credit losses under guidance within ASC 326, Financial Instruments – Credit Losses, to determine if application of an expected credit losses reserve is necessary. On a quarterly basis, receivables that resulted from revenue transactions within the scope of ASC 606 and recognized on an amortized cost basis are reviewed on a customer-level basis to analyze expectations of future collections based upon past history of collections, payment, aging of receivables and viability of the customer to continue payment, as well as estimates of future economic conditions. Receivables generally consist of two types: receivables from collaborative agreements, including milestones, reimbursements for agreed-upon activities and sales royalties; and receivables from customer product sales. Collaborative agreement receivables are closely monitored relationships with select, reputable industry peers. Collection of receivables is assessed within each collaborative partnership on a quarterly basis, including evaluation of each entity’s credit quality, financial health and past history of payment. Customer product sales receivables are independently evaluated on a monthly basis, on which unusual items or aged receivables are closely monitored for signs of credit deterioration, or indications of payment refusal. Customer product sales are with specialty pharmaceutical distributors, wholesalers, and certain public and private institutions, some of which whose financial obligations are funded by various government agencies.

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 U.S. government debt 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 March 31, 2021 and December 31, 2020, we had no allowance for doubtful accounts. We provide an allowance for doubtful accounts based on management’s assessment of the collectability of specific customer accounts, which includes consideration of the credit worthiness and financial condition of those customers, aging of such receivables, history of collectability with the customer and the general economic environment. We record an allowance to reduce the receivables to the amount that is expected to be collected.

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.

We began capitalizing PEMAZYRE inventory after FDA approval in April 2020 as the related costs were expected to be recoverable through the commercialization of the product. Costs incurred prior to FDA approval have been recorded as research and development expense in our statements of operations. As a result, cost of product revenues for the next 36 months will reflect a lower average per unit cost of materials.

JAKAFI, ICLUSIG and PEMAZYRE raw materials and work-in-process inventory are 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 March 31, 2021, 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 our condensed consolidated balance sheets. Our equity investments are accounted for at fair value using readily determinable pricing available on a securities exchange on our 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. 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. 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 any deferred lease payments. Operating lease right-of-use assets are recorded in property and equipment, net on the condensed consolidated balance sheet and lease cost is recognized on a straight-line basis. For finance leases, expense is recognized as 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, 2020 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. The primary factors used to assess the likelihood of realization are our recent history of cumulative earnings or losses, expected reversals of taxable temporary timing differences, forecasts of future taxable income and available tax planning strategies that could be implemented to realize the deferred tax assets. Upon evaluating and weighting both positive and negative evidence, we concluded that we should continue to maintain the valuation allowance on the majority of our deferred tax assets as of March 31, 2021.

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.

The Coronavirus Aid, Relief, and Economic Security (CARES) Act was signed into law in March 2020 to provide an estimated \$2.2 trillion designed to stimulate the U.S. economy during the COVID-19 pandemic. The Act includes tax relief, government loans, grants and investments for entities in affected industries, which has related accounting and financial reporting impacts. Disclosure for certain income tax accounting measures are required in the period of enactment and disclosure for government loans, investments, grants, and revenue recognition are required in future periods as federal agencies establish rules and procedures to implement the CARES Act. During the three months ended March 31, 2021, we have continued to delay the payment of certain employer payroll tax amounts to future periods as allowed under the Act. However, we do not expect the CARES Act to have a material impact on our overall financial results, our income tax provision or our liquidity. We have further described the expected impact and risks of COVID-19 on our business in Item 1. Business and in Item 1A. Risk Factors.

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 apply the following five-step model in order to determine this amount: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation, which for the Company is generally at a point

in time. We also 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 PEMAZYRE 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 sell JAKAFI and PEMAZYRE to our customers in the U.S., which include specialty pharmacies and wholesalers. We sell 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. 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. Additionally, beginning in January 2020, the amount of spending required by eligible patients in the Medicare Part D insurance coverage gap increased 30% due to the expiration of a provision in the Patient Protection and Affordable Care Act, which now results in a change in the True Out of Pocket (TrOOP) calculation methodology. The methodological change has resulted in an increase in required spending by patients and, in turn, an increase in manufacturers' contributions on behalf of patients in the Medicare Part D insurance coverage gap.

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. Royalty revenues on commercial sales for capmatinib (marketed as TABRECTA®) by Novartis are based on net sales of licensed products in the licensed territories as provided by Novartis. We recognize royalty revenues in the period the sales occur.

Milestone and Contract Revenues

For each collaborative research, development and/or commercialization agreement that results in revenue under the guidance of ASC 606, Revenue from Contracts with Customers, we identify all material performance obligations, which may include the license to intellectual property and know-how, research and development activities and/or other activities. In order to determine the transaction price, in addition to any upfront payment, we estimate the amount of variable consideration, including milestone payments, at the outset of the contract utilizing the most likely amount method. The most likely amount method is used since the milestone payments have a binary outcome (i.e., we receive all or none of the milestone payment). We constrain the estimate of variable consideration such that it is probable that a significant reversal of previously recognized revenue will not occur. When determining if variable consideration should be constrained, management considers whether there are factors outside the Company’s control that could result in a significant reversal of revenue. In making these assessments, management considers the likelihood and magnitude of a potential reversal of revenue. These estimates are re-assessed each reporting period as required. Once the estimated transaction price is established, amounts are allocated to the performance obligations that have been identified. The transaction price is generally allocated to each separate performance obligation on a relative standalone selling price basis.

Out-licensing arrangements contain the right to use functional intellectual property, which is the underlying performance obligation of these collaborative arrangements. If the license of our intellectual property is determined to be distinct from other performance obligations in the arrangement, the functional intellectual property that is transferred to the collaborative partner at the onset of the arrangement is concluded to have significant standalone functionality and value at the point in time at which the intellectual property is made available to the collaborative partner. For licenses that are not distinct from other obligations identified in the arrangement, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time. If the combined performance obligation is satisfied over time, we apply an appropriate method of measuring progress for purposes of recognizing revenue from nonrefundable, upfront license fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. For the three months ended March 31, 2021 and 2020, we had no revenues from intellectual licenses recognized over time.

For milestone revenues related to sales-based achievements, we recognize the milestone revenues in the corresponding period of the product sale, in accordance with the guidance of ASC 606-10-55-65 for contracts that include a license to intellectual property and the license is the predominant item to which the product sale relates.

Subsequent to the transfer of the intellectual property, we may earn milestones through achievement of pre-specified developmental or regulatory events and, as such, milestones are accounted for as variable consideration. We include developmental or regulatory milestones in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the milestone is subsequently resolved. Under the agreements currently in place, we do not consider these events to be within our control, but rather dependent upon the development activities of our collaborative partners and the decisions made by regulatory agencies. Accordingly, these milestones are not included in the transaction price until the counterparty, or third-party in the event of a regulatory submission, confirms the satisfaction or completion of the milestone triggering

event. Given the high level of uncertainty of achievement, variable consideration associated with milestones are fully constrained until confirmation of the satisfaction or completion of the milestone by the third-party.

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 value of these milestones is dictated within the contract and is fixed upon achievement and reflects the amount of consideration which we expect to be entitled to in exchange for the satisfaction of that milestone. 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 and therefore, subsequent milestone payments due to Incyte are recognized as revenue at the point in time when such milestones are achieved.

Our collaboration agreements may also include an option for the collaborative partner to elect to participate in research and development activities, such as shared participation in additional clinical trials using the compound. The presence of additional options for future participatory activities are assessed to determine if they represent material rights offered by us to the collaborative partner. We also determine whether the reimbursement of research and development expenses should be accounted for as collaborative revenues or an offset to research and development expenses in accordance with the provisions of gross or net revenue presentation and recognize the corresponding revenues or records the corresponding offset to research and development expenses as incurred.

Our collaborative agreements may also include provisions for additional future collaborative efforts, such as options for shared commercialization staffing or licensing of additional molecules, involvement in joint committees, or options for inclusion in negotiations of future supply rights, which at the time of each collaborative agreement's inception, are assessed to determine if these meet the definition of a performance obligation under ASC 606.

Cost of Product Revenues

Cost of product revenues includes all JAKAFI, ICLUSIG and PEMAZYRE related product costs. 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 and the amortization of our licensed intellectual property for ICLUSIG using the straight-line method over the estimated useful life of 12.5 years from the date of acquisition on June 1, 2016 of all of the outstanding shares of ARIAD Pharmaceuticals (Luxembourg) S.à.r.l. (since renamed Incyte Biosciences Luxembourg S.à.r.l.) from ARIAD Pharmaceuticals, Inc. ("ARIAD"). Cost of product revenues also includes employee personnel costs, including stock compensation, for those employees dedicated to the production of our commercial products.

Research and Development Costs. Our policy is to expense research and development costs as incurred, including amounts funded by research and development collaborations. Research and development expenses are comprised of costs we incur in performing research and development activities, including salary and benefits; stock-based compensation expense; outsourced services and other direct expenses, including clinical trial and pharmaceutical development costs; collaboration payments; expenses associated with drug supplies that are not being capitalized; and infrastructure costs, including facilities costs and depreciation expense. If a collaboration is a cost-sharing arrangement in which both we and our collaborator perform development work and share costs, we also recognize, as research and development expense in the period when our collaborator incurs development expenses, our portion of the co-development expenses that we are obligated to reimburse.

We often contract with contract 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.

Advertising Expenses. Advertising expenses, comprised primarily of television, radio, print media and Internet advertising, are expensed as incurred and are included in selling, general, and administrative expenses. For the three months ended March 31, 2021 and 2020, advertising expenses were approximately \$10.8 million and \$4.8 million, respectively.

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 consists of our future royalty obligations on future net sales of ICLUSIG to Takeda Pharmaceutical Company Limited, which acquired ARIAD (“Takeda”). Acquisition-related contingent consideration was recorded on the acquisition date of June 1, 2016 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.

Collaboration loss sharing. Under collaboration and license agreements with shared commercialization efforts, we record our share of the losses from the co-commercialization efforts in collaboration loss sharing on the condensed consolidated statement of operations. For the three months ended March 31, 2021 and 2020, collaboration loss sharing represents our 50% share of the United States loss for commercialization of MONJUVI (tafasitamab) under our agreement with MorphoSys.

Recent Accounting Pronouncements

In December 2019, the FASB issued ASU No. 2019-12, “Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes.” This guidance applies to all entities and aims to reduce the complexity of tax accounting standards

while enhancing reporting disclosures. This guidance is effective for fiscal years beginning after December 15, 2020 and interim periods therein. We adopted this guidance for the period beginning January 1, 2021. Upon adoption, ASU No. 2019-12 had an immaterial impact on the condensed consolidated financial statements.

3. Revenues

As discussed in Note 2, revenues are recognized under guidance within ASC 606. The following table presents our disaggregated revenue for the periods presented (in thousands):

	Three Months Ended	
	March 31,	
	2021	2020
JAKAFI revenues, net	\$ 465,710	\$ 459,479
ICLUSIG revenues, net	25,645	27,248
PEMAZYRE revenues, net	13,456	—
Total product revenues, net	504,811	486,727
JAKAVI product royalty revenues	65,602	56,333
OLUMIANT product royalty revenues	32,258	25,447
TABRECTA product royalty revenues	2,047	—
Total product royalty revenues	99,907	81,780
Total revenues	\$ 604,718	\$ 568,507

For further information on our revenue-generating contracts, refer to Note 9.

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 standard 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 U.S. government debt securities that are classified as available-for-sale.

At March 31, 2021 and December 31, 2020, our Level 2 U.S. government debt 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. We did not experience any transfers of financial instruments between the fair value hierarchy levels during the three months ended March 31, 2021.

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 Measurement at Reporting Date Using:			Balance as of March 31, 2021
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Cash and cash equivalents	\$ 1,669,968	\$ —	\$ —	\$ 1,669,968
Debt securities (government)	—	292,425	—	292,425
Long term investments (Note 9)	202,174	—	—	202,174
Total assets	\$ 1,872,142	\$ 292,425	\$ —	\$ 2,164,567

	Fair Value Measurement at Reporting Date Using:			Balance as of December 31, 2020
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Cash and cash equivalents	\$ 1,513,008	\$ —	\$ —	\$ 1,513,008
Debt securities (government)	—	288,369	—	288,369
Long term investments (Note 9)	222,301	—	—	222,301
Total assets	\$ 1,735,309	\$ 288,369	\$ —	\$ 2,023,678

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 Measurement at Reporting Date Using:			Balance as of March 31, 2021
	Quoted Prices in Active Markets for Identical Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Acquisition-related contingent consideration	\$ —	\$ —	\$ 263,000	\$ 263,000
Total liabilities	\$ —	\$ —	\$ 263,000	\$ 263,000

	Fair Value Measurement at Reporting Date Using:			Balance as of December 31, 2020
	Quoted Prices in Active Markets for Identical Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Acquisition-related contingent consideration	\$ —	\$ —	\$ 266,000	\$ 266,000
Total liabilities	\$ —	\$ —	\$ 266,000	\$ 266,000

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

	2021
Balance at January 1,	\$ 266,000
Contingent consideration earned during the period but not yet paid	(8,526)
Change in fair value of contingent consideration	5,526
Balance at March 31,	\$ 263,000

The fair value of the contingent consideration was determined on the date of acquisition, June 1, 2016, using an income approach based on estimated ICLUSIG revenues in the European Union and other countries for the approved third line treatment over 18 years, and discounted to present value at a rate of 10%. 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 valuation inputs utilized to estimate the fair value of the contingent consideration as of March 31, 2021 included a weighted average cost of capital of 10% and updated projections of future ICLUSIG revenues in the European

Union and other countries for the approved third line treatment. The change in fair value of the contingent consideration during the three months ended March 31, 2021 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 March 31, 2021 and December 31, 2020, contingent consideration earned but not yet paid was \$8.5 million and \$9.6 million, respectively, and was included in accrued and other current liabilities.

The following is a summary of our marketable security portfolio for the periods presented (in thousands):

	Amortized Cost	Net Unrealized Gains	Estimated Fair Value
March 31, 2021			
Debt securities (government)	\$ 292,287	\$ 138	\$ 292,425
December 31, 2020			
Debt securities (government)	\$ 288,199	\$ 170	\$ 288,369

Our available-for-sale debt securities generally have contractual maturity dates of between 12 to 18 months. Debt security assets were assessed for risk of expected credit losses per our accounting policy as described in Note 2. As of March 31, 2021 and December 31, 2020, the available-for-sale debt securities were held in U.S. government debt securities and Treasury assets and were assessed on an individual security basis to have a de minimis risk of credit loss.

5. Concentration of credit risk and current expected credit losses

In November 2009, we entered into a collaboration and license agreement with Novartis. In December 2009, we entered into a license, development and commercialization agreement with Lilly. 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 above collaboration partners comprised, in aggregate, 26% and 42% of the accounts receivable balance as of March 31, 2021 and December 31, 2020, respectively. For further information relating to these collaboration and license agreements, refer to Note 9.

In November 2011, we began commercialization and distribution of JAKAFI and in April 2020, we began commercialization and distribution of PEMAZYRE 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 and PEMAZYRE product revenues is as follows:

	Percentage of Total Net Product Revenues for the Three Months Ended	
	March 31,	
	2021	2020
Customer A	18 %	19 %
Customer B	13 %	13 %
Customer C	17 %	18 %
Customer D	10 %	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, 35% and 29% of the accounts receivable balance as of March 31, 2021 and December 31, 2020, respectively. The concentration of credit risk relating to ICLUSIG product revenues or accounts receivable is not significant.

We assessed our collaborative and customer receivable assets as of March 31, 2021 according to our accounting policy for applying reserves for expected credit losses, noting minimal history of uncollectible receivables and the

continued perceived creditworthiness of our third party sales relationships, upon which the expected credit losses were considered de minimis.

6. Inventory

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

	March 31, 2021	December 31, 2020
Raw materials	\$ 1,275	\$ 1,275
Work-in-process	27,043	21,242
Finished goods	12,061	13,456
	<u>40,379</u>	<u>35,973</u>
Inventories-current	16,700	16,425
Inventories-noncurrent	<u>\$ 23,679</u>	<u>\$ 19,548</u>

Inventories, stated at the lower of cost and net realizable value, consist of raw materials, work in process and finished goods. At March 31, 2021, \$16.7 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 March 31, 2021, \$23.7 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):

	March 31, 2021	December 31, 2020
Office equipment	\$ 18,087	\$ 17,880
Laboratory equipment	89,714	86,021
Computer equipment	67,625	66,640
Land	10,328	10,671
Building and leasehold improvements	244,872	238,042
Operating lease right-of-use assets	25,099	26,816
Construction in progress	290,350	257,929
	<u>746,075</u>	<u>703,999</u>
Less accumulated depreciation and amortization	(151,405)	(144,374)
Property and equipment, net	<u>\$ 594,670</u>	<u>\$ 559,625</u>

In March 2017, we acquired additional adjacent buildings to our global headquarters in Wilmington, Delaware and in 2019, began demolition of these buildings and construction of a new laboratory and office building totaling approximately 200,000 square feet. As of March 31, 2021, we have capitalized approximately \$103.3 million in on site preparation, design and construction costs and currently expect the building to be completed in the first half of 2022.

In February 2018, we signed an agreement to rent a building in Morges, Switzerland for an initial term of 15 years plus one year of free rent, with multiple options to extend for an additional 20 years. The building serves as our European headquarters and consists of approximately 100,000 square feet of office space. This building allowed for consolidation of our European operations that were located in Geneva and Lausanne, Switzerland. In June 2019, we obtained control of the Morges building to begin our construction activity, which was completed in 2020. At that time, we determined the lease to be a finance lease and recorded a lease liability of \$31.1 million and a finance lease right-of-use asset of \$29.1 million,

net of a lease incentive from our landlord of \$2.0 million. At March 31, 2021, we capitalized approximately \$19.1 million in leasehold improvements.

In July 2018, we signed an agreement to purchase land located in Yverdon, Switzerland. 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 March 31, 2021, we have capitalized approximately \$173.3 million in costs for construction, ground preparation and architectural and engineering studies. We currently expect the facility will be operational in the first half of 2022.

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 and are as follows (in thousands):

	March 31, 2021	December 31, 2020
Current		
Operating lease liabilities	\$ 11,659	\$ 12,674
Finance lease liabilities	2,317	2,284
Noncurrent		
Operating lease liabilities	13,193	14,188
Finance lease liabilities	32,154	32,573
Total lease liabilities	<u>\$ 59,323</u>	<u>\$ 61,719</u>

The cash paid for amounts included in the measurement of our operating lease liabilities as of March 31, 2021 and 2020 was \$3.5 million and \$3.2 million, respectively, in operating cash flows. The cash paid for amounts included in the measurement of our finance lease liabilities as of March 31, 2021 and 2020 was \$0.6 million and \$0.2 million, respectively, in financing cash flows.

As of March 31, 2021, our finance and operating leases had a weighted average lease term of approximately 14.1 and 4.9 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 3.8% and 5.5%, respectively.

For the three months ended March 31, 2021, we incurred approximately \$3.5 million of expense related to our operating leases, approximately \$0.6 million of amortization on our finance lease right-of-use assets and approximately \$0.3 million of interest expense on our finance lease liabilities. For the three months ended March 31, 2020, we incurred approximately \$3.2 million of expense related to our operating leases, approximately \$0.6 million of amortization on our finance lease right-of-use assets and approximately \$0.3 million of interest expense on our finance lease liabilities. For the three months ended March 31, 2021 and 2020, 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):

	Weighted-Average Useful Lives (Years)	Balance at March 31, 2021			Balance at December 31, 2020		
		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	\$ 104,093	\$ 166,907	\$ 271,000	\$ 98,709	\$ 172,291

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

	Remainder of 2021	2022	2023	2024	2025	Thereafter
Amortization expense	\$ 16,155	\$ 21,536	\$ 21,536	\$ 21,536	\$ 21,536	\$ 64,608

Goodwill

There were no changes to the carrying amount of goodwill for the three months ended March 31, 2021.

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.

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 sales 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 \$157.0 million for the achievement of development milestones, \$280.0 million for the achievement of regulatory milestones and \$200.0 million for the achievement of sales milestones through March 31, 2021.

We recognize development and regulatory milestones upon confirmation of achievement of the event, as development and regulatory approvals are events not controllable by us but rather development activities of Novartis and decisions made by regulatory agencies. We recognize sales milestones in the corresponding period of the product sale upon confirmation of net sales milestone threshold achievement by Novartis.

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 TABRECTA 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 months ended March 31, 2021 and 2020, such royalties payable to Novartis on net sales within the United States totaled \$17.8 million and \$17.5 million, respectively, and were reflected in cost of product revenues on the condensed consolidated statements of operations. At March 31, 2021 and December 31, 2020, \$101.6 million and \$96.4 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.

Reimbursable costs incurred after the effective date of the agreement with Novartis are recorded net against the related research and development expenses. Research and development expenses for the three months ended March 31, 2021 and 2020 were net of \$0.1 million and \$0.3 million, respectively, of costs reimbursed by Novartis. At March 31, 2021 and December 31, 2020, \$0.1 million and \$0.2 million, respectively, of reimbursable costs were included in accounts receivable on the condensed consolidated balance sheets.

Milestone and contract revenue under the Novartis agreement for the three months ended March 31, 2021 and 2020 was \$0.0 million for each period. Product royalty revenue related to Novartis net sales of JAKAVI outside of the United States for the three months ended March 31, 2021 and 2020 was \$65.6 million and \$56.3 million, respectively.

Product royalty revenue related to Novartis net sales of TABRECTA worldwide for the three months ended March 31, 2021 and 2020 was \$2.0 million and \$0.0 million, respectively.

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 sales 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 \$265.0 million for the achievement of regulatory milestones through March 31, 2021.

We recognize development and regulatory milestones upon confirmation of achievement of the event, as development and regulatory approvals are events not controllable by us but rather development activities of Lilly and decisions made by regulatory agencies. We recognize sales milestones in the corresponding period of the product sale upon confirmation of net sales milestone threshold achievement by Lilly.

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 October 2020, Lilly announced that the European Commission approved baricitinib as OLUMIANT for the treatment of moderate-to-severe atopic dermatitis in adult patients who are candidates for systemic therapy.

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.

In May 2020, we amended our agreement with Lilly to enable Lilly to develop and commercialize baricitinib for the treatment of COVID-19. As part of the amended agreement, in addition to the royalties described above, we will be entitled to receive additional royalty payments with rates in the low teens on global net sales of baricitinib for the treatment of COVID-19 that exceed a specified aggregate global net sales threshold.

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.

Milestone and contract revenue under the Lilly agreement for the three months ended March 31, 2021 and 2020 was \$0.0 million for each period. Product royalty revenue related to Lilly global net sales of OLUMIANT for the three months ended March 31, 2021 and 2020 was \$32.3 million and \$25.4 million, respectively.

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. Upon execution of the amendment, we paid Lilly an upfront payment of \$35.0 million and Lilly is eligible to receive

up to \$40.0 million in 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 15% royalties on global net sales.

In 2017 under the Amended Agreement, we paid Agenus \$20.0 million in accelerated milestones relating to the clinical development of the GITR and OX40 programs. As of March 31, 2021, we have paid Agenus additional milestones totaling \$10.0 million and Agenus is eligible to receive up to an additional \$500.0 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 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 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. After completion of our stock purchases from Agenus Inc., we held an approximate ownership interest of 18% and, under circumstances present at that time, concluded that we had the ability to exercise significant influence, but not control, over Agenus Inc., primarily due to the level of intra-entity transactions between us and Agenus related to development expenses, as well as other qualitative factors. In the second quarter of 2020, we sold an aggregate of approximately 1.2 million shares of Agenus Inc. common stock. The sales transactions were priced at market, with per share pricing ranging from \$3.57 to \$4.21, resulting in gross proceeds of approximately \$4.5 million. In the third quarter of 2020, we sold an aggregate of approximately 2.5 million shares of Agenus Inc. common stock. The sales transactions were priced at market, with per

share pricing ranging from \$4.28 to \$5.25, resulting in gross proceeds of approximately \$12.7 million. In the first quarter of 2021, we sold approximately 0.2 million shares of Agenus Inc. common stock priced at market at \$5.45, resulting in gross proceeds of approximately \$1.1 million. As of March 31, 2021, we owned approximately 7% of the outstanding shares of Agenus Inc. common stock. As a result of having a less than 10% ownership interest and the recent diversification of Agenus Inc.'s development pipeline with other collaboration partners, we concluded that we no longer have significant influence over Agenus Inc. As such, we no longer account for our equity investment in Agenus Inc. as an equity method investment previously accounted for under the fair value option. We account for our investment in Agenus Inc. at fair value, whereby the investment is marked to market through earnings in each reporting period. For the three months ended March 31, 2021 and 2020, we recorded an unrealized loss of \$5.9 million and \$28.8 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 March 31, 2021 and December 31, 2020 was \$37.7 million and \$44.7 million, respectively.

Research and development expenses for the three months ended March 31, 2021 and 2020 also included \$0.5 million and \$0.1 million, respectively, of development costs incurred pursuant to the Agenus arrangement. At March 31, 2021 and December 31, 2020, a total of \$0.5 million and \$0.5 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 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 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. In January 2021, we purchased 350,000 common shares in Merus' underwritten public offering of 4,848,485 common shares at the public offering price of \$24.75 per share, or an aggregate purchase price of \$8.7 million. The fair market value of our total long term investment in Merus at March 31, 2021 and December 31, 2020 was \$74.2 million and \$56.1 million, respectively.

We 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 March 31, 2021, we owned approximately 9% of the outstanding common shares of Merus 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 months ended March 31, 2021 and 2020 we recorded an unrealized gain of \$9.4 million and an unrealized loss of \$6.3 million, respectively, based on the change in fair value of Merus' common shares during these periods.

Research and development expenses for the three months ended March 31, 2021 and 2020 included \$2.3 million of additional development costs incurred pursuant to the Merus agreement. At March 31, 2021 and December 31, 2020, a total of \$1.6 million 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 INCB01158. 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.

As of March 31, 2021, we have paid Calithera an upfront license fee of \$45.0 million and an additional \$12.0 million milestone payment. In August 2020, Calithera delivered notice of its decision to opt out of its co-funding obligation,

effective on September 30, 2020. As a result, the U.S. profit sharing will no longer be in effect, we will be responsible for funding all of the development costs of INCB01158 and any other licensed products, and the agreement provides that we will 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 eligible to receive \$738.0 million in potential future development, regulatory and sales milestone payments and will have no further rights to research, develop or co-detail INCB001158. We will have the right to take over the conduct of all activities related to the research, development and commercialization of INCB001158 for all indications in the hematology/oncology field.

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 March 31, 2021 and December 31, 2020 was \$4.2 million and \$8.4 million, respectively.

We 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 March 31, 2021, we owned approximately 2% 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 therefore, are accounting for our shares held in Calithera at fair value, 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 sheets. For the three months ended March 31, 2021 and 2020 we recorded an unrealized loss of \$4.3 million and \$2.2 million, respectively, based on the change in fair value of Calithera's common stock during these periods.

Research and development expenses for the three months ended March 31, 2021 and 2020 included \$2.5 million of additional development costs incurred pursuant to the Calithera agreement. At March 31, 2021 and December 31, 2020, a total of \$0.5 million and \$0.6 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.

As of March 31, 2021, we have paid MacroGenics an upfront payment of \$150.0 million and developmental milestones totaling \$65.0 million. MacroGenics is eligible to receive up to an additional \$355.0 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.

Research and development expenses for the three months ended March 31, 2021 and 2020 also included \$13.6 million and \$16.4 million, respectively, of additional development costs incurred pursuant to the MacroGenics agreement. At March 31, 2021 and December 31, 2020, a total of \$1.0 million and \$0.1 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 sales milestones. Syros is also eligible to receive low single-digit royalties on net sales of products resulting from the collaboration.

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 March 31, 2021 and December 31, 2020 was \$7.0 million and \$10.2 million, respectively.

We 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 March 31, 2021, 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, 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 sheets. For the three months ended March 31, 2021 and 2020, we recorded an unrealized loss of \$3.2 million and \$0.9 million, respectively, based on the change in fair market 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 pascalisib 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 functional 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. The upfront milestone was recognized as revenue at a point in time upon our transfer of the licenses to Innovent for the right to use the functional intellectual property. In addition, we are eligible to receive up to an additional \$104.0 million in potential development and regulatory milestones.

We recognize development and regulatory milestones upon confirmation of achievement of the event, as development and regulatory approvals are events not controllable by us but rather development activities of Innovent and decisions made by regulatory agencies.

In the event of commercialization of the licensed molecule, we are eligible to receive up to \$202.5 million in potential sales milestones from Innovent. We will recognize sales milestones in the corresponding period of the product sale upon confirmation of net sales milestone threshold achievement by Innovent. 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.

Research and development expenses for the three months ended March 31, 2021 and 2020 were net of \$0.0 million of costs reimbursed by Innovent. At March 31, 2021 and December 31, 2020, \$2.4 million and \$1.2 million, respectively, 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. In August 2019, we recognized an upfront payment under this agreement of \$17.5 million.

The agreement allows for Zai Lab to continue development of the licensed molecule and to submit the licensed molecule to authorities for regulatory approval within the agreement territory, upon which we are eligible for up to \$22.5 million in potential development and regulatory milestones. We recognize development and regulatory milestones upon confirmation of achievement of the event, as development and regulatory approvals are events not controllable by us but rather development activities of Zai Lab and decisions made by regulatory agencies.

In the event of commercialization of the licensed molecule, we are eligible to receive up to \$37.5 million in potential sales milestones from Zai Lab. We will recognize sales milestones in the corresponding period of the product sale upon confirmation of net sales milestone threshold achievement by Zai Lab. We are also eligible to receive tiered royalties from the low to mid-twenties on future product sales resulting from the collaboration. We also retain an option to assist in the promotion of INCMGA0012 in Zai Lab's licensed territories.

Research and development expenses for the three months ended March 31, 2021 and 2020 were net of \$0.0 million and \$0.2 million, respectively, of costs reimbursed by Zai Lab. At March 31, 2021 and December 31, 2020, \$0.7 million

and \$0.6 million, respectively, of reimbursable costs were included in accounts receivable on the condensed consolidated balance sheet.

MorphoSys

In January 2020, we entered into a Collaboration and License Agreement with MorphoSys AG and MorphoSys US Inc., a wholly-owned subsidiary of MorphoSys AG (together with MorphoSys AG, “MorphoSys”), covering the worldwide development and commercialization of MOR208 (tafasitamab), an investigational Fc engineered monoclonal antibody directed against the target molecule CD19 that is currently in clinical development by MorphoSys. MorphoSys has exclusive worldwide development and commercialization rights to tafasitamab under a June 2010 collaboration and license agreement with Xencor, Inc. In December 2019, MorphoSys submitted a Biologics License Application to the FDA for tafasitamab for the treatment of relapsed or refractory diffuse large B cell lymphoma. The agreement became effective in March 2020 after clearance by the German and Austrian antitrust authorities and expiration of the waiting period under the Hart-Scott Rodino Antitrust Improvements Act of 1976.

Under the terms of the agreement, we received exclusive commercialization rights outside of the United States, and MorphoSys and we have co-commercialization rights in the United States, with respect to tafasitamab. MorphoSys is responsible for leading the commercialization strategy and booking all revenue from sales of tafasitamab in the United States, and we and MorphoSys are both responsible for commercialization efforts in the United States and will share equally the profits and losses from the co-commercialization efforts. We will lead the commercialization strategy outside of the United States, and will be responsible for commercialization efforts and book all revenue from sales of tafasitamab outside of the United States, subject to our royalty payment obligations set forth below. We and MorphoSys have agreed to co-develop tafasitamab and to share development costs associated with global and U.S.-specific clinical trials, with Incyte responsible for 55% of such costs and MorphoSys responsible for 45% of such costs. Each company is responsible for funding any independent development activities, and we are responsible for funding development activities specific to territories outside of the United States. All development costs related to the collaboration are subject to a joint development plan.

In March 2020, we paid MorphoSys an upfront non-refundable payment of \$750.0 million which was recorded in research and development expense on the condensed consolidated statement of operations for the three months ended March 31, 2020. MorphoSys is eligible to receive up to \$740.0 million in future contingent development and regulatory milestones and up to \$315.0 million in commercialization milestones as well as tiered royalties ranging from the mid-teens to mid-twenties of net sales outside of the United States. MorphoSys’ right to receive royalties in any particular country will expire upon the last to occur of (a) the expiration of patent rights in that particular country, (b) a specified period of time after the first post-marketing authorization sale of a licensed product comprising tafasitamab in that country, and (c) the expiration of any regulatory exclusivity for that licensed product in that country.

In July 2020, we and MorphoSys announced that the FDA approved MONJUVI® (tafasitamab-cxix) in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant. MONJUVI was approved under accelerated approval based on overall response rate.

In addition, under the collaboration agreement and pursuant to a related purchase agreement, we agreed to purchase American Depositary Shares (“ADSs”), each representing 0.25 of an ordinary share of MorphoSys AG, for an aggregate purchase price of \$150.0 million or \$41.33 per ADS (such ADSs to be purchased, the “New ADSs”). We agreed, subject to limited exceptions, not to sell or otherwise transfer any of the New ADSs for an 18-month period after the closing date of the sale. We completed the purchase of the ADSs on March 3, 2020 when the closing price on The Nasdaq Stock Market was \$27.65 per ADS. The New ADSs were not registered under the Securities Act of 1933 on the purchase date, and accordingly, we estimated a discount for lack of marketability on the shares of \$4.9 million, which resulted in a net fair value of the shares on the issuance date of \$95.5 million. Of the \$150.0 million aggregate purchase price paid, \$95.5 million was allocated to our stock purchase in MorphoSys and was recorded within long term investments and \$54.5 million, representing the premium paid on the purchase, was allocated to research and development expense. The fair market value of our long term investment in MorphoSys as of March 31, 2021 and December 31, 2020, was \$79.1 million and \$102.9 million, respectively.

We concluded MorphoSys 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 March 31, 2021, we owned approximately 3% of the outstanding shares of MorphoSys common stock and there are several other stockholders who hold larger positions of MorphoSys. As we do not hold a significant position of the voting shares of MorphoSys 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 MorphoSys for the foreseeable future and therefore, are accounting for our shares held in MorphoSys at fair value, 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 sheets. For the three months ended March 31, 2021 and 2020, we recorded an unrealized loss of \$23.7 million and \$9.9 million, respectively, based on the change in fair market value of MorphoSys' common stock during these periods.

Our 50% share of the United States loss for the commercialization of tafasitamab for the three months ended March 31, 2021 and 2020 was \$10.5 million and \$2.1 million, respectively, and is recorded as collaboration loss sharing on the condensed consolidated statement of operations. Research and development expenses for the three months ended March 31, 2021 and 2020, includes \$14.9 million and \$11.6 million, respectively, related to our 55% share of the co-development costs for tafasitamab. At March 31, 2021 and December 31, 2020, \$47.2 million and \$54.2 million, respectively, was included in accrued and other liabilities on the condensed consolidated balance sheet for amounts due to MorphoSys under the agreement.

Nimble

In September 2020, we entered into a collaboration and license agreement with Nimble Therapeutics, Inc. ("Nimble"). Under the terms of this agreement, Nimble will utilize their peptide synthesis, screening and optimization platform for discovery and validation of peptides against specified targets. Under the agreement, Nimble is eligible to receive up to \$8.0 million in future contingent discovery milestones and up to \$127.0 million in future contingent development and regulatory milestones. Additionally, in the event of successful commercialization, Nimble is eligible to receive up to \$130.0 million in future contingent sales milestones and tiered royalties on net sales in the low single digits.

10. Stock compensation

We recorded \$47.3 million and \$42.5 million, respectively, of stock compensation expense on the condensed consolidated statements of operations for the three months ended March 31, 2021 and 2020. Stock compensation expense included within our condensed consolidated statements of operations for the three months ended March 31, 2021 and 2020 included research and development expense of \$29.9 million and \$28.7 million, respectively. Stock compensation expense included within our condensed consolidated statements of operations for the three months ended March 31, 2021 and 2020 also included selling, general and administrative expense of \$17.2 million and \$13.6 million, respectively. Stock compensation expense included within our condensed consolidated statements of operations for the three months ended March 31, 2021 and 2020 also included cost of product revenues of \$0.2 million for each period. For the three months ended March 31, 2021 and 2020, we capitalized \$0.5 million and \$0.2 million, respectively, of stock compensation expense as part of the cost of an asset.

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		Employee Stock Purchase Plan	
	For the Three Months Ended March 31,			
	2021	2020	2021	2020
Average risk-free interest rates	0.34 %	1.56 %	0.16 %	0.23 %
Average expected life (in years)	4.68	4.65	0.25	0.25
Volatility	39 %	40 %	39 %	52 %
Weighted-average fair value (in dollars)	29.88	28.43	19.08	16.00

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 our 2010 Amended and Restated Stock Incentive Plan (the “2010 Stock Plan”) was as follows:

	Shares Subject to Outstanding Options	
	Shares	Weighted Average Exercise Price
Balance at December 31, 2020	12,115,288	\$ 88.31
Options granted	910,673	\$ 90.06
Options exercised	(321,415)	\$ 69.74
Options cancelled	(197,570)	\$ 89.34
Balance at March 31, 2021	<u>12,506,976</u>	<u>\$ 88.90</u>

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.

Restricted stock unit (“RSU”) and performance share (“PSU”) award activity under the 2010 Stock Plan was as follows:

	Shares Subject to Outstanding Awards	
	Shares	Grant Date Value
Balance at December 31, 2020	3,284,583	\$ 87.42
RSUs granted	485,381	\$ 90.35
RSUs released	(94,189)	\$ 86.45
RSUs cancelled	(88,895)	\$ 92.15
PSUs cancelled	(1,500)	\$ 65.76
Balance at March 31, 2021	<u>3,585,380</u>	<u>\$ 87.74</u>

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.

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 one of the existing long term incentive plans with performance based milestones and cliff vesting. For one of the existing 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 will convert is at a multiplier of 142% based on the performance conditions being achieved as of March 31, 2019 and will continue to vest through June 2022. For an existing long term incentive plan, under which 150,000 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 100% if all performance conditions were achieved or 0% if no performance conditions were achieved. The actual number of shares of our common stock into which each PSU will convert is at a multiplier of 100% based on the performance

conditions being achieved as of December 31, 2019 and will cliff vest in June 2021. 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 period ended March 31, 2021, 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 March 31, 2021, 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. These PSUs will continue to vest through July 2022.

In July 2019, we granted 86,975 PSUs to executives with a performance milestone 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 125% 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 will convert is at a multiplier of 101.8% based on the performance condition being achieved as of December 31, 2019. These PSUs will continue to vest through July 2023.

In July 2020, we granted 92,347 PSUs to executives with performance milestones and cliff vesting on the third anniversary from date of grant. The shares of our common stock into which each PSU may convert is subject to a multiplier up to 200% based on the level at which the financial and developmental performance conditions are achieved over the service period which ends December 31, 2022. 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 period ended March 31, 2021, 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 March 31, 2021, no stock compensation expense was recognized.

The following table summarizes our shares available for grant under the 2010 Stock Plan:

	Shares Available for Grant
Balance at December 31, 2020	5,515,182
Options, RSUs and PSUs granted	(1,881,435)
Options, RSUs and PSUs cancelled	364,802
Balance at March 31, 2021	<u>3,998,549</u>

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 March 31, 2021, was \$78.6 million, which is expected to be recognized over the weighted average period of approximately 1.2 years. Total compensation cost of RSUs granted but not yet vested, as of March 31, 2021, was \$131.1 million, which is expected to be recognized over the weighted average period of approximately 1.8 years. Total compensation cost of PSUs granted but not yet vested, as of March 31, 2021, was \$23.0 million, which is expected to be recognized over the weighted average period of 1.1 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):

	March 31, 2021	December 31, 2020
Royalties	\$ 110,097	\$ 106,011
Clinical related costs	99,461	115,897
Sales allowances	101,721	73,204
Construction in progress	21,262	22,807
Operating lease liabilities	11,659	12,674
Other current liabilities	76,682	47,811
Total accrued and other current liabilities	<u>\$ 420,882</u>	<u>\$ 378,404</u>

12. 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 and Japan. Employees may contribute a portion of their compensation, which is then matched by us, subject to certain limitations. Defined contribution expense for the three months ended March 31, 2021 and 2020 was \$4.1 million and \$3.3 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 Months Ended March 31,	
	2021	2020
Service cost	\$ 1,955	\$ 1,457
Interest cost	22	46
Expected return on plan assets	(15)	(30)
Amortization of prior service cost	54	54
Amortization of actuarial losses	288	167
Net periodic benefit cost	<u>\$ 2,304</u>	<u>\$ 1,694</u>

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 \$5.3 million to the pension plans in 2021 inclusive of the amounts contributed to the plan during the current period.

13. Income taxes

For the three months ended March 31, 2021 and 2020, we recorded income tax expense of approximately \$15.8 million and \$16.6 million, respectively. The tax expense for the three months ended March 31, 2021 and 2020 represents primarily driven by federal and state tax liabilities that are not fully sheltered by net operating losses or research and development tax credit carryforwards.

As of March 31, 2021, a full valuation allowance continues to be recorded against our U.S. and Swiss net deferred tax assets. Based upon our analysis of our historical operating results, as well as projections of our future taxable income

(losses) during the periods in which the temporary differences will be recoverable, we believe the uncertainty regarding the realization of our U.S. and Swiss net deferred tax assets requires a full valuation allowance against such net assets as of March 31, 2021. 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.

The balance of our unrecognized tax benefits (including penalties and interest) increased by approximately \$0.9 million during the three months ended March 31, 2021. The overall increase is primarily driven by unrecognized tax benefits related to current year operations and research and development tax credits. After considering valuation allowance impacts, the change in unrecognized tax benefits resulted in a negligible increase to noncurrent other liabilities on the condensed consolidated balance sheet.

14. Net income (loss) per share

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

<u>(in thousands, except per share data)</u>	March 31,	
	2021	2020
<u>Basic Net Income (Loss) Per Share</u>		
Basic net income (loss)	\$ 53,535	\$ (720,642)
Weighted average common shares outstanding	219,801	216,721
Basic net income (loss) per share	\$ 0.24	\$ (3.33)
<u>Diluted Net Income (Loss) Per Share</u>		
Diluted net income (loss)	\$ 53,535	\$ (720,642)
Weighted average common shares outstanding	219,801	216,721
Dilutive stock options and awards	2,066	—
Weighted average shares used to compute diluted net income (loss) per share	221,867	216,721
Diluted net income (loss) per share	<u>\$ 0.24</u>	<u>\$ (3.33)</u>

The potential common shares that were excluded from the diluted net income (loss) per share computation are as follows:

	Three Months Ended March 31,	
	2021	2020
Outstanding stock options and awards	8,871,744	15,544,348
Common shares issuable upon conversion of the 1.25% Convertible Senior Notes due 2020	—	368,939
Total potential common shares excluded from diluted net income (loss) per share computation	<u>8,871,744</u>	<u>15,913,287</u>

15. Contingencies

We have entered into the collaboration agreements described in Note 9, as well as various other collaboration agreements that are not individually, or in the aggregate, significant to our operating results or financial condition at this time. We 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 agreements, we may be required to pay upfront fees, milestone payments, and royalties on sales of future products.

In December 2018, we received a civil investigative demand from the U.S. Department of Justice (“DOJ”) 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 have cooperated with this inquiry. In November 2019, the *qui tam* complaint underlying the DOJ inquiry was unsealed (“Complaint”), at which time we learned that a former employee whom we had terminated had made certain allegations relating to the programs described above (“Relator”). The DOJ has not intervened to date. We filed an Answer to the Complaint on January 22, 2020 and on November 12, 2020 we filed a Motion for Summary Judgment (Motion). All briefing on the Motion was completed on December 22, 2020. A trial date has not been set. Incyte denies any improper claims were submitted to government payers; however, we have reached a settlement in principle with the DOJ Civil Division. A reserve of \$13.2 million was recorded with respect to these matters as of March 31, 2021 and was included in accrued and other current liabilities.

In the ordinary course of our business, we may become involved in lawsuits, proceedings, and other disputes, including commercial, intellectual property, regulatory, employment, and other matters. We record a reserve for these matters when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated.

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 months ended March 31, 2021 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, 2010 included in our Annual Report on Form 10-K for the year ended December 31, 2020 previously filed with the SEC.

Forward-Looking Statements

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), PEMAZYRE[®] (pemigatinib), ICLUSIG[®] (ponatinib) and MONJUVI[®] (tafasitamab-cxix);
- our plans to further develop our operations outside of the United States;
- conducting clinical trials internally, with collaborators, or with clinical research organizations;
- our collaboration and strategic relationship strategy, and anticipated benefits and disadvantages of entering into collaboration agreements;
- our licensing, investment and commercialization strategies, including our plans to commercialize our drug products and drug candidates;
- 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;
- plans for our manufacturing operations;
- 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 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 and governmental proceedings;*
- *our expectations regarding competition;*
- *expectations relating to the anticipated completion dates for our Delaware headquarters expansion project and our large molecule production facility;*
- *our investments, including anticipated expenditures, losses and expenses;*
- *our patent prosecution and maintenance efforts; and*
- *the potential effects of the COVID-19 pandemic and efforts undertaken or to be undertaken by us or applicable governmental authorities on local and global economic conditions, and on our business, results of operations and financial condition.*

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 our drug products and drug candidates;*
- *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 JAKAVI, OLUMIANT, TABRECTA and the drug candidates licensed from us;
- 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 Delaware headquarters expansion project and our 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;
- risks relating to our ability to sustain profitability;
- risks related to public health pandemics such as the COVID-19 pandemic; 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, JAKAFI and PEMAZYRE are our registered trademarks. We also refer to trademarks of other corporations and organizations in this Quarterly Report on Form 10-Q.

Summary Risk Factors

Our business is subject to numerous risks and uncertainties that could affect our ability to successfully implement our business strategy and affect our financial results. You should carefully consider all of the information in this report and, in particular, the following principal risks and all of the other specific factors described in Item 1A. of this report, “Risk Factors,” before deciding whether to invest in our company.

- We depend heavily on JAKAFI/JAKAVI (ruxolitinib), and if we are not able to maintain revenues from JAKAFI/JAKAVI or those revenues decrease, our business may be materially harmed.
- If we or our collaborators are unable to obtain, or maintain at anticipated levels, reimbursement for JAKAFI/JAKAVI or our other products from government and other third-party payors, our results of operations and financial condition could be harmed.
- A limited number of specialty pharmacies and wholesalers represent a significant portion of revenues from JAKAFI, and the loss of, or significant reduction in sales to, any one of these specialty pharmacies or wholesalers could harm our 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.
- 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.
- If the use of our products harms or is perceived to harm patients, our regulatory approvals could be revoked or otherwise negatively impacted or we could be subject to costly product liability claims.
- If we market our products in a manner that violates various laws and regulations, we may be subject to civil or criminal penalties.
- Competition for our products, in particular JAKAFI/JAKAVI, could harm our business and result in a decrease in our revenue.
- The COVID-19 pandemic and measures to address the pandemic have adversely affected and can in the future adversely affect our business and results of operations.
- We or our collaborators may be unsuccessful in discovering and developing drug candidates, and we may spend significant time and money attempting to do so, in particular with our later stage drug candidates.
- If we or our collaborators are unable to obtain regulatory approval in and outside of the United States for drug candidates, we and our collaborators will be unable to commercialize those drug candidates.
- Health care reform measures could impact the pricing and profitability of pharmaceuticals, and adversely affect the commercial viability of our or our collaborators’ products and drug candidates.
- Conflicts between us and our collaborators or termination of our collaboration agreements could limit future development and commercialization of our drug candidates and harm our business.
- If we are unable to establish collaborations to fully exploit our drug discovery and development capabilities or if future collaborations are unsuccessful, our future revenue prospects could be diminished.
- If we fail to enter into additional in-licensing agreements or if these arrangements are unsuccessful, we may be unable to increase our number of successfully marketed products and our revenues.
- Even if one of our drug candidates receives regulatory approval, we may determine that commercialization would not be worth the investment.
- 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.

- 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 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.
- Our reliance on others to manufacture our drug products and drug candidates could result in drug supply constraints, delays in clinical trials, increased costs, and withdrawal or denial of regulatory approvals.
- 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.
- The illegal distribution and sale by third parties of counterfeit or unfit versions of our or our collaborators' products or stolen products could harm our business and reputation.
- As most of 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.
- If we lose any of our key employees or are unable to attract and retain additional personnel, our business and ability to achieve our objectives could be harmed.
- If we fail to manage our growth effectively, our ability to develop and commercialize products 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.
- Risks associated with our operations outside of the United States could adversely affect our business.
- 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.
- 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 expect to continue to incur significant expenses to discover and develop drugs, which could result in future losses and impair our achievement of and ability to sustain profitability in the future.
- If we are unable to raise additional capital in the future when we require it, our efforts to broaden our product portfolio or commercialization efforts could be limited.
- Our marketable securities and long term investments are subject to risks that could adversely affect our overall financial position.
- If we are unable to achieve milestones, develop product candidates to license or renew or enter into new collaborations, our royalty and milestone revenues and future prospects for those revenues may decrease.
- Any arbitration or litigation involving us and regarding intellectual property infringement claims could be costly and disrupt our drug discovery and development efforts.
- Our inability to adequately protect or enforce our proprietary information may result in loss of revenues or otherwise reduce our ability to compete.
- If the effective term of our patents is decreased 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.
- International patent protection is particularly uncertain and costly, and our involvement in opposition proceedings may result in the expenditure of substantial sums and management resources.
- Significant disruptions of information technology systems, breaches of data security, or unauthorized disclosures of sensitive data could harm our business and subject us to liability or reputational damage.
- Increasing use of social media could give rise to liability, breaches of data security, or reputational damage, which could harm our business and results of operations.

Overview

Incyte is a biopharmaceutical company focused on the discovery, development and commercialization of proprietary therapeutics. Our global headquarters is located in Wilmington, Delaware, where we conduct global commercial and clinical development operations. We also conduct commercial and clinical development operations from our European headquarters in Morges, Switzerland and our Japanese office in Tokyo.

As described in more detail below, we operate in two therapeutic areas that are defined by the indications of our approved medicines and the diseases for which our clinical candidates are being developed. One therapeutic area is Hematology/Oncology, which is comprised of Myeloproliferative Neoplasms (MPNs) and Graft-Versus-Host Disease (GVHD), as well as solid tumors and hematologic malignancies. The other therapeutic area is Inflammation and Autoimmunity (IAI)/Dermatology commercial franchise. We are also eligible to receive milestones and royalties on molecules discovered by us and licensed to third parties.

Hematology and Oncology

Our hematology and oncology franchise is comprised of four approved products, which are JAKAFI (ruxolitinib), MONJUVI (tafasitamab-cxix), PEMAZYRE (pemigatinib) and ICLUSIG (ponatinib), as well as numerous clinical development programs.

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 (MF), in December 2014 for the treatment of adults with polycythemia vera (PV) 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 myeloproliferative neoplasms (MPNs), a type of rare blood cancer, and GVHD is an adverse immune response to an allogeneic hematopoietic stem cell transplant (HSCT). Under our collaboration agreement with our collaboration partner Novartis Pharmaceutical International 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.

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 FDA-approved product in all three of its current indications. JAKAFI remains the first-line standard of care in MF and remains the only FDA-approved product for PV and steroid-refractory acute GVHD. The FDA has granted JAKAFI orphan drug status for MF, PV and GVHD.

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. MF 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-I and 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 steroid-refractory acute and chronic GVHD is approximately 3,000 per year in the United States.

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 sales 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.

MONJUVI (tafasitamab-cxix)

In January 2020, we and MorphoSys AG entered into a collaboration and license agreement to further develop and commercialize MorphoSys' proprietary anti-CD19 antibody tafasitamab (MOR208) globally. The agreement became effective March 2020. Tafasitamab is an Fc-engineered antibody against CD19 currently in clinical development for the treatment of B cell malignancies. We have rights to co-commercialize tafasitamab in the United States with MorphoSys, and we have exclusive development and commercialization rights outside of the United States.

In July 2020, we and MorphoSys announced that the FDA approved MONJUVI (tafasitamab-cxix), which is indicated in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT). MONJUVI was approved under accelerated approval based on overall response rate.

In August 2020, we and MorphoSys announced that MONJUVI in combination with lenalidomide had been included in the latest National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology for B-cell Lymphomas.

DLBCL is the most common type of non-Hodgkin lymphoma in adults worldwide, comprising 40% of all cases. DLBCL is characterized by rapidly growing masses of malignant B-cells in the lymph nodes, spleen, liver, bone marrow or other organs. It is an aggressive disease with ~40% of patients not responding to initial therapy or relapsing thereafter. We estimate that there are ~10,000 patients diagnosed in the United States each year with relapsed or refractory diffuse large B-cell lymphoma (r/r DLBCL) who are not eligible for ASCT.

The approval of MONJUVI was based on data from the MorphoSys-sponsored Phase II L-MIND study, an open label, multicenter, single arm trial of MONJUVI in combination with lenalidomide as a treatment for adult patients with r/r DLBCL. Results from the study showed an objective response rate (ORR) of 55% (39 out of 71 patients; primary endpoint) and a complete response (CR) rate of 37% (26 out of 71 patients). The median duration of response (mDOR) was 21.7 months. The most frequent serious adverse reactions were infections (26%), including pneumonia (7%) and febrile neutropenia (6%).

PEMAZYRE (pemigatinib)

In April 2020, we announced that the FDA approved PEMAZYRE (pemigatinib), a selective fibroblast growth factor receptor (FGFR) kinase inhibitor, for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with an FGFR2 fusion or other rearrangement as detected by an FDA-approved test. PEMAZYRE is the first and only FDA-approved treatment for this indication, which was approved under accelerated approval based on overall response rate and duration of response (DOR).

In March 2021, PEMAZYRE was approved by the Japanese Ministry of Health, Labour and Welfare (MHLW) for the treatment of patients with unresectable biliary tract cancer (BTC) with an FGFR2 fusion gene, worsening after cancer chemotherapy. Also in March 2021, PEMAZYRE was approved by the European Commission (EC) for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with an FGFR2 fusion or rearrangement that have progressed after at least one prior line of systemic therapy.

PEMAZYRE is the first internally discovered product to be globally commercialized by us.

Cholangiocarcinoma is a rare 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 it is currently estimated that there are 2,000-3,000 patients in the United States, Europe and Japan.

The approval of PEMAZYRE was based on data from FIGHT-202, a multi-center, open-label, single-arm study evaluating PEMAZYRE as a treatment for adults with cholangiocarcinoma. In FIGHT-202, and in patients harboring FGFR2 fusions or rearrangements (Cohort A), PEMAZYRE monotherapy resulted in an overall response rate of 36% (primary endpoint), and median DOR of 9.1 months (secondary endpoint). FIGHT-302, a Phase III trial of pemigatinib for the first-line treatment of patients with cholangiocarcinoma and FGFR2 fusions or rearrangements, is ongoing.

We have retained all rights to PEMAZYRE globally, other than those granted to Innovent Biologics, Inc. to develop and commercialize pemigatinib in hematology and oncology in mainland China, Hong Kong, Macau and Taiwan.

ICLUSIG (ponatinib)

In June 2016, we acquired the European operations of ARIAD Pharmaceuticals, Inc. 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 Hematology and Oncology

Ruxolitinib and itacitinib

As part of our development efforts to evaluate JAK inhibition in GVHD, the REACH clinical program is evaluating 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 us and Novartis.

In October 2019, we and Novartis announced that REACH2 met its primary endpoint of superior 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 April 2020, we and Novartis announced that data from REACH2 were published in the *New England Journal of Medicine*.

In July 2020, we and Novartis announced that REACH3 met its primary endpoint of superior ORR at Month 6 with ruxolitinib treatment compared to best available therapy (BAT), as well as both key secondary endpoints, significantly improving patient-reported symptoms and failure-free survival. No new safety signals were observed, and the ruxolitinib safety profile in REACH3 was consistent with that seen in previously reported studies in steroid-refractory chronic GVHD. Additional data announced in December 2020 showed that best overall response (BOR) rate, defined as any response up to week 24, was achieved in a significantly higher percentage of patients with ruxolitinib therapy compared to BAT. An sNDA seeking FDA approval of ruxolitinib in steroid-refractory chronic GVHD has been accepted for Priority Review.

A second JAK inhibitor in development is itacitinib, which is a selective JAK1 inhibitor. Itacitinib is being evaluated in GRAVITAS-309, a pivotal Phase III trial of itacitinib in patients with steroid-naïve chronic GVHD. The FDA has granted itacitinib orphan drug status for GVHD.

As part of our ongoing LIMBER (Leadership In MPNs BEyond Ruxolitinib) clinical development initiative, which is designed to improve and expand therapeutic options for patients with myeloproliferative neoplasms, we are evaluating combinations of ruxolitinib with other therapeutic modalities, as well as developing a once-a-day formulation of ruxolitinib for potential use as monotherapy and combination therapy.

Based on positive Phase II data, we opened two pivotal trials of ruxolitinib in combination with piasclisib (PI3K δ) in first-line MF (LIMBER-313) and in MF patients with a suboptimal response to ruxolitinib monotherapy (LIMBER-304), respectively, and both trials are ongoing. Additional Phase II trials combining ruxolitinib with investigational agents from our portfolio such as INCB57643 (BET) and INCB00928 (ALK2) in patients with MF are in preparation, and additional discovery and development initiatives are also ongoing within the LIMBER program, which are evaluating both internally-discovered compounds, including itacitinib (JAK1), and candidates from collaboration partners.

Tafasitamab

Tafasitamab is an anti-CD19 antibody and is being investigated as a therapeutic option in B cell malignancies in a number of ongoing and planned combination trials. An open-label Phase II combination trial (L-MIND) is investigating the safety and efficacy of tafasitamab in combination with lenalidomide in patients with relapsed or refractory diffuse large B-cell lymphoma (r/r DLBCL), and the ongoing Phase III B-MIND trial is assessing the combination of tafasitamab and bendamustine versus rituximab and bendamustine in r/r DLBCL. firstMIND is a Phase Ib safety trial of tafasitamab as a first-line therapy for patients with DLBCL, and frontMIND, a placebo-controlled Phase III trial evaluating tafasitamab in

combination with lenalidomide added to rituximab plus chemotherapy (R-CHOP) as a first-line therapy for patients with DLBCL, is planned to begin in 2021.

A placebo-controlled Phase III trial (inMIND) of tafasitamab added to lenalidomide plus rituximab (R²) in patients with relapsed or refractory follicular or marginal zone lymphomas is ongoing, and we are preparing to initiate both a proof-of-concept study (topMIND) of tafasitamab in combination with piasclisib (PI3K δ) in patients with relapsed or refractory B-cell malignancies and a proof-of-concept study of tafasitamab, lenalidomide and plamotamab in patients with r/r DLBCL.

In May 2020, we announced the validation of the European Marketing Authorization Application (MAA) for tafasitamab seeking approval of tafasitamab in combination with lenalidomide, followed by tafasitamab monotherapy, for the treatment of adult patients with r/r DLBCL; the validation of the MAA by the European Medicines Agency (EMA) confirms that the submission is ready to enter the formal review process. In January 2021, we announced that Health Canada accepted the New Drug Submission (NDS) for tafasitamab in combination with lenalidomide, followed by tafasitamab monotherapy, as a treatment for adults with r/r DLBCL.

In January 2021, the FDA granted orphan drug designation to tafasitamab as a treatment for patients with follicular lymphoma.

Pemigatinib

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 have initiated additional trials, including FIGHT-207, which is an ongoing solid tumor-agnostic trial evaluating pemigatinib in patients with driver-alterations of FGF/FGFR.

Pemigatinib has Breakthrough Therapy designation as a treatment for patients with myeloid/lymphoid neoplasms with FGFR1 rearrangement (8p11 MPN) who have relapsed or are refractory to initial chemotherapy.

Parsaclisib

The PI3K δ pathway mediates oncogenic signaling in B cell malignancies. Parsaclisib is a PI3K δ 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. The FDA has granted orphan drug designation and Fast Track designation to parsaclisib as a treatment for patients with follicular lymphoma, marginal zone lymphoma and mantle cell lymphoma.

In December 2020, we announced preliminary results from the ongoing CITADEL monotherapy development program, which was designed to enable registration of parsaclisib. Results from four cohorts were presented at the American Society of Hematology (ASH), including in r/r follicular lymphoma (CITADEL-203), in BTK-naïve r/r marginal zone lymphoma (CITADEL-204) and in both BTK-naïve and BTK-experienced r/r mantle cell lymphoma (CITADEL-205).

Retifanlimab

In October 2017, we and MacroGenics, Inc. announced an exclusive global collaboration and license agreement for MacroGenics' retifanlimab (formerly INCMGA0012), an investigational monoclonal antibody that inhibits PD-1. Under this collaboration, we obtained exclusive worldwide rights for the development and commercialization of

retifanlimab in all indications. The molecule is currently being evaluated both as monotherapy and in combination therapy across various tumor types. Potentially registration-enabling trials in squamous cell carcinoma of the anal canal (SCAC), microsatellite instability-high (MSI-H) endometrial cancer and Merkel cell carcinoma are ongoing.

In January 2021, we announced that the FDA had accepted for Priority Review the Biologics License Application (BLA) for retifanlimab as a treatment for previously treated patients with advanced squamous cell carcinoma of the anal canal (SCAC) who have progressed following standard platinum-based chemotherapy. In March 2021, the Marketing Authorization Application (MAA) seeking approval of retifanlimab in SCAC was validated by the European Medicines Agency (EMA). The submissions were based on data from the Phase II POD1UM-202 trial of retifanlimab in patients with locally advanced or metastatic SCAC who have progressed following standard platinum-based chemotherapy, preliminary results of which were presented at ESMO in September 2020. The Phase III POD1UM-303 trial of retifanlimab in combination with platinum-based chemotherapy as a first-line treatment for patients with SCAC is underway.

The Phase III POD1UM-304 trial is evaluating retifanlimab in combination with platinum-based chemotherapy as a first-line treatment for patients with non-small cell lung cancer (NSCLC), and in October 2020, our collaboration partner Zai Lab announced dosing of the first patient in China.

Retifanlimab has been granted Fast Track designation for the treatment of certain patients with advanced or metastatic MSI-H or DNA mismatch repair (dMMR) endometrial cancer, for the treatment of certain patients with locally advanced or metastatic SCAC and for the treatment of Merkel cell carcinoma (MCC). The FDA and EMA have granted orphan drug designation to retifanlimab as a treatment for patients with locally advanced or metastatic SCAC and the FDA has granted orphan drug designation to retifanlimab as a treatment for patients with MCC.

	Indication and status
ruxolitinib (JAK1/JAK2)	Steroid-refractory chronic GVHD ¹ : sNDA under Priority Review
itacitinib (JAK1)	Treatment-naïve chronic GVHD: Phase III (GRAVITAS-309)
Once-a-day ruxolitinib (JAK1/JAK2)	Myelofibrosis, polycythemia vera and GVHD: clinical pharmacology studies
ruxolitinib + piasclisib (JAK1/JAK2 + PI3Kδ)	Myelofibrosis: Phase III (first-line therapy) (LIMBER-313) Myelofibrosis: Phase III (suboptimal responders to ruxolitinib) (LIMBER-304)
ruxolitinib + INCB57643 (JAK1/JAK2 + BET)	Myelofibrosis: Phase II in preparation
ruxolitinib + INCB00928 (JAK1/JAK2 + ALK2)	Myelofibrosis: Phase II in preparation
itacitinib (JAK1)	Myelofibrosis: Phase II (low platelets)
ruxolitinib + CK0804² (JAK1/JAK2 + CB-Tregs)	Myelofibrosis: PoC in preparation
tafasitamab (CD19)³	r/r DLBCL: Phase II (L-MIND); Phase III (B-MIND); MAA and NDS under review 1L DLBCL: Phase Ib (firstMIND); Phase III (frontMIND) in preparation r/r follicular & marginal zone lymphomas: Phase III (inMIND) r/r B-cell malignancies: PoC with piasclisib (PI3Kδ) (topMIND) in preparation r/r B-cell malignancies: PoC with lenalidomide and plamotamab in preparation ⁴
pemigatinib (FGFR)	CCA: Phase II (FIGHT-202), Phase III (FIGHT-302) 8p11 MPN: Phase II (FIGHT-203) Tumor agnostic: Phase II (FIGHT-207)
piasclisib (PI3Kδ)	r/r follicular lymphoma: Phase II (CITADEL-203) r/r marginal zone lymphoma: Phase II (CITADEL-204)

	r/r mantle cell lymphoma: Phase II (CITADEL-205) r/r follicular or marginal zone lymphoma: Phase III (CITADEL-302) in preparation 1L mantle cell lymphoma: Phase III (CITADEL-310) in preparation
retifanlimab (PD-1)⁵	SCAC: Phase II (POD1UM-202); Phase III (PODIUM-303); BLA under Priority Review; MAA under review MSI-high endometrial cancer: Phase II (POD1UM-101, POD1UM-204) Merkel cell carcinoma: Phase II (POD1UM-201) NSCLC: Phase III (POD1UM-304)

- ¹ Clinical development of ruxolitinib in GVHD conducted in collaboration with Novartis.
- ² Development collaboration with Cellenkos, Inc.
- ³ tafasitamab development in collaboration with MorphoSys.
- ⁴ Clinical collaboration with MorphoSys and Xencor, Inc. to investigate the combination of tafasitamab plus lenalidomide in combination with Xencor’s CD20xCD3 XmAb bispecific antibody, plamotamab.
- ⁵ retifanlimab licensed from MacroGenics.

Earlier-Stage Development Programs in Hematology and Oncology

We also have a number of other earlier-stage clinical programs in hematology and oncology, 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), epacadostat (IDO1), INCB86550 (PD-L1), INCB106385 (A _{2A} /A _{2B})
Monoclonal antibodies²	INCAGN1876 (GITR), INCAGN2385 (LAG-3), INCAGN1949 (OX40), INCAGN2390 (TIM-3), INCA00186 (CD73)
Bispecific antibodies	MCLA-145 (PD-L1xCD137) ³

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

Inflammation and AutoImmunity (IAI)

We do not yet have any approved products in IAI. In anticipation of the potential FDA approval of our most advanced program, ruxolitinib cream for use in mild-to-moderate atopic dermatitis (AD), we recently established Incyte Dermatology as a new commercial franchise in the United States.

Clinical Programs in Dermatology

Ruxolitinib cream is a potent, selective inhibitor of JAK1 and JAK2 that provides the opportunity to directly target diverse pathogenic pathways that underlie certain dermatologic conditions, including atopic dermatitis and vitiligo.

In April 2020, safety and efficacy data from the two Phase III trials in the TRuE-AD program evaluating ruxolitinib cream in mild-to-moderate atopic dermatitis (AD) were presented at the Revolutionizing Atopic Dermatitis (RAD) virtual symposium; both trials met their primary endpoints. The 44-week long-term safety and efficacy portion of both the TRuE-AD1 and TRuE-AD2 trials have been completed. Additional pooled analysis from the TRuE-AD program were presented at the American Academy of Dermatology (AAD) in April 2021, with results demonstrating ruxolitinib cream’s safety and efficacy across various patient subgroups.

In September 2020, we purchased a priority review voucher (PRV) from a third party, with the intent to use it in connection with our submission seeking FDA approval of ruxolitinib cream for the treatment of mild-to-moderate AD. In February 2021, we announced that the NDA seeking approval for ruxolitinib cream as a treatment for patients with mild-to-moderate AD was accepted for Priority Review by the FDA. The Prescription Drug User Fee Act (PDUFA) action date is June 21, 2021.

AD is a skin disorder that causes long term inflammation of the skin resulting in itchy, red, swollen and cracked skin. Onset can occur at any age, but is more common in infants and children. In the United States, we estimate that there are approximately 10 million diagnosed adolescent and adult patients with AD.

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. In April 2021, updated 104-week data from the Phase II trial were presented at AAD, with results showing continued efficacy in patients treated with ruxolitinib cream through 104 weeks, with a longer duration of treatment being associated with greater levels of repigmentation.

Vitiligo is a long-term skin condition characterized by patches of the skin losing their pigment. It is estimated that vitiligo affects 0.5-2% of the US population and, therefore, there are at least 1.5 million patients in the United States with this disorder. There are no FDA approved treatments for repigmentation of vitiligo lesions.

We are also developing INCB54707, which is an oral small molecule selective JAK1 inhibitor. INCB54707 is undergoing evaluation in patients with hidradenitis suppurativa (HS), a chronic skin condition where lesions develop as a result of inflammation and infection of the sweat glands. In October 2020, initial results from the clinical program were presented and a randomized Phase IIb trial of INCB54707 is underway in patients with HS. In March 2021, we initiated a Phase II trial evaluating INCB54707 in patients with vitiligo.

Clinical Programs in Other IAI

A Phase II trial of piasclisib in patients with autoimmune hemolytic anemia (AIHA), a rare red blood cell disorder, is ongoing. The FDA has granted orphan drug designation to piasclisib as a treatment for patients with AIHA.

A Phase II trial of INCB00928 is in preparation for patients with fibrodysplasia ossificans progressiva (FOP), a disorder in which muscle tissue and connective tissue are gradually replaced by bone. The FDA has granted Fast Track designation and orphan drug designation to INCB00928 as a treatment for patients with FOP.

Indication and status	
ruxolitinib cream¹ (JAK1/JAK2)	Atopic dermatitis: Phase III (TRuE-AD1, TRuE-AD2; primary endpoint met); NDA under Priority Review Vitiligo: Phase III (TRuE-V1, TRuE-V2; recruitment complete in both trials)
INCB54707 (JAK1)	Hidradenitis suppurativa: Phase II Vitiligo: Phase II
piasclisib (PI3Kδ)	Autoimmune hemolytic anemia: Phase II
INCB00928 (ALK2)	Fibrodysplasia ossificans progressiva: Phase II in preparation

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

Collaborative Partnered Programs

As described below under “—License Agreements and Business Relationships,” we are eligible for milestone payments and royalties on certain products that we licensed to third parties. These include OLUMIANT (baricitinib), which is licensed to our collaborative partner Eli Lilly and Company, and JAKAVI (ruxolitinib) and TABRECTA (capmatinib), which are licensed to Novartis.

Baricitinib

We have a second JAK1 and JAK2 inhibitor, baricitinib, which is subject to our collaboration agreement with Lilly, in which Lilly received exclusive worldwide development and commercialization rights to the compound for inflammatory and autoimmune diseases.

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.

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 an NDA to the FDA and an MAA to the EMA 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, the Japanese Ministry of Health, Labour 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.

Atopic Dermatitis. Lilly has conducted a Phase IIa trial and a Phase III program 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 AD.

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 AD 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 AD. In January 2020, we and Lilly announced that baricitinib met the primary endpoint in both BREEZE-AD4 and BREEZE-AD5, the results of which completed the placebo-controlled data program intended to support global registrations. An sNDA for baricitinib has been submitted by Lilly for the treatment of patients with AD. In April 2021, we and Lilly announced the FDA extended the review period for the sNDA for baricitinib for the treatment of moderate to severe atopic dermatitis by three months to allow time for additional data analyses.

In January 2020, Lilly announced that baricitinib had been submitted for regulatory review in Europe as a treatment for patients with moderate-to-severe AD. In October 2020, Lilly announced that the European Commission approved baricitinib as OLUMIANT for the treatment of moderate-to-severe AD in adult patients who are candidates for systemic therapy. In December 2020, baricitinib was approved by the MHLW for the treatment of patients with moderate-to-severe AD.

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 two Phase III trials of baricitinib in patients with SLE, BRAVE I and BRAVE II.

Alopecia Areata. Alopecia areata is an autoimmune disorder in which the immune system attacks the hair follicles, causing hair loss in patches. In March 2020, Lilly announced that baricitinib received Breakthrough Therapy designation for the treatment of alopecia areata, based on the positive Phase II results of Lilly's adaptive Phase II/III study BRAVE-AA1. In March 2021, we and Lilly announced positive results from BRAVE-AA2, the Phase III trial evaluating the efficacy and safety of once-daily baricitinib in adults with severe alopecia areata. In April 2021, we and Lilly announced positive results from the Phase III portion of BRAVE-AA1. The two studies showed statistically significant improvement in scalp hair regrowth across both baricitinib dosing groups when compared to placebo.

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 May 2020, we and Novartis announced the FDA approval of capmatinib as TABRECTA for the treatment of adult patients with metastatic NSCLC whose tumors have a mutation that leads to MET exon 14 skipping (METex14) as detected by an FDA-approved test. TABRECTA is the first and only treatment approved to specifically target NSCLC with this driver mutation and is approved for first-line and previously treated patients regardless of prior treatment type.

The FDA approval of TABRECTA was based on results from the pivotal GEOMETRY mono-1 study. In the METex14 population (n=97), the confirmed overall response rate was 68% and 41% among treatment-naive (n=28) and previously treated patients (n=69), respectively, based on the Blinded Independent Review Committee (BIRC) assessment per RECIST v1.1. In patients taking TABRECTA, the study also demonstrated a median duration of response of 12.6 months in treatment-naive patients (19 responders) and 9.7 months in previously treated patients (28 responders). The most common treatment-related adverse events (AEs) (incidence $\geq 20\%$) are peripheral edema, nausea, fatigue, vomiting, dyspnea, and decreased appetite. In September 2020, we and Novartis announced that GEOMETRY mono-1 results were published in The New England Journal of Medicine.

In June 2020, we and Novartis announced that the MHLW approved TABRECTA for METex14 mutation-positive advanced and/or recurrent unresectable NSCLC.

NSCLC is the most common type of lung cancer, impacting more than 2 million people per year globally. Approximately 3-4 percent of all patients with NSCLC have tumors with a mutation that leads to MET exon 14 skipping. Though rare, this mutation is an indicator of especially poor prognosis and poor responses to standard therapies, including immunotherapy.

Indication and status	
baricitinib (JAK1/JAK2)¹	Atopic dermatitis: Phase III (BREEZE-AD); approved in European Union and Japan; sNDA under review Severe alopecia areata: Phase III (BRAVE-AA1, BRAVE-AA2) Systemic lupus erythematosus: Phase III (BRAVE I, BRAVE II)
capmatinib (MET)²	NSCLC (with MET exon 14 skipping mutations): approved in United States and Japan

¹ baricitinib licensed to Lilly.

² capmatinib licensed to Novartis.

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 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. Additional information regarding our collaboration agreements, including their financial and accounting impact on our business and results of operations, can be found in Note 9 of notes to our condensed consolidated financial statements.

Out-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 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. 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.

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. 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. In May 2020, we amended our agreement with Lilly to enable Lilly to commercialize baricitinib for the treatment of COVID-19.

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 pemigatinib and our clinical-stage product candidates itacitinib and pascalisib in hematology and oncology indications in mainland China, Hong Kong, Macau and Taiwan.

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 retained an option to assist in the promotion of INCMGA0012 in Zai Lab's licensed territories.

In-License Agreements

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. Under the terms of this agreement, as amended in February 2017, 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, two of which were removed from the collaboration under the February 2017 amendments.

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.

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.

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 II clinical trials, for multiple myeloma.

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. MacroGenics has retained the right to develop and commercialize, at its cost and expense, its pipeline assets in combination with INCMGA0012.

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.

MorphoSys

In January 2020, we entered into a Collaboration and License Agreement with MorphoSys AG and MorphoSys US Inc., a wholly-owned subsidiary of MorphoSys AG, covering the worldwide development and commercialization of MOR208 (tafasitamab), an investigational Fc engineered monoclonal antibody directed against the target molecule CD19. Under the terms of the agreement, we received exclusive commercialization rights outside of the United States, and MorphoSys and we have co-commercialization rights in the United States, with respect to tafasitamab.

COVID-19

In December 2019, coronavirus disease of 2019, or COVID-19, was first reported in Wuhan, China. In March 2020, the World Health Organization declared COVID-19 a pandemic (“the COVID-19 Pandemic”). We and our collaboration partners Lilly and Novartis initiated a number of clinical trials to address COVID-19.

In April 2020, we announced the initiation of a Phase III clinical trial (RUXCOVID) to evaluate the efficacy and safety of ruxolitinib plus standard-of-care (SoC), compared to SoC therapy alone, in patients not on mechanical ventilation and who have COVID-19 associated cytokine storm. We sponsored this collaborative study in the United States and our collaboration partner Novartis International Pharmaceutical Ltd. sponsored the study outside of the United States.

In December 2020, we announced initial results from RUXCOVID, where treatment with ruxolitinib plus SoC did not prevent complications compared to SoC treatment alone in patients with COVID-19 associated cytokine storm. The RUXCOVID study has been completed and the data will be further analyzed to determine any potential impact on other studies of ruxolitinib in patients with COVID-19, including our Expanded Access Program in the United States, which allows eligible patients with severe COVID-19 associated cytokine storm to receive ruxolitinib.

In March 2021, results from a second Phase III clinical trial to evaluate the efficacy and safety of ruxolitinib plus SoC, compared to SoC therapy alone, in COVID-19 patients on mechanical ventilation and who have acute respiratory distress syndrome (ARDS), a type of respiratory failure characterized by rapid onset of widespread inflammation in the lungs were announced. Ruxolitinib failed to reduce mortality due to any cause through Day 29 although in the U.S. study population (91% of total study patients), there was a clinically and statistically significant improvement in mortality in each of the 5mg and 15mg ruxolitinib arms.

In April 2020, Lilly announced that it has entered into an agreement with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, to study baricitinib as an arm in NIAID's Adaptive COVID-19 Treatment Trial (ACTT-2). The study is investigating the efficacy and safety of baricitinib as a potential treatment for hospitalized patients diagnosed with COVID-19 in the United States, and Lilly is also planning an expansion to include Europe and Asia.

In September 2020, we and Lilly announced initial results from ACTT-2, where baricitinib in combination with remdesivir reduced the time to recovery in comparison with remdesivir alone. Additional data announced in October 2020 showed that baricitinib plus remdesivir resulted in a numerical decrease in mortality through Day 29 compared to remdesivir alone, with a more pronounced reduction seen in more severely ill patients.

In November 2020, we and Lilly announced that the FDA issued an Emergency Use Authorization (EUA) for the distribution and emergency use of baricitinib to be used in combination with remdesivir in hospitalized adult and pediatric patients two years of age or older with suspected or laboratory confirmed COVID-19 who require supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation. In December 2020, we and Lilly announced that data from ACTT-2 supportive of the EUA were published in the New England Journal of Medicine.

In April 2021, we and Lilly announced that the primary endpoint was not met in COV-BARRIER, the Phase III randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of baricitinib in hospitalized adults not on mechanical ventilation and who have COVID-19. There was, however, a 38% reduction in mortality by Day 28 in patients treated with baricitinib in addition to SoC.

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 in an amount that reflects the consideration we expect to receive in exchange for those goods or services. We apply the following five-step model in order to determine this amount: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation, which for the Company is generally at a point in time. We also 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 PEMAZYRE 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 United States. 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 United States 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. 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. If actual future funding varies from estimates, we may need to adjust prior period accruals, which would affect revenue in the period of adjustment. Additionally, beginning in January 2020, the amount of spending required by eligible patients in the Medicare Part D insurance coverage gap increased 30% due to the expiration of a provision in the Patient Protection and Affordable Care Act, which now results in a change in the True Out of Pocket (TrOOP) calculation methodology. The methodological change has resulted in an increase in required spending by patients and, in turn, an increase in manufacturers' contributions on behalf of patients in the Medicare Part D insurance coverage gap.

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 JAKAVI and TABRECTA 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 a contract, we determine the transaction price, in addition to any upfront payment, by estimating the amount of variable consideration, including milestone payments, at the outset of the contract utilizing the most likely amount method. Our contractual milestones 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. We include milestones in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the milestone is subsequently resolved. Given the high level of uncertainty of achievement, variable consideration associated with milestones are fully constrained until confirmation of the satisfaction or completion of the milestone by the third-party. We review our estimate of the transaction price each period, and make revisions to such estimates as necessary.

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 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. 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 United States, Canada, 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 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 a discount rate 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 December 2019, the FASB issued ASU No. 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes." This guidance applies to all entities and aims to reduce the complexity of tax accounting standards while enhancing reporting disclosures. This guidance is effective for fiscal years beginning after December 15, 2020 and interim periods therein. We adopted this guidance for the period beginning January 1, 2021. Upon adoption, ASU No. 2019-12 had an immaterial impact on the condensed consolidated financial statements.

Results of Operations

We recorded net income of \$53.5 million and basic and diluted net income per share of \$0.24 for the three months ended March 31, 2021, as compared to net loss of \$720.6 million and basic and diluted net loss per share of \$3.33 in the corresponding period in 2020.

Revenues.

	For the Three Months Ended, March 31,	
	2021	2020
	(in millions)	
JAKAFI revenues, net	\$ 465.7	\$ 459.5
ICLUSIG revenues, net	25.6	27.2
PEMAZYRE revenues, net	13.5	—
Total product revenues, net	504.8	486.7
JAKAVI product royalty revenues	65.6	56.3
OLUMIANT product royalty revenues	32.3	25.5
TABRECTA product royalty revenues	2.0	—
Total product royalty revenues	99.9	81.8
Total revenues	\$ 604.7	\$ 568.5

The increase in JAKAFI product revenues for the three months ended March 31, 2021 as compared to the corresponding period in 2020 was comprised of a volume decrease of \$4.9 million, including the impact of a decline in new patient starts due to the COVID-19 pandemic, and higher patient demand and channel inventory stocking in the prior year comparative period, due to the potential for COVID-19 related supply disruptions, offset by a price increase of \$11.1 million. Additionally, 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):

Three Months Ended March 31, 2021	Discounts and Distribution Fees	Government Rebates and Chargebacks	Co-Pay Assistance and Other Discounts	Product Returns	Total
Balance at January 1, 2021	\$ 8,536	\$ 66,991	\$ 1,284	\$ 1,568	\$ 78,379
Allowances for current period sales	15,448	111,306	8,150	313	135,217
Allowances for prior period sales	63	(1,010)	—	—	(947)
Credits/payments for current period sales	(8,470)	(56,786)	(7,015)	—	(72,271)
Credits/payments for prior period sales	(5,614)	(26,632)	(407)	(131)	(32,784)
Balance at March 31, 2021	<u>\$ 9,963</u>	<u>\$ 93,869</u>	<u>\$ 2,012</u>	<u>\$ 1,750</u>	<u>\$ 107,594</u>

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 product 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 and TABRECTA 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.

Cost of Product Revenues.

	For the Three Months Ended, March 31,	
	2021	2020
	(in millions)	
Product costs	\$ 4.5	\$ 3.4
Salary and benefits related	1.3	0.8
Stock compensation	0.2	0.2
Royalty expense	17.8	17.5
Amortization of definite-lived intangible assets	5.4	5.4
Total cost of product revenues	<u>\$ 29.2</u>	<u>\$ 27.3</u>

Cost of product revenues includes all JAKAFI, ICLUSIG and PEMAZYRE 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.

Operating Expenses.

Research and development expenses

	For the Three Months Ended, March 31,	
	<u>2021</u>	<u>2020</u>
	(in millions)	
Salary and benefits related	\$ 76.6	\$ 68.1
Stock compensation	29.9	28.7
Clinical research and outside services	171.8	963.6
Occupancy and all other costs	28.6	24.9
Total research and development expenses	<u>\$ 306.9</u>	<u>\$ 1,085.3</u>

We account for research and development costs by natural expense line and not costs by project. The increase in salary and benefits related expense for the three months ended March 31, 2021 as compared to the corresponding period in 2020 was 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 for the three months ended March 31, 2021 as compared to the corresponding period in 2020 was primarily due to upfront consideration related to our collaborative agreement with MorphoSys recorded during 2020. Research and development expenses include upfront and milestone expenses related to our collaborative agreements of \$11.5 million and \$805.5 million, respectively, for the three months ended March 31, 2021 and 2020. Research and development expenses for the three months ended March 31, 2021 and 2020 were net of \$3.6 million and \$1.7 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, timing of drug supply, including API, 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

	For the Three Months Ended, March 31,	
	<u>2021</u>	<u>2020</u>
	(in millions)	
Salary and benefits related	\$ 47.9	\$ 36.1
Stock compensation	17.2	13.6
Other contract services and outside costs	88.7	61.4
Total selling, general and administrative expenses	<u>\$ 153.8</u>	<u>\$ 111.1</u>

The increase in salary and benefits related expense for the three months ended March 31, 2021 as compared to the corresponding period in 2020 was due primarily to increased headcount. This increased headcount was due primarily to the ongoing commercialization efforts related to JAKAFI for intermediate or high-risk myelofibrosis, uncontrolled polycythemia vera and GVHD as well as increased headcount related to our European operations. 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 increase in other contract services and outside costs for the three months ended March 31, 2021, as compared to the corresponding

period in 2020, was due primarily to expenses related to the establishment of our dermatology commercial organization, expenses related to activities to support the potential launch of ruxolitinib cream for the treatment of atopic dermatitis, expense recognized in connection with a legal reserve, as discussed in Note 15 of notes to our condensed consolidated financial statements, and the timing of certain expenses.

Change in fair value of acquisition-related contingent consideration

Acquisition-related contingent consideration, which consists of our future royalty obligations to ARIAD/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 months ended March 31, 2021 and 2020 was \$5.5 million and \$6.6 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 for the three months ended March 31, 2021 and 2020 was due primarily to the passage of time as there were no other significant changes in the key assumptions during the periods.

Collaboration loss sharing

Under the collaboration and license agreement with MorphoSys, which was executed in March 2020, we and MorphoSys are both responsible for the commercialization efforts of tafasitamab in the United States and will share equally the profits and losses from the co-commercialization efforts. For the three months ended March 31, 2021 and 2020, our 50% share of the costs for tafasitamab was \$10.5 million and \$2.1 million, respectively, as recorded in collaboration loss sharing on the condensed consolidated statement of operations.

Other income (expense).

Other income (expense), net. Other income (expense), net for the three months ended March 31, 2021 and 2020 was (\$1.4) million and \$8.7 million, respectively. The decrease in other income (expense), net primarily relates to lower interest income for the three months ended March 31, 2021.

Interest expense. Interest expense for the three months ended March 31, 2021 and 2020 was \$0.4 million and \$0.6 million, respectively. Included in interest expense for the three months ended March 31, 2020 was \$0.2 million of non-cash charges to amortize the discounts on our convertible senior notes due November 2020. Included in interest expense for the three months ended March 31, 2021 and 2020 was \$0.3 million of interest expense on our finance lease liabilities.

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 the Three Months Ended, March 31,	
	2021	2020
	(in millions)	
Agenus	\$ (5.9)	\$ (28.8)
Calithera	(4.3)	(2.2)
Merus	9.4	(6.3)
MorphoSys	(23.7)	(9.9)
Syros	(3.2)	(0.9)
Total unrealized loss on long term investments	<u>\$ (27.7)</u>	<u>\$ (48.1)</u>

Provision for income taxes. The provision for income taxes for the three months ended March 31, 2021 and 2020 was \$15.8 million and \$16.6 million, respectively.

Liquidity and Capital Resources

Due to historical net losses, we had an accumulated deficit of \$1.7 billion as of March 31, 2021. 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 March 31, 2021, 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, and U.S. government debt 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 for the three months ended March 31, 2021 was \$206.1 million and net cash used in operating activities for the three months ended March 31, 2020 was \$683.4 million. The \$889.5 million increase in cash provided by operating activities was due primarily to cash outflows in March 2020 related to our collaboration and license agreement with MorphoSys and 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 in investing activities was \$59.8 million for the three months ended March 31, 2021, which represented purchases of marketable securities of \$39.3 million, capital expenditures of \$48.1 million and purchase of long term equity investment of \$8.7 million, offset in part by the sale and maturity of marketable securities of \$35.2 million and the sale of long term investment of \$1.1 million. Net cash used in investing activities was \$108.6 million for the three months ended March 31, 2020, which represented purchases of marketable securities of \$147.4 million, capital expenditures of \$39.3 million, and purchase of long term equity investment of \$95.5 million, offset in part by the sale and maturity of marketable securities of \$173.6 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, capital expenditures and maturities/sales and purchases of marketable securities.

Net cash provided by financing activities was \$12.8 million and \$2.5 million, respectively, for the three months ended March 31, 2021 and 2020, 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.

Our capital expenditures for construction activities and our non-operating contractual operating and finance lease obligations are discussed in Note 7 of notes to our condensed consolidated financial statements. In addition, 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. Under that 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; and expenditures for future strategic equity investments or potential acquisitions. 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. These contingent future payments are discussed in detail in Note 9 of notes to our condensed consolidated financial statements.

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 U.S. government debt 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 March 31, 2021, marketable securities were \$292.4 million. Due to the nature of these investments, if market interest rates were to increase immediately and uniformly by 10% from levels as of March 31, 2021, 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 March 31, 2021, 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 maintain revenues from JAKAFI or those revenues decrease, our business may be materially harmed.

JAKAFI is our first product marketed by us that is approved for sale in the United States. JAKAFI 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, 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, and in May 2019 for the treatment of steroid-refractory acute graft-versus-host disease in adult and pediatric patients 12 years and older. Although we have received regulatory approval for these indications, such approval does not guarantee future

revenues. While we also sell ICLUSIG in the European Union, or EU, and other countries for the treatment of certain types of leukemia, PEMAZYRE in the United States and Europe for the treatment of certain metastatic cholangiocarcinoma indications, and MONJUVI in the United States for the treatment of certain lymphoma indications and our exclusive licensees sell OLUMIANT (baricitinib) for the treatment of specified rheumatoid arthritis and atopic dermatitis indications and TABRECTA for the treatment of a certain type of non small-cell lung cancer, 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 maintain and continue to increase revenues from the sale of JAKAFI will depend on a number of factors, including:

- the number of patients with intermediate or high-risk myelofibrosis, uncontrolled polycythemia vera or steroid-refractory acute graft-versus-host disease who are diagnosed with the diseases 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 and pricing;
- 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 effects of the COVID-19 Pandemic, any associated quarantine, travel restriction, stay-at-home or shutdown orders, guidelines or practices, and any disruption in our supply chain for JAKAFI on our ability to provide marketing and distribution support for JAKAFI, our ability to produce sufficient quantities of JAKAFI that meet all applicable quality standards, patient demand (including new patient prescriptions) and other risks detailed further below under “—Other Risks Relating to our Business—Public health epidemics, such as the COVID-19 Pandemic, could adversely affect our business, results of operations, and financial condition”;
- 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 able to maintain revenues from JAKAFI in the United States, or our revenues from JAKAFI decrease, our business may be materially harmed and we may need to delay other drug discovery, development and commercialization initiatives or even significantly curtail operations, and our ability to license or acquire new products to diversify our revenue base could be limited.

In addition, our receipt of royalties under our collaboration agreements with Novartis for sales of JAKAFI outside the United States and TABRECTA globally and with Eli Lilly and Company for worldwide sales of OLUMIANT will depend on factors similar to those listed above, with similar regulatory, pricing and reimbursement issues driven by applicable regulatory authorities and governmental and third-party payors 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. The costs of JAKAFI, ICLUSIG, PEMAZYRE and MONJUVI are not insignificant 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 or our collaborators’ products and drug candidates. Our ability to generate revenues will be diminished if we or our collaborators 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 will harm our operating results and financial condition and could adversely affect our ability to conduct our research and development operations.” 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, reduce previously approved levels of coverage and reimbursement, or delay reimbursement payments due to budgetary constraints relating to the COVID-19 Pandemic, 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.

We have established commercial capabilities in the United States and outside of 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. 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 any new 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.

To the extent that we are able to obtain marketing approval for ruxolitinib cream for dermatology indications such as atopic dermatitis and vitiligo, we will have to establish and maintain sales, marketing and distribution capabilities that will generally be separate from our existing capabilities for oncology indications, and we have no prior experience in commercializing products for dermatology indications. Successful commercialization of our drug candidates for dermatology indications, if approved, will require us to establish new physician and payor relationships, reimbursement strategies and governmental interactions. Our inability to commercialize successfully products in indications outside of oncology could harm our business and operating results.

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, ICLUSIG, PEMAZYRE and MONJUVI, the manufacturing, marketing and sale of JAKAFI and PEMAZYRE and the marketing and sale of ICLUSIG and MONJUVI 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, uncontrolled polycythemia vera or acute graft-versus-host disease 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, PEMAZYRE and MONJUVI.

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 collaborator Novartis for jurisdictions in which it has development and commercialization rights, to ICLUSIG for jurisdictions outside the United States, to our collaborator Lilly for all jurisdictions and to our collaborator Innovent for PEMAZYRE in the jurisdictions in which it has development and commercialization rights.

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, uncontrolled polycythemia vera and acute graft-versus-host disease 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 improper 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 improper 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. Similar risks exist for our marketing of PEMAZYRE and our and our collaborator MorphoSys’s marketing of MONJUVI.

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, and the EU also maintains strict controls on advertising and promotional materials. 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. Numerous states and localities have enacted or are considering enacting legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. 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, which could be significant in amount or result in exclusion from federal healthcare programs such as Medicare and Medicaid. Any action initiated against us for violation of these laws, even if we successfully defend against it, could require the expenditure of significant resources and generate negative publicity, which could harm our business and operating results. 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 August 2019, Celgene Corporation, now a subsidiary of Bristol-Myers Squibb Company, announced that the FDA had approved INREBIC (fedratinib) for the treatment of myelofibrosis. 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 (PTAB) of United States Patent and Trademark Office denied a petition challenging our patent covering deuterated ruxolitinib analogs and the PTAB subsequently denied the petitioner’s request for rehearing in May 2018. Nevertheless, the petitioner still has the right separately to challenge the validity of our 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, generic versions of imatinib are available and, while 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.

MONJUVI currently competes with existing therapies that are approved for the treatment of patients with diffuse large B-cell lymphoma on the basis of, among other things, efficacy, cost, breadth of approved use and the safety and side-effect profile. These existing therapies are offered by major pharmaceutical and biotechnology companies, as well as specialty pharmaceutical firms. Potential competitors for PEMAZYRE could include major pharmaceutical and biotechnology companies, as well as specialty pharmaceutical firms.

OTHER RISKS RELATING TO OUR BUSINESS

Public health epidemics, such as the COVID-19 Pandemic, could adversely affect our business, results of operations, and financial condition.

Our global operations expose us to risks associated with public health epidemics, such as the COVID-19 Pandemic that has spread globally. The extent to which the COVID-19 Pandemic and the measures taken to limit COVID-19’s spread impact our operations and those of our suppliers, collaborators, service providers and healthcare organizations serving patients, as well as demand for our drug products, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak and any future resurgence of the outbreak, additional or modified government actions, including any further restrictions or reopening of local, state or national social or economic activity, new information that may emerge concerning the severity of COVID-19 and the actions taken to contain COVID-19 or treat its impact, among others.

As a result of the COVID-19 Pandemic, we may experience disruptions that could severely impact our business, results of operations and financial condition, including the following:

- To protect the health of our employees and their families, and our communities, in accordance with – and in some cases in advance or - direction from state and local government authorities, we currently have limited access to certain of our facilities and instituted additional precautions in our facilities that have reopened, and a significant percentage of our personnel continue to work remotely a significant portion of their time. In the event that governmental authorities were to modify current restrictions or re-establish greater restrictions, our employees conducting research and development activities may not be able to access our laboratory space, and our research and development activities may be significantly limited or curtailed, possibly for an extended period of time. These research and development activities could include completing Investigational New Drug (IND)/Clinical Trial Application (CTA)-enabling studies, our ability to select future development candidates, and initiation of additional clinical trials for our development programs. Having a significant portion of our employees work from home can strain our information technology infrastructure, which may affect our ability to operate effectively, may make us more susceptible to communications disruptions, and expose us to greater cybersecurity risks.
- Our sales and marketing activities, including our interactions with healthcare professionals, have been limited and made more difficult by the work from home orders and travel restrictions. In addition, demand for our products has been affected by decreases in new patients, which we believe resulted in large part from decreases in patient visits to healthcare professionals and prioritization of hospital resources for the COVID-19 Pandemic, resulting in decreases in disease screening and diagnosis. We cannot predict the effects on patient demand or future sales if there are prolonged quarantines, work from home orders or travel restrictions.
- Our clinical trials have been and may in the future be affected by delays in site initiation, patient screening, patient enrollment, and monitoring and data collection as a result of prioritization of hospital resources for the COVID-19 Pandemic, travel restrictions, and the inability to access sites for initiation and monitoring. In addition, some patients may be unable to comply with clinical trial protocols if quarantines or stay at home orders impede patient movement or interrupt health services, we may be unable to obtain blood samples for testing, and we may not be able to provide the trial drug candidate to patients.
- Health regulatory agencies globally have experienced disruptions in their operations as a result of the coronavirus pandemic. The FDA and comparable foreign regulatory agencies may have slower response times or be under-resourced to continue to monitor our clinical trials and, as a result, review, inspection, and other timelines may be materially delayed. If any of these disruptions occur or continue to occur, we cannot predict how long they may last. Our drug candidate application reviews and potential approvals could be impacted or delayed by these disruptions, if they occur or continue to occur.
- The outbreak and measures taken to limit the spread of the outbreak, especially if prolonged, could also disrupt our supply chain or limit our ability to obtain sufficient materials for our drug products and product candidates, which could adversely affect our revenues and clinical trial timelines. Currently, our supply chain for our drug products and product candidates depends on operations by us and by other companies in multiple countries around the world, and the effects of the COVID-19 Pandemic on any or all of these countries is uncertain and unpredictable and potential disruption is possible. In addition, our third-party manufacturers might experience capacity constraints and delays in producing materials for our drug products and product candidates if they are required, under the U.S. Defense Production Act or similar governmental mandates, to prioritize production of raw materials, supplies, drugs or vaccines to address COVID-19. And, for JAKAFI, while our strategy is to maintain a 24 month stock of active pharmaceutical ingredient, or API, inclusive of finished product, ruxolitinib phosphate might be used by us either to make JAKAFI or for ruxolitinib drug candidates in clinical trials.
- Any deterioration of worldwide credit and financial markets could result in losses on our holdings of cash and investments due to failures of financial institutions and other parties, and interruptions and delays in our ability to collect, or potential losses on, our accounts receivable.

Our collaborators could be affected by similar factors as those that have or could affect our business. The ultimate impact of the COVID-19 Pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential impacts or delays on our or our collaborators' businesses, our revenues, including milestone and royalty revenues from our collaborators, our and our collaborators' clinical trials, healthcare systems or the

global economy as a whole. However, these effects could have a material adverse impact on our business, results of operations, and financial condition.

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

Our long-term success, revenue growth and diversification of revenues depends on our ability to obtain regulatory approval for new drug products and new indications for our existing drug products. Our ability to discover and develop drug candidates and to commercialize additional drug products and indications 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, marketing, distribution and manufacturing 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 may not be successful in discovering, developing, or commercializing additional drug products or our existing drug products in new indications. 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 and our collaborators might not be able to commercialize any of our or their 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. We and our collaborator MorphoSys have submitted a European Marketing Authorization Application with the EMA for tafasitamab in combination with lenalidomide for the treatment of patients with a specified type of lymphoma. We have submitted a

supplemental New Drug Application (sNDA) for ruxolitinib for the treatment of patients with steroid-refractory chronic graft-versus-host disease and ruxolitinib is in other clinical trials. We have submitted an NDA for ruxolitinib cream for the treatment of patients with atopic dermatitis and ruxolitinib cream is also in Phase III clinical trials for the treatment of patients with vitiligo. Itacitinib is in Phase III clinical trials for the treatment of patients with chronic 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 April 2018, we along with Merck stopped the ECHO-301 study with epacadostat, and we also significantly downsized the epacadostat development program. In addition, in January 2020 we announced that itacitinib did not meet the primary endpoint in the Phase III clinical trial for the treatment of patients with acute graft-versus-host disease. 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 or our collaborators' 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 or our collaborators' 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 or our collaborators' 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 and in January 2020 we stopped our Phase III trial of itacitinib for the treatment of acute graft-versus-host-disease. If clinical trials of any of our or our collaborators' 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.

Even if any of our applications receives an FDA priority review designation (including based on a priority review voucher, one of which we recently acquired and used in connection with our submission seeking FDA approval of ruxolitinib cream for atopic dermatitis), this designation may not result in faster review or approval for our product candidate compared to product candidates considered for approval under conventional FDA procedures and, in any event, does not assure ultimate approval of our product candidate by FDA.

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 or our collaborators' products and drug candidates. Our ability to generate revenues will be diminished if we or our collaborators 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 will harm our operating results and financial condition and 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 United States and abroad.

In recent years, through legislative and regulatory actions and executive orders, 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, including executive orders issued by the Trump Administration in July 2020, 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 and the July 2020 executive orders 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 United States from other countries and limit allowable prices for drugs to a function of an average international reference price that 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 prices, 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.

The consequences of the COVID-19 Pandemic, including the economic effect on government budgets in the United States and elsewhere, may accelerate any of the healthcare reform efforts described above or result in future reform efforts, any of which could have adverse effects on our business, including higher costs for us, lower reimbursement rates for our products and lower demand for our products.

If third parties institute high co-payment amounts or other benefit limits for our products, the demand for our products and, accordingly, our revenues and results of operations, could be adversely affected. Our patient assistance programs have provided support for non-profit organizations that provide financial assistance to eligible patients or in some cases have provided our products without charge to patients who have no or limited insurance coverage through these charitable organizations. Substantial support in this manner could harm our profitability in the future. Further, those organizations' ability to provide assistance to patients is dependent on funding from external sources, and we cannot guarantee that such funding will be provided at adequate levels, or at all.

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, including TABRECTA, 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 have from time to time occurred, and may in the future arise, relating to, among other things, disputes about the achievement and payment of milestone amounts and royalties owed, the ownership of intellectual property that is developed during the course of a collaborative relationship or the operation or interpretation of other provisions in our collaboration agreements. These disputes could lead to litigation or arbitration, which could be costly and divert the efforts of our management and scientific staff, and could diminish the expected effectiveness of the collaboration.

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, financial condition and future revenue prospects.

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, our revenues and our future revenue prospects.

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 or future 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., MorphoSys, 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. For example, we may make or incur contractual obligations to make significant upfront payments in connection with licenses for late-stage drug candidates, as we did in March 2020 in connection with the effectiveness of our collaboration agreement with MorphoSys, and if any of those drug candidates do not receive marketing approval or commercial sales as anticipated or we have to fund additional clinical trials before marketing approval can be obtained, we will have expended significant funds that might otherwise be applied for other

uses or have to expend funds that were not otherwise budgeted or anticipated in connection with the collaboration, and such developments could have a material adverse effect on our stock price and our ability to pursue other transactions. 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, and we may be unable to increase our number of successfully marketed products and our revenues.

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 or our collaborators are successful in gaining regulatory approval of any of our or our collaborators’ drug candidates in addition to JAKAFI, OLUMIANT, PEMAZYRE and MONJUVI or acquire rights to approved drug products in addition to ICLUSIG, we may not generate significant product revenues if these drug products do not achieve an adequate level of acceptance. Physicians may not recommend our or our collaborators’ drug products until longer-term clinical data or other factors demonstrate the safety and efficacy of our or our collaborators’ drug products as compared to other alternative treatments. Even if the clinical safety and efficacy of our or our collaborators’ 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 or our collaborators’ 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 following, and market acceptance of our collaborators’ drug products will depend on similar factors:

- 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 contract 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, PEMAZYRE and our other drug candidates or for ICLUSIG or MONJUVI. We currently hire third parties to manufacture the raw materials, API and finished drug product of JAKAFI, ICLUSIG, PEMAZYRE and our other drug candidates for clinical trials and our collaborator MorphoSys is currently responsible for sourcing manufacturing of MONJUVI. 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 drug products such as JAKAFI and PEMAZYRE 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. To the extent our supply chain involves parties in China or materials originating in areas of China that are or could be affected by disease outbreaks such as the COVID-19 Pandemic in 2020, we could see disruptions to our supply chain. Currently, our supply chain for our drug products and product candidates depends on operations by us and by other companies in multiple countries around the world, and the effects of the COVID-19 Pandemic and measures to address the COVID-19 Pandemic on any or all of these countries is uncertain and unpredictable and potential disruption is possible. And, for JAKAFI, while our strategy is to maintain a 24 months stock of API, inclusive of finished product, ruxolitinib phosphate might be used by us either to make JAKAFI or for ruxolitinib drug candidates in clinical trials. 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 our drug products 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 and have instituted pricing disclosure and other requirements for companies selling pharmaceuticals. 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, improper 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, and any settlement of these proceedings could result in significant payments by us. 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.

The illegal distribution and sale by third parties of counterfeit or unfit versions of our or our collaborators' products or stolen products could harm our business and reputation.

We are aware that counterfeit versions of our products have been distributed or sold by entities not authorized by us using product packaging suggesting that the product was provided by us. If unauthorized third parties illegally distribute and sell counterfeit versions of our or our collaborators' products, those products may not meet our or our collaborators' rigorous manufacturing, distribution and handling standards. In addition, inventory that is stolen from warehouses, plants or while in-transit, and that is subsequently improperly stored and sold through unauthorized channels, may not meet our or our collaborators' distribution and handling standards. A patient who receives a counterfeit or unfit drug may suffer dangerous health consequences. Our reputation and business could suffer harm as a result of counterfeit or unfit drugs sold under our brand name and could result in lost sales for us and decreased revenues. If counterfeit or unfit drugs are sold under our or our collaborators' brand names, our reputation and business could suffer harm and we could experience decreased royalty revenues.

As most of 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 most of our drug discovery, research, development and marketing activities. In addition, natural disasters, the effects of or measures taken to limit the effects of health epidemics such as the COVID-19 Pandemic, 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. 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 three month periods ended March 31, 2020, September 30, 2020 and March 31, 2021, we recorded unrealized losses related to our investments in our collaboration partners, and we may in experience additional losses related to our investments in future period. 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 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. For example, as part of our plans to expand our activities outside of the United States, we now conduct some of our operations in Canada, commercial and clinical development activities in Japan and have opened an office in China. 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, compliance with which can increase in complexity as we enter into additional jurisdictions;
- difficulties in staffing and managing operations in diverse countries 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 implementation of the relationship between the United Kingdom and the European Union;
- public health risks, such as the spread globally of COVID-19 in 2020, and related effects on supply chain, travel and employee health and availability; 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 in other countries, such as the U.K. Anti-Bribery Act and the U.K. Criminal Finances Act, which may have similarly broad extraterritorial reach.

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. 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 \$1.7 billion as of March 31, 2021. 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 substantial revenues from the drug candidates that we license or develop, including ICLUSIG, PEMAZYRE and MONJUVI, 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 under “Risks Relating to Commercialization of our Products” and in the above paragraphs 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, ICLUSIG, PEMAZYRE and MONJUVI, 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 acquisition of businesses, technologies, or drug candidates, or the licensing of technologies or drug candidates, if any;
- 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;
- 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 or payment 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 equity-linked 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 pay dividends or other distributions on our common stock or 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, money market funds, U.S. government backed-funds and Treasury assets, 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, Merus and Morphosys, 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 condensed consolidated balance sheets and condensed consolidated statements of operations.

We derive a substantial portion of our revenues from royalties, milestone payments and other payments under our collaboration agreements. If we are unable to achieve milestones, develop product candidates to license 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 a substantial portion of our revenues for the year ended December 31, 2020 and the three months ended March 31, 2021 from JAKAVI and OLUMIANT product royalties and from milestone payments under our collaboration agreements. 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.

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 provide a term of patent protection of 20 years from the earliest effective filing date of the patent 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 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. 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. In addition, having a significant portion of our employees work remotely due to the COVID-19 Pandemic can strain our information technology infrastructure, which may affect our ability to operate effectively, may make us more susceptible to communications disruptions, and expose us to greater cybersecurity risks.

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 has adopted a comprehensive general data privacy regulation, known as the GDPR, which 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. Moreover, the European Court of Justice in July 2020 invalidated the Privacy Shield framework that had been in place between the European Union and the United States, which invalidation has created uncertainty about how data can now be shared in a compliant manner. Additionally, the California Consumer Privacy Act (CCPA) affords a private right of action to such consumers if certain data breaches result in the loss or theft of their personal information. The GDPR, CCPA and other similar laws or regulations enacted in the United States or other jurisdictions 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 6. Exhibits

Exhibit Number	Description of Document
10.1*	Second Amendment, dated as of January 8, 2021, to Collaboration and License Agreement entered into as of January 12, 2020 by and among the Company, MorphoSys AG and MorphoSys US, Inc.
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. Section 1350)
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.

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: May 4, 2021

By: /s/ HERVÉ HOPPENOT
Hervé Hoppenot
Chairman, President, and Chief Executive Officer
(Principal Executive Officer)

Dated: May 4, 2021

By: /s/ CHRISTIANA STAMOULIS
Christiana Stamoulis
Chief Financial Officer
(Principal Financial Officer)

**SECOND AMENDMENT
TO COLLABORATION AND LICENSE AGREEMENT**

This Second Amendment ("**Second Amendment**") to the Collaboration and License Agreement, (as subsequently amended, the "**Agreement**") is effective as of January 8, 2021 (the "**Effective Date**"), by and between:

MorphoSys AG, a German stock corporation having a place of business at Semmelweisstrasse 7, 82152 Planegg, Germany ("**MorphoSys AG**"), and **MorphoSys US Inc.**, a Delaware corporation, wholly-owned by MorphoSys AG, having its place of business at 470 Atlantic Avenue, 14th floor. Boston, MA 02210, USA ("**MorphoSys Inc.**"), (both MorphoSys AG and MorphoSys Inc., "**MorphoSys**")

and

Incyte Corporation, a Delaware corporation with its principal place of business at 1801 Augustine Cut-Off, Wilmington, Delaware 19803, USA ("**COMPANY**").

MorphoSys and COMPANY each may be referred to herein individually as a "**Party**," or collectively as the "**Parties**."

WHEREAS, the Agreement, as more specifically set forth in Section 16.4, provides for the Parties to be able to disclose Confidential Information of the other Party only in certain instances; and

WHEREAS, COMPANY and MorphoSys have agreed to amend the Agreement to expand the group of third parties to which disclosure may be made to include existing or potential distributors.

NOW and THEREFORE, the Parties hereby agree as follows:

All capitalized terms used in this Second Amendment shall have the meaning ascribed to them in the Agreement, except as otherwise expressly stated herein.

1. Section 16.4(e) to the Agreement shall be deleted in its entirety and replaced by the following (added language underlined only to show its addition):

- (e) made by a Receiving Party on a need-to-know-basis to (i) existing or potential acquirers or merger candidates; (ii) existing or potential Sublicensees, existing or potential distributors or existing or potential contractors (to the extent contemplated hereunder); (iii) investment bankers; (iv) existing or potential investors, venture capital firms or other financial institutions or investors for purposes of obtaining financing; or to Affiliates or Sublicensees, each of whom prior to disclosure must be bound by obligations of confidentiality and non-use equivalent in scope to those set forth in this Article 16 or in accordance with applicable industry standards but for no less than five (5) years from disclosure

2. Performance under all other terms of the Agreement.

Except as expressly amended hereby, the Agreement shall continue in full force and effect. This Second Amendment is incorporated and made a part of the Agreement between MorphoSys and COMPANY. In the event of any conflict or inconsistency between the Agreement and this Second Amendment, the latter shall prevail.

3. Counterparts.

This Second Amendment may be executed in three (3) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[remainder of page intentionally blank]

In Witness Whereof, the Parties have by duly authorized persons, executed this Second Amendment, as of the Effective Date.

MorphoSys AG

By: /s/ Dr. Barbara Krebs-Pohl

By: /s/ Samuel White

Name: Dr. Barbara Krebs-Pohl

Name: Samuel White

Title: SVP Global BD&L and Alliance Management

Title: Senior Director, Head of Commercial Alliance Management

MorphoSys US Inc.

By: /s/ David Trexler

By: /s/ Ben Looker

Name: David Trexler

Name: Ben Looker

Title: President

Title: Secretary

INCYTE CORPORATION

By: /s/ Vijay Iyengar

Name: Vijay Iyengar

Title: EVP, GSCD

[Signature page to Second Amendment to the Collaboration and License Agreement]

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;
 - c) 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: May 4, 2021

/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;
 - c) 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: May 4, 2021

/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 March 31, 2021, 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
May 4, 2021

**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 March 31, 2021, 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
May 4, 2021
