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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, 2024

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	**94-3136539**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
1801 Augustine Cut-Off Wilmington, DE 19803	**19803**
(Address of principal executive offices)	(Zip Code)

(302) 498-6700

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of exchange on which registered
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 224,540,751 as of April 23, 2024.

INCYTE CORPORATION

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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, 2024 (unaudited)	December 31, 2023*
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,346,204	$ 3,213,376
Marketable securities—available-for-sale (amortized cost $506,379 and $442,816 as of March 31, 2024 and December 31, 2023, respectively; allowance for credit losses $0 as of March 31, 2024 and December 31, 2023)	504,484	442,667
Accounts receivable	745,526	743,557
Inventory	63,642	62,972
Prepaid expenses and other current assets	189,235	182,830
Total current assets	4,849,091	4,645,402
Restricted cash	1,627	1,845
Long term investments	287,663	187,716
Inventory	264,292	206,965
Property and equipment, net	719,999	751,513
Finance lease right-of-use assets, net	25,533	25,535
Other intangible assets, net	117,841	123,545
Goodwill	155,593	155,593
Deferred income tax asset	666,566	631,886
Other assets, net	47,400	52,107
Total assets	$ 7,135,605	$ 6,782,107
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 164,238	$ 109,601
Accrued compensation	89,109	153,348
Accrued and other current liabilities	1,102,268	935,569
Finance lease liabilities	3,678	3,439
Acquisition-related contingent consideration	37,160	38,422
Total current liabilities	1,396,453	1,240,379
Acquisition-related contingent consideration	164,840	173,578
Finance lease liabilities	28,934	29,162
Other liabilities	151,107	149,151
Total liabilities	1,741,334	1,592,270
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; none issued or outstanding	—	—
Common stock, $0.001 par value; 400,000,000 shares authorized; 224,533,449 and 224,286,862 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	224	224
Additional paid-in capital	5,070,286	5,016,122
Accumulated other comprehensive (loss) income	(6,172)	13,106
Retained earnings	329,933	160,385
Total stockholders' equity	5,394,271	5,189,837
Total liabilities and stockholders' equity	$ 7,135,605	$ 6,782,107

* The condensed consolidated balance sheet at December 31, 2023 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,	
	2024	2023
Revenues:		
Product revenues, net	$ 729,923	$ 693,237
Product royalty revenues	125,966	115,436
Milestone and contract revenues	25,000	—
Total revenues	880,889	808,673
Costs, expenses and other:		
Cost of product revenues (including definite-lived intangible amortization)	60,956	56,822
Research and development	429,260	406,641
Selling, general and administrative	300,256	315,606
(Gain) loss on change in fair value of acquisition-related contingent consideration	(456)	6,196
(Profit) and loss sharing under collaboration agreements	(1,025)	(1,362)
Total costs, expenses and other	788,991	783,903
Income from operations	91,898	24,770
Interest income and other, net	44,744	32,873
Interest expense	(430)	(469)
Unrealized gain (loss) on long term investments	99,947	(5,318)
Income before provision for income taxes	236,159	51,856
Provision for income taxes	66,611	30,153
Net income	$ 169,548	$ 21,703
Net income per share:		
Basic	$ 0.76	$ 0.10
Diluted	$ 0.75	$ 0.10
Shares used in computing net income per share:		
Basic	224,484	222,960
Diluted	227,219	225,589

See accompanying notes.

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

	Three Months Ended March 31,	
	2024	2023
Net income	$ 169,548	$ 21,703
Other comprehensive (loss) income:		
Foreign currency translation (loss) gain	(17,820)	3,260
Unrealized (loss) gain on marketable securities, net of tax	(1,746)	2,420
Defined benefit pension gain, net of tax	288	193
Other comprehensive (loss) income	(19,278)	5,873
Comprehensive income	$ 150,270	$ 27,576

See accompanying notes.

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

	Common Stock	Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Retained Earnings	Total Stockholders' Equity
Balances at January 1, 2024	$ 224	$ 5,016,122	$ 13,106	$ 160,385	$ 5,189,837
Issuance of 245,228 shares of Common Stock upon exercise of stock options and settlement of employee restricted stock units, net of shares withheld for taxes	—	(5,697)	—	—	(5,697)
Issuance of 1,359 shares of Common Stock for services rendered	—	80	—	—	80
Stock compensation	—	59,781	—	—	59,781
Other comprehensive loss	—	—	(19,278)	—	(19,278)
Net income	—	—	—	169,548	169,548
Balance at March 31, 2024	$ 224	$ 5,070,286	$ (6,172)	$ 329,933	$ 5,394,271

	Common Stock	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
Balances at January 1, 2023	$ 223	$ 4,792,041	$ 15,069	$ (437,214)	$ 4,370,119
Issuance of 313,995 shares of Common Stock upon exercise of stock options and settlement of employee restricted stock units, net of shares withheld for taxes	—	11,235	—	—	11,235
Issuance of 1,073 shares of Common Stock for services rendered	—	80	—	—	80
Stock compensation	—	53,558	—	—	53,558
Other comprehensive income	—	—	5,873	—	5,873
Net income	—	—	—	21,703	21,703
Balances at March 31, 2023	$ 223	$ 4,856,914	$ 20,942	$ (415,511)	$ 4,462,568

See accompanying notes.

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

	Three Months Ended March 31,	
	2024	2023
Cash flows from operating activities:		
Net income	$ 169,548	$ 21,703
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Depreciation and amortization	21,947	19,211
Stock-based compensation	59,778	53,379
Deferred income taxes	(34,251)	(22,163)
Other, net	2,954	(2,651)
Unrealized (gain) loss on long term investments	(99,947)	5,318
(Gain) loss on change in fair value of acquisition-related contingent consideration	(456)	6,196
Changes in operating assets and liabilities:		
Accounts receivable	(1,969)	21,091
Prepaid expenses and other assets	(1,698)	(24,354)
Inventory	(57,197)	(33,320)
Accounts payable	54,637	(221,913)
Accrued and other liabilities	105,465	71,900
Net cash provided by (used in) operating activities	218,811	(105,603)
Cash flows from investing activities:		
Sale of long term investments	—	45
Capital expenditures	(9,549)	(11,906)
Payments for intangible assets	—	(15,000)
Purchases of marketable securities	(165,808)	(54,887)
Sale and maturities of marketable securities	102,245	53,189
Net cash used in investing activities	(73,112)	(28,559)
Cash flows from financing activities:		
Proceeds from issuance of common stock under stock plans	477	13,988
Tax withholdings related to restricted and performance share vesting	(6,174)	(2,753)
Payment of finance lease liabilities	(871)	(802)
Payment of contingent consideration	(5,845)	(6,424)
Net cash (used in) provided by financing activities	(12,413)	4,009
Effect of exchange rates on cash, cash equivalents, and restricted cash	(676)	(199)
Net increase (decrease) in cash, cash equivalents, and restricted cash	132,610	(130,352)
Cash, cash equivalents, and restricted cash at beginning of period	3,215,221	2,953,120
Cash, cash equivalents, and restricted cash at end of period	$ 3,347,831	$ 2,822,768
Supplemental Schedule of Cash Flow Information		
Income taxes paid	$ 2,691	$ 7,107
Unpaid purchases of property and equipment	$ 383	$ 3,059
Leased assets obtained in exchange for new operating lease liabilities	$ —	$ 809
Leased assets obtained in exchange for new finance lease liabilities	$ 550	$ 385

See accompanying notes.

INCYTE CORPORATION
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2024
(Unaudited)

Note 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), OPZELURA® (ruxolitinib cream), MINJUVI® (tafasitamab), MONJUVI® (tafasitamab-cxix), and ZYNYZ® (retifanlimab-dlwr). Our operations are treated as one operating segment.

Note 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, 2024, the condensed consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for the three months ended March 31, 2024 and 2023, 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, 2023 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 (the "SEC").

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, 2023.

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.

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.

Recent Accounting Pronouncements and Regulatory Updates

In November 2023, the Financial Accounting Standards Board (the "FASB") issued ASU No. 2023-07, "*Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*." This amended guidance applies to all public entities and aims to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses, to enable investors to develop more decision-useful financial analyses. This guidance is effective for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. We are currently evaluating the impact that ASU No. 2023-07 will have on our annual consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09, "*Income Taxes (Topic 740): Improvements to Income Tax Disclosures*." This amended guidance applies to all entities and broadly aims to enhance the transparency and decision usefulness of income tax disclosures. For public business entities, the amendments in this Update are effective for fiscal years beginning after December 15, 2024. Early adoption is permitted for any annual periods for which financial statements have not been issued or made available for issuance. We are currently evaluating the impact that ASU No. 2023-09 will have on our consolidated financial statements.

In March 2024, the SEC issued Release Nos. 33-11275; 34-99678 "*The Enhancement and Standardization of Climate-Related Disclosures for Investors*" to require public companies to provide certain climate-related information in their registration statements and annual reports. The compliance dates for the rules amended by this release begin in fiscal year 2025 for large accelerated filers. On April 4, 2024, the SEC issued an order staying the newly adopted rules. We are currently evaluating the impact of this release on our financial disclosures.

Note 3. Revenues

Revenues are recognized under guidance within ASC 606, *Revenue from Contracts with Customers*. The following table presents our disaggregated revenue for the periods presented (in thousands):

	Three Months Ended March 31,	
	2024	2023
JAKAFI revenues, net	$ 571,839	$ 579,969
OPZELURA revenues, net	85,724	56,552
ICLUSIG revenues, net	30,343	27,685
PEMAZYRE revenues, net	17,676	22,475
MINJUVI/MONJUVI revenues, net	23,874	6,556
ZYNYZ revenues, net	467	—
Total product revenues, net	729,923	693,237
JAKAVI product royalty revenues	89,595	76,692
OLUMIANT product royalty revenues	30,589	34,155
TABRECTA product royalty revenues	5,234	4,177
PEMAZYRE product royalty revenues	548	412
Total product royalty revenues	125,966	115,436
Milestone and contract revenues	25,000	—
Total revenues	$ 880,889	$ 808,673

For further information on the MINJUVI/MONJUVI revenues, refer to Note 6, and for further information on our revenue-generating contracts, refer to Note 8.

Note 4. Fair Value of Financial Instruments

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

	Amortized Cost	Net Unrealized Losses	Estimated Fair Value
March 31, 2024			
Debt securities (government)	$ 506,379	$ (1,895)	$ 504,484
December 31, 2023			
Debt securities (government)	$ 442,816	$ (149)	$ 442,667

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. As of March 31, 2024 and December 31, 2023, the available-for-sale debt securities were held in U.S.-government backed securities and in Treasury bonds and were assessed on an individual security basis to have a de minimis risk of credit loss.

Fair Value Measurements

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, 2024 and December 31, 2023, 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, 2024.

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:			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of March 31, 2024
Cash and cash equivalents	$ 3,346,204	$ —	$ —	$ 3,346,204
Debt securities (government)	—	504,484	—	504,484
Long term investments (Note 8)	287,663	—	—	287,663
Total assets	$ 3,633,867	$ 504,484	$ —	$ 4,138,351

	Fair Value Measurement at Reporting Date Using:			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of December 31, 2023
Cash and cash equivalents	$ 3,213,376	$ —	$ —	$ 3,213,376
Debt securities (government)	—	442,667	—	442,667
Long term investments (Note 8)	187,716	—	—	187,716
Total assets	$ 3,401,092	$ 442,667	$ —	$ 3,843,759

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:			
	Quoted Prices in Active Markets for Identical Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of March 31, 2024
Acquisition-related contingent consideration	$ —	$ —	$ 202,000	$ 202,000
Total liabilities	$ —	$ —	$ 202,000	$ 202,000

	Fair Value Measurement at Reporting Date Using:			
	Quoted Prices in Active Markets for Identical Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of December 31, 2023
Acquisition-related contingent consideration	$ —	$ —	$ 212,000	$ 212,000
Total liabilities	$ —	$ —	$ 212,000	$ 212,000

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

	2024
Balance at January 1,	$ 212,000
Contingent consideration earned during the period but not yet paid	(9,544)
Change in fair value of contingent consideration	(456)
Balance at March 31,	$ 202,000

The initial fair value of the contingent consideration was determined on the date of acquisition, June 1, 2016, using an income approach based on projected future net revenues of ICLUSIG 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, 2024 and December 31, 2023 included a discount rate of 10% and updated projections of future net revenues of ICLUSIG 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, 2024 was due primarily to fluctuations in foreign currency exchange rates impacting future revenue projections of ICLUSIG and the passage of time.

We generally make payments to Takeda Pharmaceutical Company Limited quarterly based on the royalties or any additional milestone payments earned in the previous quarter. At March 31, 2024 and December 31, 2023, contingent consideration earned but not yet paid was $9.5 million and $10.3 million, respectively, and was included in accrued and other current liabilities.

Note 5. Concentration of Credit Risk and Current Expected Credit Losses

In November 2009, we entered into a collaboration and license agreement with Novartis Pharmaceutical International Ltd. ("Novartis"). In December 2009, we entered into a license, development and commercialization agreement with Eli Lilly and Company ("Lilly"). The above collaboration partners comprised, in aggregate, 17% and 20% of the accounts receivable balance as of March 31, 2024 and December 31, 2023, respectively. For further information relating to these collaboration and license agreements, refer to Note 8.

In November 2011, we began commercialization and distribution of JAKAFI and in October 2021, we began commercialization and distribution of OPZELURA. Our product revenues are concentrated in a number of customers for these products. The concentration of credit risk related to our JAKAFI and OPZELURA product revenues is as follows:

	Percentage of Total Net Product Revenues for the Three Months Ended March 31,	
	2024	2023
Customer A	17 %	17 %
Customer B	11 %	11 %
Customer C	18 %	18 %
Customer D	9 %	10 %
Customer E	12 %	12 %

We are exposed to risks associated with extending credit to customers related to the sale of products. Customers A, B, C, D, and E comprised, in aggregate, 41% and 40% of the accounts receivable balance as of March 31, 2024 and December 31, 2023, respectively. The concentration of credit risk relating to our other product revenues or accounts receivable is not significant.

We assessed our collaborative and customer receivable assets as of March 31, 2024 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. As of March 31, 2024 and December 31, 2023, we had no allowance for doubtful accounts.

Note 6. Asset Acquisition

On February 5, 2024, we entered into a purchase agreement with MorphoSys AG and MorphoSys US Inc., a wholly-owned subsidiary of MorphoSys AG (together with MorphoSys AG, "MorphoSys"), under which we gained exclusive global rights to tafasitamab, a humanized Fc-modified CD19-targeting immunotherapy marketed in the United States as MONJUVI (tafasitamab-cxix) and outside of the United States as MINJUVI (tafasitamab). We previously had the rights to tafasitamab outside of the United States under our prior collaboration and license agreement with MorphoSys entered into in January 2020, which has now been terminated; therefore, this new agreement gave us all of the remaining global rights to tafasitamab. Under the terms of the purchase agreement, we made a payment of $25.0 million to MorphoSys and gained global development and commercialization rights for tafasitamab along with MONJUVI inventory. We will recognize revenue and costs for all U.S. commercialization and clinical development and MorphoSys will no longer be eligible to receive future milestone, profit split and royalty payments under the now-terminated collaboration and license agreement with MorphoSys.

We evaluated the set of activities and assets acquired under the purchase agreement, and concluded that it did not meet the definition of a business because the acquired set did not include a substantive process. Therefore, the transaction was accounted for as an asset acquisition and the total purchase price, inclusive of direct transaction costs, was allocated to the acquired MONJUVI inventory, in accordance with applicable accounting guidance.

Under the purchase agreement, we have also become the successor to MorphoSys under its collaboration and license agreement with Xencor, Inc. ("Xencor"), pursuant to which Xencor granted MorphoSys an exclusive, worldwide license, including the right to sublicense under certain conditions, for tafasitamab. Xencor is entitled to receive up to $186.5 million in future contingent development and regulatory milestones, and up to $50.0 million in sales milestones. Furthermore, Xencor is eligible to receive tiered royalties on global net sales of tafasitamab in the single-digit to sub-teen double-digit percentage range. Our royalty obligations continue on a country-by-country basis until the later to occur of the expiration of the last valid claim in the licensed patent covering tafasitamab in such country, or 11 years after the first sale thereof following marketing authorization in such country. The term of the Xencor collaboration agreement will continue until all of our royalty payment obligations have expired, unless terminated earlier. The Xencor collaboration agreement may be terminated by either party upon written notice to the other party immediately in the event of the other party's insolvency or upon 120 days' written notice for the other party's uncured material breach (or upon 30 days' written notice in the case of a breach of a payment obligation). Moreover, we may terminate the Xencor collaboration agreement without cause upon 90 days' advance written notice to Xencor. In the event that (i) we terminate this agreement for convenience or (ii) Xencor terminates due to our material breach, our challenge of Xencor's licensed patents or our insolvency, worldwide rights to develop, manufacture and commercialize licensed products, including tafasitamab, revert back to Xencor.

Note 7. Inventory

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

	March 31, 2024	December 31, 2023
Raw materials	$ 23,427	$ 23,282
Work-in-process	255,039	209,793
Finished goods	49,468	36,862
Total inventory	$ 327,934	$ 269,937

Inventories, stated at the lower of cost and net realizable value, consist of raw materials, work in process and finished goods. At March 31, 2024, $63.6 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, 2024, $264.3 million of inventory was classified as non-current on the condensed consolidated balance sheet 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.

We capitalize inventory after regulatory approval as the related costs are expected to be recoverable through the commercialization of the product. Costs incurred prior to regulatory approval are recorded as research and development expense in our statements of operations. At March 31, 2024, inventory with approximately $38.2 million of product costs incurred prior to regulatory approval had not yet been sold. We expect to sell the pre-commercialization inventory over the next 9 to 12 months and, as a result, cost of product revenues will reflect a lower average per unit cost of materials.

Note 8. 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 were initially eligible to receive 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 addition, we were initially eligible to receive up to $75.0 million of additional potential development and regulatory milestones relating to graft-versus-host-disease ("GVHD"). Since the inception of the agreement through March 31, 2024, we have recognized and received, in the aggregate, $157.0 million for the achievement of development milestones, $345.0 million for the achievement of regulatory milestones, and $200.0 million for the achievement of sales milestones.

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 TABRECTA net sales that range from 12% to 14%. We are obligated to pay to Novartis tiered royalties in the low single-digits on future JAKAFI net sales within the United States contingent on certain conditions. During the three months ended March 31, 2024 and 2023, such royalties on net sales within the United States totaled $23.0 million and $23.4 million, respectively, and were reflected in cost of product revenues on the condensed consolidated statements of operations. At March 31, 2024 and December 31, 2023, $398.6 million and $375.6 million, respectively, of accrued royalties were included in accrued and other current liabilities on the condensed consolidated balance sheets, payment of which is dependent on the outcome of a contract dispute with Novartis. 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.

Product royalty revenue related to Novartis net sales of JAKAVI outside of the United States for the three months ended March 31, 2024 and 2023 was $89.6 million and $76.7 million, respectively. Product royalty revenue related to Novartis net sales of TABRECTA worldwide for the three months ended March 31, 2024 and 2023 was $5.2 million and $4.2 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.

Under this agreement, we were initially eligible to receive 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. Since the inception of the agreement through March 31, 2024, we have recognized and received, in aggregate, $149.0 million for the achievement of development milestones, $335.0 million for the achievement of regulatory milestones and $50.0 million for the achievement of sales milestones. We are also eligible to receive tiered, double-digit royalties on future global sales with rates ranging up to the mid-twenties if a product is successfully commercialized.

Product royalty revenue related to Lilly net sales of OLUMIANT outside of the United States for the three months ended March 31, 2024 and 2023 was $30.6 million and $34.2 million, respectively.

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, which was amended in February 2017, the parties have agreed to collaborate on the discovery of novel immuno-therapeutics using Agenus' antibody discovery platforms.

Since the inception of the agreement through March 31, 2024, we have paid Agenus milestones totaling $30.0 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.

As of March 31, 2024, we held an investment of approximately 12.1 million shares of Agenus Inc. common stock. The fair market value of our long term investment in Agenus Inc. at March 31, 2024 and December 31, 2023 was $7.0 million and $10.0 million, respectively. For the three months ended March 31, 2024 and 2023, we recorded an unrealized loss of $3.0 million and $10.6 million, respectively, based on the change in fair value of Agenus Inc.'s common stock during the respective periods.

Merus

In December 2016, we entered into a Collaboration and License Agreement with Merus N.V. ("Merus"). Under this agreement, 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 ten independent programs.

Since the inception of the agreement through March 31, 2024, we have paid and expensed Merus milestones totaling $10.0 million.

As of March 31, 2024, we held an investment of approximately 4.0 million common shares. The fair market value of our total long term investment in Merus at March 31, 2024 and December 31, 2023 was $180.3 million and $110.1 million, respectively. For the three months ended March 31, 2024 and 2023, we recorded an unrealized gain of $70.2 million and $10.4 million, respectively, based on the change in fair value of Merus' common shares during the respective periods.

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 have sole authority over and bear all costs and expenses in connection with the development and commercialization of INCMGA0012 in all indications, whether as a monotherapy or as part of a combination regimen. MacroGenics has retained the right to develop and commercialize, at its cost and expense, its pipeline assets in combination with INCMGA0012. In addition, MacroGenics has the right to manufacture a portion of both companies' global clinical and commercial supply needs of INCMGA0012.

In March 2023, we made a $15.0 million regulatory milestone payment to MacroGenics for the FDA approval of ZYNYZ for the treatment of adults with Merkel cell carcinoma. This milestone payment was capitalized as an intangible asset and included in Other intangible assets, net on the condensed consolidated balance sheet as of March 31, 2024, and is being amortized through cost of product revenues over the estimated useful life of 13.5 years.

Since the inception of the agreement, inclusive of the July 2022 amendment to the agreement, through March 31, 2024, we have paid MacroGenics developmental and regulatory milestones totaling $115.0 million. After the amendment and subsequent payments, MacroGenics will be eligible to receive up to an additional $320.0 million in future contingent development and regulatory milestones, and up to $330.0 million in sales milestones as well as tiered royalties ranging from 15% to 24% of global net sales.

Research and development expenses for the three months ended March 31, 2024 and 2023 also included $12.1 million and $17.8 million, respectively, of development costs incurred pursuant to the MacroGenics agreement. At March 31, 2024 and December 31, 2023, a total of $0.4 million and $0.3 million of such costs were included in accrued and other liabilities on the condensed consolidated balance sheets.

MorphoSys

As described in Note 6, on February 5, 2024, we entered into a purchase agreement with MorphoSys that became effective as of that date, as a result of which we now hold exclusive global rights for tafasitamab, a humanized Fc-modified CD19-targeting immunotherapy marketed in the United States as MONJUVI (tafasitamab-cxix) and outside of the United States as MINJUVI (tafasitamab). Prior to the acquisition, pursuant to a now-terminated collaboration and license agreement, we and MorphoSys 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 was responsible for funding any independent development activities, and we were responsible for funding development activities specific to territories outside of the United States.

As of March 31, 2024, we held an investment of approximately 3.6 million American Depository Shares, each representing 0.25 of an ordinary share of MorphoSys AG. The fair market value of our long term investment in MorphoSys AG as of March 31, 2024 and December 31, 2023 was $65.8 million and $35.9 million, respectively. For the three months ended March 31, 2024 and 2023, we recorded an unrealized gain of $29.9 million and $1.4 million, respectively, based on the change in fair value of MorphoSys AG's ordinary shares during the respective periods.

Our 50% share of the United States loss or profit for the commercialization of tafasitamab for the period from January 1, 2024 to the asset acquisition on February 5, 2024, was a profit of $1.0 million, and is recorded as (Profit) and loss sharing under collaboration agreements on the condensed consolidated statement of operations. As described in Note 6, subsequent to the asset acquisition, we will recognize revenue and costs for all commercialization and clinical development of tafasitamab in the United States. Our 50% share of the United States profit or loss for the commercialization of tafasitamab for the three months ended March 31, 2023 was a profit of $1.4 million, and is recorded as (Profit) and loss sharing under collaboration agreements on the condensed consolidated statement of operations. Research and development expenses for the period from January 1, 2024 to the asset acquisition on February 5, 2024, includes $10.7 million, related to our 55% share of the co-development costs for tafasitamab. Research and development expenses for the three months ended March 31, 2023, includes $25.2 million, related to our 55% share of the co-development costs for tafasitamab. At March 31, 2024 and December 31, 2023, $3.5 million and $18.8 million, respectively, was included in accrued and other liabilities on the condensed consolidated balance sheets for amounts due to MorphoSys under the former agreement.

Syndax

In September 2021, we entered into a Collaboration and License Agreement with Syndax Pharmaceuticals, Inc. ("Syndax"), covering the worldwide development and commercialization of SNDX-6352 ("axatilimab"). We and Syndax have agreed to co-develop axatilimab and to share development costs associated with global and U.S.-specific clinical trials, with Incyte responsible for 55% of such costs and Syndax responsible for 45% of such costs. Each company is responsible for funding any independent development activities.

Inclusive of an upfront, non-refundable payment, since the inception of the agreement through March 31, 2024, we have made payments of $117.0 million to Syndax, which were previously recorded in research and development expense. Syndax is eligible to receive up to $220.0 million in future contingent development and regulatory milestones and up to $230.0 million in sales milestones as well as tiered royalties ranging in the mid-teens on net sales in Europe and Japan and low double digit percentage on net sales in the rest of the world outside of the United States.

As of March 31, 2024, we held an investment of approximately 1.4 million shares of Syndax common stock. The fair market value of our long term investment in Syndax as of March 31, 2024 and December 31, 2023 was $33.8 million and $30.7 million. For the three months ended March 31, 2024 and 2023, we recorded an unrealized gain of $3.1 million and an unrealized loss of $6.2 million, respectively, based on the change in fair value of Syndax's common stock during the respective periods.

Research and development expenses for the three months ended March 31, 2024, includes $7.1 million related to our 55% share of the co-development costs for axatilimab. At March 31, 2024 and December 31, 2023, $1.9 million and $1.8 million, respectively, was included in accrued and other liabilities on the condensed consolidated balance sheet for amounts due to Syndax under the agreement.

China Medical Systems Holdings Limited

In March 2024, we entered into a Collaboration and License Agreement with China Medical System Skinhealth, a wholly-owned dermatology medical aesthetic company and subsidiary of China Medical System Holdings Limited ("CMSHL"), for the development and commercialization of povorcitinib, a selective oral JAK1 inhibitor, in certain indications in certain Asian territories. In March 2024, we recognized an upfront payment under this agreement of $25.0 million upon our transfer of the functional intellectual property related to povorcitinib to CMSHL which was recorded in milestone and contract revenues on the condensed consolidated statement of operations for the three months ended March 31, 2024. We are eligible to receive additional potential development and commercial milestones, as well as royalties on net sales of the licensed product in CMSHL's territory. CMSHL received an exclusive license to develop and commercialize and a non-exclusive license to manufacture povorcitinib in autoimmune and inflammatory dermatologic diseases, including non-segmental vitiligo, hidradenitis suppurativa, prurigo nodularis, asthma and chronic spontaneous urticaria, for patients in mainland China, Hong Kong, Macau, Taiwan and certain countries in Southeast Asia.

Other Agreements

In addition to the license and collaboration agreements discussed above, we have various other license and collaboration agreements that are not individually material to our operating results or financial condition at this time. Pursuant to the terms of those agreements, we may be required to pay, or we may receive, additional amounts contingent upon the occurrence of various future events such as future discovery, development, regulatory or commercial milestones, which in the aggregate could be material. In addition, if any products related to these collaborations are approved for sale, we may be required to pay, or we may receive, royalties on future sales. The payment or receipt of these amounts, however, is contingent upon the occurrence of various future events, the likelihood of which cannot presently be determined.

Note 9. Property and Equipment, net

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

	March 31, 2024	December 31, 2023
Office equipment	$ 23,417	$ 23,417
Laboratory equipment	217,437	220,677
Computer equipment	150,181	147,570
Land	10,561	10,931
Building and leasehold improvements	572,491	584,755
Operating lease right-of-use assets	18,037	20,553
Construction in progress	10,773	13,544
	1,002,897	1,021,447
Less accumulated depreciation and amortization	(282,898)	(269,934)
Property and equipment, net	$ 719,999	$ 751,513

Note 10. Accrued and Other Current Liabilities

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

	March 31, 2024	December 31, 2023
Royalties	$ 410,312	$ 387,362
Clinical related costs	94,554	109,618
Sales allowances	358,541	279,914
Sales and marketing	41,971	37,369
Accrued Taxes	126,762	42,295
Operating lease liabilities	4,783	5,686
Other current liabilities	65,345	73,325
Total accrued and other current liabilities	$ 1,102,268	$ 935,569

Note 11. Stock Compensation

2010 Stock Incentive Plan. In May 2010 the Board of Directors adopted the 2010 Stock Incentive Plan (the "2010 Stock Plan"), which was most recently amended in April 2023, for issuance of common stock to employees, non-employee directors, consultants, and scientific advisors. Awards under the 2010 Stock Plan include stock options, RSUs and PSUs.

2024 Inducement Stock Incentive Plan. In January 2024, our Board of Directors adopted the Incyte Corporation 2024 Inducement Stock Incentive Plan (the "2024 Inducement Plan"). In reliance on Nasdaq Marketplace Rule 5635(c)(4), stockholder approval was not obtained. A total of 1,000,000 shares of common stock are reserved for issuance pursuant to the 2024 Inducement Plan.

We recorded $59.8 million and $53.4 million of stock compensation expense on our condensed consolidated statements of operations for the three months ended March 31, 2024 and 2023, respectively. Stock compensation expense included within our condensed consolidated statements of operations included research and development expense of $36.8 million and $31.0 million for the three months ended March 31, 2024 and 2023, respectively. Stock compensation expense included within our condensed consolidated statements of operations also included selling, general and administrative expense of $22.4 million and $21.6 million for the three months ended March 31, 2024 and 2023, respectively. Stock compensation expense included within our condensed consolidated statements of operations also included cost of product revenues of $0.6 million and $0.8 million, respectively, for the three months ended March 31, 2024 and 2023.

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,		For the Three Months Ended March 31,	
	2024	2023	2024	2023
Average risk-free interest rates	4.08 %	3.72 %	5.38 %	4.06 %
Average expected life (in years)	4.71	4.73	0.50	0.50
Volatility	31 %	33 %	23 %	22 %
Weighted-average fair value (in dollars)	$ 20.67	$ 28.24	$ 10.85	$ 13.70

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 Stock Plan and 2024 Inducement Plan was as follows:

	Shares Subject to Outstanding Options	
	Shares	Weighted Average Exercise Price
Balance at December 31, 2023	12,457,158	$ 85.40
Options granted	596,329	$ 61.35
Options exercised	(7,500)	$ 64.55
Options cancelled	(131,662)	$ 86.44
Balance at March 31, 2024	12,914,325	$ 84.29

Our annual stock option grants 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.

Restricted stock unit ("RSU") and performance share ("PSU") award activity under the 2010 Stock Plan and 2024 Inducement Plan was as follows:

	Shares Subject to Outstanding Awards	
	Shares	Grant Date Value
Balance at December 31, 2023	7,165,342	$ 72.17
RSUs granted	330,699	$ 61.16
Additional PSUs earned	21,866	$ 83.58
RSUs released	(339,217)	$ 80.82
RSUs cancelled	(42,871)	$ 70.83
Balance at March 31, 2024	7,135,819	$ 71.29

RSUs and PSUs are granted 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 in connection with our annual equity awards will vest 25% annually over four years, while each RSU granted as outstanding merit awards or as part of retention award programs will vest in a single installment at the end of four years.

We grant PSUs with performance and/or service-based milestones with graded and/or cliff vesting over three to four years. The shares of our common stock into which each PSU may convert is subject to a multiplier based on the level at which the financial, developmental and market performance conditions are achieved over the service period. Compensation expense for PSUs with financial and developmental performance conditions is recorded over the estimated service period for each milestone when the performance conditions are deemed probable of achievement. For PSUs containing performance conditions which were not deemed probable of achievement, no stock compensation expense is recorded. Compensation expense for PSUs with market performance conditions is calculated using a Monte Carlo simulation model as of the date of grant and recorded over the requisite service period. For the three months ended March 31, 2024 and 2023 we recorded $3.4 million and $6.5 million, respectively, of stock compensation expense for PSUs on our condensed consolidated statements of operations.

The following table summarizes our shares available for grant under the 2010 Stock Plan and 2024 Inducement Plan. Each RSU and PSU grant reduces the available share pool by 2 shares.

	Shares Available for Grant
Balance at December 31, 2023	10,815,026
Additional authorization - 2024 Inducement Plan	1,000,000
Options, RSUs and PSUs granted	(1,279,593)
Options, RSUs and PSUs cancelled	217,404
Balance at March 31, 2024	10,752,837

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, 2024, was $30.6 million, which is expected to be recognized over the weighted average period of approximately 1.1 years. Total compensation cost of RSUs granted but not yet vested, as of March 31, 2024, was $204.3 million, which is expected to be recognized over the weighted average period of approximately 1.6 years. Total compensation cost of PSUs granted but not yet vested, as of March 31, 2024, was $13.3 million, which is expected to be recognized over the weighted average period of 1.2 years, should the underlying performance conditions be deemed probable of achievement.

Note 12. Income Taxes

For the three months ended March 31, 2024 and 2023, we recorded the following provisions for income taxes and effective tax rates as compared to our income before provision for income taxes (in thousands):

	Three Months Ended March 31,	
	2024	2023
Income before provision for income taxes	$ 236,159	$ 51,856
Provision for income taxes	66,611	30,153
Effective tax rate	28.2%	58.1%

Our effective tax rate for the three months ended March 31, 2024 and 2023 was higher than the U.S. statutory rate primarily due to foreign losses with no associated tax benefit (i.e., full valuation allowance) and an increase in our valuation allowance against certain U.S. federal and state deferred tax assets offset to a lesser extent by tax rate benefits associated with research and development and orphan drug tax credit generations and the foreign derived intangible income deductions.

The effective tax rate for the three months ended March 31, 2024 decreased as compared to the prior year period primarily due to the decrease in foreign losses with no associated tax benefit, and to a lesser extent, the tax effects of unrealized gains on long term investments.

The balance of our unrecognized tax benefits (including penalties and interest) increased by $4.2 million during the three months ended March 31, 2024. This movement was primarily driven by increases related to prior period tax positions of $3.1 million and $1.4 million of interest and penalties. We accrue interest and penalties related to unrecognized tax benefits as a component of its provision for income taxes.

The Organization for Economic Cooperation and Development Pillar 2 guidelines, which were supported by over 130 countries worldwide, are designed to impose a 15% global minimum tax on adjusted financial results. Certain aspects of Pillar 2 took effect on January 1, 2024, while other aspects go into effect on January 1, 2025. We are evaluating the potential impact of Pillar 2 on our business, as many of the countries in which we operate are enacting legislation implementing Pillar 2. Although many aspects of Pillar 2 remain to be clarified, at this time there are no material impacts on our effective tax rate.

Note 13. Net Income Per Share

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

	Three Months Ended March 31,	
	2024	2023
Basic net income	$ 169,548	$ 21,703
Weighted average common shares outstanding	224,484	222,960
Basic net income per share	$ 0.76	$ 0.10
Diluted net income	$ 169,548	$ 21,703
Weighted average common shares outstanding	224,484	222,960
Dilutive stock options and awards	2,735	2,629
Weighted average shares used to compute diluted net income per share	227,219	225,589
Diluted net income per share	$ 0.75	$ 0.10

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

	Three Months Ended March 31,	
	2024	2023
Outstanding stock options and awards	13,165,842	10,078,342

Note 14. 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, 2024 and 2023 was $5.4 million and $5.6 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,	
	2024	2023
Service cost	$ 2,621	$ 2,088
Interest cost	441	617
Expected return on plan assets	(1,483)	(1,540)
Amortization of prior service cost	201	103
Amortization of actuarial losses	87	90
Net periodic benefit cost	$ 1,867	$ 1,358

The components of net periodic benefit cost other than the service cost component are included in Interest income and other, net on the condensed consolidated statements of operations. We expect to contribute a total of $10.0 million to the pension plans in 2024 inclusive of the amounts contributed to the plan during the current period.

Note 15. Commitments and Contingencies

We have entered into the collaboration agreements described in Note 8, 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 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.

We brought a lawsuit against the U.S. Centers for Medicare and Medicaid Services (“CMS”) alleging that a recent regulation issued by CMS on the definition of “line extension” for purposes of the Medicaid rebate program is too broad and has the unintended consequence of treating OPZELURA as a “line extension” of JAKAFI under this program. We believe that such a reading would violate CMS’s statutory authority and be arbitrary and capricious given that OPZELURA, among other differentiators, is indicated to treat entirely different medical conditions and entirely different patient populations than JAKAFI. As of March 31, 2024, we have accrued approximately $73.7 million within accrued and other current liabilities on the condensed consolidated balance sheet, relating to the incremental rebates that would be owed were OPZELURA considered a line extension of JAKAFI. The impact on OPZELURA gross to net deductions for the quarter ending March 31, 2024 is approximately 7.2%. If OPZELURA is not treated as a line extension of JAKAFI, this would result in a reversal of our accrual and a lower future gross to net deduction for OPZELURA.

In addition, as described in Note 8, we have an outstanding contractual dispute with Novartis relating to royalties on JAKAFI net sales within the United States.

Note 16. Subsequent Event

In April 2024, Incyte and a wholly-owned subsidiary of Incyte (“Merger Sub”) entered into an agreement and plan of merger (the “Merger Agreement”) with Escient Pharmaceuticals, Inc. (“Escient”), pursuant to which Merger Sub will merge with and into Escient and Escient will become a wholly-owned subsidiary of Incyte. Escient is a clinical-stage drug development company advancing novel small molecule therapeutics for systemic immune and neuro-immune disorders. Upon the terms and subject to the conditions set forth in the Merger Agreement, we will acquire Escient for consideration of $750.0 million plus Escient’s net cash remaining at the close of the transaction, subject to adjustments set forth in the Merger Agreement. The acquisition is subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, among other customary conditions, and will become effective promptly following the satisfaction or waiver of these conditions.

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, 2024 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, 2023 included in our Annual Report on Form 10-K for the year ended December 31, 2023 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), MONJUVI®(tafasitamab-cxix) / MINJUVI® (tafasitamab), OPZELURA® (ruxolitinib) cream and ZYNYZ® (retifanlimab-dlwr);*
- *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 regulatory 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 non-U.S. operations and 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;*
- *our investments, including anticipated expenditures, losses and expenses; and*
- *our patent prosecution and maintenance efforts.*

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

- *our ability to successfully commercialize our drug products and drug candidates;*
- *our ability to obtain, or maintain at anticipated levels, coverage and 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, including geopolitical risks;*
- *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 delays or changes in plans or regulatory agency interactions or other issues relating to 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, natural disasters, or geopolitical events such as the Russian invasion of Ukraine; 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, MINJUVI, MONJUVI, OPZELURA, PEMAZYRE and ZYNYZ 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, coverage and reimbursement for our 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 most of our other products, 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 could harm our business and result in a decrease in our revenue.
- 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.
- Business disruptions, including those resulting from public health pandemics, natural disasters, and other geopolitical events, could adversely affect our business and results of operations.
- Even if one of our drug candidates receives regulatory approval, we may determine that commercialization would not be worth the investment.
- 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.
- 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, and tax law changes could adversely affect our results of operations and financial condition.
- 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 and new technology 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 global biopharmaceutical company engaged in the discovery, development and commercialization of proprietary therapeutics. Our global headquarters is located in Wilmington, Delaware, where we conduct discovery, clinical development and commercial operations. We also conduct clinical development and commercial operations from our European headquarters in Morges, Switzerland and our other offices across Europe, as well as our Japanese office in Tokyo and our Canadian headquarters in Montreal.

We are focused 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 comprises Myeloproliferative Neoplasms (MPNs), Graft-Versus-Host Disease (GVHD), solid tumors and hematologic malignancies. The other therapeutic area is Inflammation and Autoimmunity (IAI), which includes our 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 comprises five approved products, which are JAKAFI (ruxolitinib), MONJUVI (tafasitamab-cxix)/MINJUVI (tafasitamab), PEMAZYRE (pemigatinib), ICLUSIG (ponatinib) and ZYNYZ (retifanlimab-dlwr), 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; in May 2019 for the treatment of steroid-refractory acute graft-versus-host disease (GVHD) in adult and pediatric patients 12 years and older; and in September 2021 for the treatment of chronic GVHD after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older. MF and PV 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, was the first FDA-approved product in MF, PV and steroid-refractory acute GVHD, and was recently approved in steroid-refractory chronic GVHD. JAKAFI remains the first-line standard of care in MF and remains the only FDA-approved product for 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.

In September 2023, we were notified by the Centers for Medicare and Medicaid Services (CMS) that ruxolitinib phosphate qualified for the Small Biotech Exception.

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 3 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 3 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 3 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%).

In September 2021, the FDA approved JAKAFI for the treatment of chronic GVHD after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older. This approval was based on data from REACH3, a Phase 3, randomized, open-label, multicenter study of JAKAFI in comparison to best available therapy for treatment of steroid-refractory chronic GVHD after allogeneic stem cell transplantation. The overall response rate through Cycle 7 Day 1 was 70% for JAKAFI compared to 57% for best available therapy. The most common hematologic adverse reactions (incidence > 35%) were anemia and thrombocytopenia. The most common non-hematologic adverse reactions (incidence ≥ 20%) were infections (pathogen not specified) and viral infection. In addition, the FDA updated labeling for JAKAFI to include warnings of increased risk of major adverse cardiovascular events, thrombosis, and secondary malignancies related to another JAK-inhibitor treating rheumatoid arthritis, a condition for which JAKAFI is not indicated. In patients with MF and PV treated with JAKAFI in clinical trials, the rates of thromboembolic events were similar in JAKAFI and control treated patients.

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 and its salt. These patents, including applicable extensions, currently expire in mid and late 2028. In December 2022, we were granted pediatric exclusivity, which adds six months to the expiration for all ruxolitinib patents listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) as of the date of the grant of pediatric exclusivity.

MONJUVI (tafasitamab-cxix) / MINJUVI (tafasitamab)

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. Tafasitamab is an Fc-engineered antibody against CD19 currently in clinical development for the treatment of B cell malignancies. Under the terms of the collaboration and license agreement, we received rights to co-commercialize tafasitamab in the United States with MorphoSys, and exclusive development and commercialization rights outside of the United States. As more fully described in Note 6 of Notes to the Condensed Consolidated Financial Statements, in February 2024, we entered into a purchase agreement with MorphoSys, the result of which we now hold exclusive global rights for tafasitamab, and the collaboration and license agreement was terminated.

In July 2020, we and MorphoSys announced that the FDA had 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 from the MorphoSys-sponsored Phase 2 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%). Updated three-year data from L-MIND were presented at the American Society of Clinical Oncology (ASCO) 2021 and final five-year data were presented at the American Association for Cancer Research (AACR) 2023, which showed that the MONJUVI plus lenalidomide regimen followed by MONJUVI monotherapy provided prolonged, durable responses in adult patients with r/r DLBCL.

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.

In August 2021, we and MorphoSys announced that the European Commission had granted conditional marketing authorization for MINJUVI (tafasitamab) in combination with lenalidomide, followed by MINJUVI monotherapy, for the treatment of adult patients with relapsed or refractory DLBCL who are not eligible for autologous stem cell transplant (ASCT). The conditional approval was based on the three-year results from the L-MIND study evaluating the safety and efficacy of MINJUVI in combination with lenalidomide as a treatment for patients with r/r DLBCL who are not eligible for ASCT. The results showed best objective response rate (ORR) of 56.8% (primary endpoint), including a complete response (CR) rate of 39.5% and a partial response rate (PR) of 17.3%, as assessed by an independent review committee. The median duration of response (mDOR) was 43.9 months after a minimum follow up of 35 months (secondary endpoint). MINJUVI together with lenalidomide was shown to provide a clinically meaningful response and the side effects were manageable. Warnings and precautions for MINJUVI include infusion-related reactions, myelosuppression, including neutropenia and thrombocytopenia, infections and tumour lysis syndrome.

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 r/r DLBCL who are not eligible for ASCT. In the EU, we estimate there are ~14,000 patients diagnosed each year with r/r DLBCL who are not eligible for ASCT.

PEMAZYRE (pemigatinib)

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

In April 2020, we announced that the FDA had 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 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 for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with an FGFR2 fusion or rearrangement that has progressed after at least one prior line of systemic therapy.

In July 2021, the UK's National Institute for Health and Care Excellence (NICE) recommended PEMAZYRE for patients with cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy. NICE's guidance enables all eligible patients in England and Wales to have access to PEMAZYRE through the National Health Service (NHS).

In March 2022, PEMAZYRE was approved by the National Medical Products Administration (NMPA) of the People's Republic of China for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth receptor 2 (FGFR2) fusion or rearrangement as confirmed by a validated diagnostic test that has progressed after at least one prior line of systemic therapy.

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 3 trial of pemigatinib for the first-line treatment of patients with cholangiocarcinoma and FGFR2 fusions or rearrangements, is ongoing.

In August 2022, PEMAZYRE was approved by the FDA as the first and only targeted treatment for myeloid/lymphoid neoplasms (MLNs) with FGFR1 rearrangement. MLNs with FGFR1 rearrangement are extremely rare and aggressive blood cancers.

In March 2023, PEMAZYRE was approved by the MHLW for the treatment of MLNs with FGFR1 fusion.

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.

ZYNYZ (retifanlimab-dlwr)

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 currently is being evaluated both as monotherapy and in combination therapy across various tumor types. Two Phase 3 trials evaluating retifanlimab in squamous cell anal cancer (SCAC) and non-small cell lung cancer (NSCLC) are ongoing.

In March 2023, we announced that the FDA had approved ZYNYZ (retifanlimab-dlwr), a humanized monoclonal antibody targeting programmed death receptor-1 (PD-1), under accelerated approval, for the treatment of adults with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC). This represents the first regulatory approval for our PD-1 inhibitor.

In April 2024, the European Commission approved ZYNYZ (retifanlimab) as monotherapy for the first-line treatment of adult patients with metastatic or recurrent locally advanced MCC not amenable to curative surgery or radiation therapy following a positive opinion from the Committee for Medicinal Products for Human Use (CHMP).

Clinical Programs in Hematology and Oncology

Ruxolitinib

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. Bioavailability and bioequivalence data were published for ruxolitinib's once-daily (QD) extended release (XR) formulation at the European Hematology Association (EHA) Virtual Congress in June 2021. In March 2023, the FDA issued a complete response letter for ruxolitinib extended-release (XR) tablets for once-daily (QD) use in the treatment of certain types of MF, PV and GVHD. In December 2023, we received FDA feedback and agreed on the requirements to address the complete response letter.

Phase 2 trials combining ruxolitinib with investigational agents from our portfolio such as INCB57643 (BET) and INCB00928 (Zilurgisertib) in patients with MF are ongoing, and updated data demonstrating early signals of clinical activity of both agents in monotherapy and in combination with ruxolitinib were presented in June 2023 at the American Society of Clinical Oncology (ASCO) annual meeting and in December 2023 at the American Society of Hematology (ASH) meeting. Additional discovery and development initiatives are also ongoing, advancing two Phase 1 studies with INCA33989 (mCALR) and INCB160058 (JAK2V617Fi), both of which hold the potential to be disease modifying therapeutics and address significant unmet need in MF, PV and ET.

Axatilimab

In September 2021, we and Syndax Pharmaceuticals, Inc. announced an exclusive worldwide collaboration and license agreement to develop and commercialize axatilimab, Syndax's anti-CSF-1R monoclonal antibody. Together, we plan to develop axatilimab as a therapy for patients with chronic GVHD where CSF-1R-dependent monocytes and macrophages are believed to contribute to organ fibrosis. In December 2021, updated positive data were presented at ASH from the Phase 1/2 trial evaluating axatilimab as a monotherapy in patients with recurrent or refractory chronic GVHD after two or more prior lines of therapy. A 68% overall response rate and broad clinical benefit across multiple organs were observed at doses being assessed in AGAVE-201, a global pivotal trial evaluating axatilimab monotherapy in patients with chronic GVHD in the third line setting. In May 2022, Syndax announced that axatilimab had been granted fast-track designation by the FDA for the treatment of patients with chronic GVHD after failure of two or more lines of systemic therapy.

In July 2023, we and Syndax announced that AGAVE-201 had met its primary endpoint across all cohorts with an overall response rate (ORR) of 74% at the dose of 0.3 mg/kg administered every two weeks. The data highlight the durable response seen at the 0.3 mg/kg dose with 60% of patients who responded to axatilimab still responding at one year. In December 2023, a Biologics License Application (BLA) was submitted to the FDA for axatilimab for the treatment of patients with chronic GVHD after failure of two or more lines of systemic therapy and accepted for Priority Review in February 2024. Plans are underway to initiate two combination trials with axatilimab in cGVHD in mid-2024, including a randomized Phase 2 combination trial with ruxolitinib and a randomized Phase 3 combination trial with steroids, both directed at treating patients with cGVHD in earlier lines of therapy.

INCA033989 (mCALR)

In December 2022, new research detailing the development and mechanism of action of INCA033989, an Incyte-discovered, investigational novel anti-mutant calreticulin (CALR)-targeted monoclonal antibody, was featured in the Plenary Scientific Session at the 64th American Society of Hematology (ASH) Annual Meeting. INCA033989 binds with high affinity to mutant CALR and inhibits oncogenesis, the process of cells becoming cancerous, in cells expressing this oncoprotein. CALR mutations are responsible for disease development in approximately 25-35% of patients with MF and ET. In July 2023, a Phase 1 study evaluating INCA033989 was initiated.

INCB160058 (JAK2V617Fi)

In December 2023, new research detailing the development and mechanism of action of INCB160058, an Incyte-discovered, investigational novel potent and selective JAK2 pseudokinase domain binder with potential to be a disease modifying therapeutic was disclosed at the 65th American Society of Hematology (ASH) Annual Meeting. Pseudokinase binding offers a new mechanism of action for selective inhibition of JAK2V617F, with potential to eradicate mutant clones. In preclinical studies, INCB160058 inhibited cytokine independent activity of JAK2V617F while sparing WT JAK2. The JAK2V617F mutation is found in 55% of primary myelofibrosis, 95% of polycythemia vera and 60% of essential thrombocythemia patients. A Phase 1 study of INCB160058 was initiated in the first quarter of 2024.

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 2 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 3 B-MIND trial is assessing the combination of tafasitamab and bendamustine versus rituximab and bendamustine in r/r DLBCL. firstMIND is a Phase 1b safety trial of tafasitamab as a first-line therapy for patients with DLBCL, and frontMIND, a placebo-controlled Phase 3 trial evaluating tafasitamab in combination with lenalidomide added to rituximab plus chemotherapy (R-CHOP) as a first-line therapy for patients with DLBCL, is ongoing.

A placebo-controlled Phase 3 trial (inMIND) of tafasitamab added to lenalidomide plus rituximab (R^2) in patients with relapsed or refractory follicular or marginal zone lymphomas is ongoing.

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 2 trials – FIGHT-201 in patients with bladder cancer, FIGHT-202 in patients with cholangiocarcinoma, and FIGHT-203 in patients with myeloid/lymphoid neoplasms with FGFR1 rearrangement. Based on data generated from these trials, we have initiated additional trials including FIGHT-302, a Phase 3 study in first-line cholangiocarcinoma. FIGHT-207, a solid tumor-agnostic trial evaluating pemigatinib in patients with driver-alterations of FGF/FGFR, is now closed to recruitment. Based on findings from this study, we have identified populations that potentially may benefit from treatment with pemigatinib, and a Phase 2 trial, FIGHT-209, in patients with glioblastoma is ongoing.

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

Retifanlimab

The Phase 3 POD1UM-303 trial of retifanlimab in combination with platinum-based chemotherapy as a first-line treatment for patients with squamous cell carcinoma of the anal canal (SCAC) is ongoing. In July 2021, we announced that the FDA issued a complete response letter (CRL) for the BLA of retifanlimab for the treatment of SCAC. In October 2021, we announced that we withdrew the MAA seeking approval of retifanlimab in SCAC.

The Phase 3 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).

Oral PD-L1

In November 2021, we highlighted Phase 1 clinical safety and efficacy data for our oral PD-L1 program which included two compounds, INCB99280 and INCB99318. Tumor shrinkage was observed for both oral PD-L1 inhibitors and both were generally well tolerated. We plan to evaluate INCB99280 in Phase 2 as monotherapy and in combination with other antitumor agents. Further dose escalation and dose expansion trials are ongoing with INCB99318.

In November 2022, (i) updated safety and preliminary efficacy data for INCB99280 and INCB99318 was presented at the Society for Immunotherapy of Cancer, and (ii) we and Mirati Therapeutics, Inc. announced a clinical trial collaboration and supply agreement to investigate the combination of INCB99280 and adagrasib, a KRASG12C selective inhibitor, in patients with KRASG12C-mutated solid tumors.

In July 2023, we initiated two Phase 1 studies evaluating INCB99280 in combination with axitinib (VEGF) and in combination with ipilimumab (CTLA-4). A Phase 2 study evaluating INCB99280 in patients with select solid tumors who are checkpoint inhibitor naive also was initiated. Additionally, we initiated a Phase 2 study evaluating INCB99280 in metastatic cutaneous squamous cell carcinoma (cSCC) or locally advanced cSCC. We and Replimune Group, Inc. announced a clinical trial collaboration and supply agreement to investigate the combination of INCB99280 and RP1 in patients with cutaneous squamous cell carcinoma. RP1 is Replimune's lead oncolytic immunotherapy product candidate and is based on a proprietary new strain of herpes simplex virus engineered for robust tumor selective replication and genetically armed with a fusogenic protein (GALV-GP R-) and GM-CSF, intended to maximize tumor killing potency, the immunogenicity of tumor cell death and the activation of a systemic anti-tumor immune response.

MPN, GVHD and Oncology Programs	Indication and Phase
Ruxolitinib XR (QD) (JAK1/JAK2)	Myelofibrosis, polycythemia vera and GVHD
Ruxolitinib + zilurgisertib (JAK1/JAK2 + ALK2)	Myelofibrosis: Phase 2
Ruxolitinib + INCB57643 (JAK1/JAK2 + BET)	Myelofibrosis: Phase 2
Ruxolitinib + CK0804[1] (JAK1/JAK2 + CB-Tregs)	Myelofibrosis: Phase 1
Axatilimab (anti-CSF-1R)[2]	Chronic GVHD: Pivotal Phase 2 (third-line plus therapy) (AGAVE-201); BLA under review in the U.S.
Ruxolitinib + axatilimab[2] (JAK1/JAK2 + anti-CSF-1R)	Chronic GVHD: Phase 2 in preparation
Steroids + axatilimab[2] (Steroids + anti-CSF-1R)	Chronic GVHD: Phase 3 in preparation
INCA033989 (mCALR)	Myelofibrosis, essential thrombocythemia: Phase 1
INCB160058 (JAK2V617Fi)	Phase 1
Pemigatinib (PEMAZYRE) (FGFR1/2/3)	Myeloid/lymphoid neoplasms (MLN): approved in the U.S. and Japan Cholangiocarcinoma (CCA): Phase 3 (FIGHT-302)
Tafasitamab (MONJUVI/MINJUVI) (CD19)	Relapsed or refractory diffuse large B-cell lymphoma (DLBCL): Phase 3 (B-MIND) First-line DLBCL: Phase 3 (*front*MIND) Relapsed or refractory follicular lymphoma (FL) and relapsed or refractory marginal zone lymphoma (MZL): Phase 3 (*in*MIND)
Retifanlimab (ZYNYZ)[3] (PD-1)	Merkel cell carcinoma (MCC): approved in the U.S. Squamous cell anal cancer (SCAC): Phase 3 (POD1UM-303) Non-small cell lung cancer (NSCLC): Phase 3 (POD1UM-304) MSI-high endometrial cancer: Phase 2 (POD1UM-101, POD1UM-204)
INCB99280 (Oral PD-L1)	Solid tumors (combination): Phase 1 Solid tumors (monotherapy): Phase 2 Cutaneous squamous cell carcinoma (cSCC): Phase 2
INCB99318 (Oral PD-L1)	Solid tumors: Phase 1
INCB123667 (CDK2i)	Solid tumors with Amplification/ Overexpression of CCNE1: Phase 1
INCB161734 (KRASG12D)	Advanced metastatic solid tumors with a KRAS G12D mutation: Phase 1

1. Development collaboration with Cellenkos, Inc.
2. Clinical development of axatilimab in GVHD conducted in collaboration with Syndax Pharmaceuticals.
3. Retifanlimab licensed from MacroGenics.

Earlier-Stage Development Programs in Hematology and Oncology

INCB123667 (CDK2)

In the cell cycle, the serine threonine kinase, CDK2, regulates the transition from the G1 phase (cell growth) to the S-phase (DNA replication). INCB123667 is a novel, potent and selective oral small molecule inhibitor of CDK2 which has been shown to suppress tumor growth as monotherapy and in combination with standard of care, in Cyclin E amplified tumor models, in vivo.

In April 2023, we presented data at the American Association for Cancer Research (AACR) Annual Meeting, demonstrating that INCB123667 exhibited significant single-agent activity in vivo, in CCNE1 high breast cancer xenograft and patient-derived xenograft models. INCB123667 currently is being evaluated in a Phase 1 clinical trial in patients with advanced malignancies including CCNE1 high TNBC and HR+HER2- tumors post-CDK4/6 inhibitors.

In January 2024, we disclosed that early clinical activity was observed in patients with amplification/over expression of CCNE1 in a Phase 1 clinical trial, with significant tumor shrinkage observed. Several patients achieved partial responses (PR) across multiple tumor types including ovarian cancer patients with CCNE1 amplification and/or over expression. The safety data seen during this disclosure aligns with CDK2 mechanism of action. Additional data from this trial is anticipated in 2024.

INCA32459 (LAG-3xPD-1)

In collaboration with Merus N.V. we have developed INCA32459, a novel LAG3xPD-1 bispecific antibody that is currently being evaluated in clinical studies.

INCA33890 (TGFβR2xPD-1)

INCA33890 is a TGFβR2xPD-1 bispecific antibody that has been engineered to avoid the known toxicity of broad TGFβ pathway blockade. INCA33890 has a 10-fold higher binding affinity for PD-1 relative to TGFβR2, and specifically blocks TGFβ signaling in cells co-expressing PD-1. In April 2023, we presented preclinical data at AACR that showed that INCA33890 inhibits tumor growth in PD-1-resistant mouse models. In July 2023, we initiated a Phase 1 study evaluating INCA33890 in patients with select advanced solid tumors.

Our earlier-stage clinical programs in hematology and oncology are included 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
Monoclonal antibodies	INCAGN2385 (LAG-3)[1], INCAGN2390 (TIM-3)[1]
Bi-specific antibodies	INCA32459 (LAG-3xPD-1)[2], INCA33890 (TGFβR2xPD-1)[2]

[1.] Discovery collaboration with Agenus Inc.
[2.] Development collaboration with Merus.

Inflammation and AutoImmunity (IAI)

Incyte Dermatology launched its first approved product, OPZELURA (ruxolitinib) cream, in October 2021, following FDA approval for atopic dermatitis in September 2021. OPZELURA subsequently was approved by the FDA and European Commission for vitiligo in July 2022 and April 2023, respectively.

Incyte's IAI efforts also include numerous clinical development programs.

OPZELURA (ruxolitinib) cream

Atopic Dermatitis. In September 2021, we announced that the FDA approved OPZELURA (ruxolitinib) cream, a novel cream formulation of Incyte's selective JAK1/JAK2 inhibitor ruxolitinib, for the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis (AD) in non-immunocompromised patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies, or when those therapies are not advisable.

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.

The approval of OPZELURA was based on data from two randomized, double-blind, vehicle-controlled Phase 3 studies (TRuE-AD1 and TRuE-AD 2) evaluating the safety and efficacy of OPZELURA in adolescents and adults with mild to moderate AD. Significantly more patients treated with OPZELURA achieved Investigator's Global Assessment (IGA) Treatment Success at Week 8 (defined as an IGA score of 0 or 1 with at least a 2-point improvement from baseline, the primary endpoint: 53.8% in TRuE-AD1 and 51.3% in TRuE-AD2, compared to vehicle (15.1% in TRuE-AD1, 7.6% in TRuE-AD2; P<0.0001)). Significantly more patients treated with OPZELURA experienced a clinically meaningful reduction in itch from baseline at Week 8, as measured by a ≥4-point reduction in the itch Numerical Rating Scale (itch NRS4): 52.2% in TRuE-AD1 and 50.7% in TRuE-AD2, compared to vehicle (15.4% in TRuE-AD1, 16.3% in TRuE-AD2; P<0.0001), among patients with an NRS score of at least 4 at baseline. The most common (≥1%) treatment-emergent adverse reactions in patients treated with OPZELURA were nasopharyngitis, diarrhea, bronchitis, ear infection, eosinophil count increased, urticaria, folliculitis, tonsillitis and rhinorrhea.

Vitiligo. In July 2022, we announced that the FDA approved OPZELURA for the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older. OPZELURA was approved for continuous use and no limits to duration as a treatment for nonsegmental vitiligo.

Vitiligo is a chronic autoimmune depigmenting skin disease characterized by patches of the skin losing their pigment. It is estimated that there are at least 1.5 million patients diagnosed with vitiligo in the United States, with the majority of patients (approximately 85%) suffering from nonsegmental vitiligo. OPZELURA is the first and only FDA approved treatment for repigmentation of vitiligo lesions.

The approval of OPZELURA in vitiligo was based on two randomized, double-blind, vehicle-controlled Phase 3 studies (TRuE-V1 and TRuE-V2) evaluating the safety and efficacy of OPZELURA in adolescents and adults with nonsegmental vitiligo. Treatment with 1.5% ruxolitinib cream twice daily (BID) resulted in greater improvement versus vehicle for the primary and all key secondary endpoints in both the TRuE-V1 and TRuE-V2 studies. Results, which were consistent across both studies, showed that 29.9% of patients applying ruxolitinib cream achieved >75% improvement from baseline in the facial Vitiligo Area Scoring Index (F-VASI75) at Week 24, the primary endpoint. At Week 52, approximately 50% of patients achieved F-VASI75. The most common (>1%) treatment-emergent adverse reactions in patients treated with OPZELURA were application site acne, application site pruritus, nasopharyngitis, headache, urinary tract infection, application site erythema and pyrexia. In March 2023, long-term 104-week safety and efficacy data for ruxolitinib cream in vitiligo were presented at the American Academy of Dermatology (AAD) conference, demonstrating that patients who achieved a high level of facial repigmentation (≥F-VASI90) at Week 52 maintained durable response one year following withdrawal of treatment and that those patients who continued treatment with OPZELURA for up to two years demonstrated sustained facial repigmentation and further improvements in facial and total body repigmentation.

In April 2023, we announced that the European Commission had approved OPZELURA for the topical treatment of nonsegmental vitiligo with facial involvement in adults and adolescents 12 years and older following a positive opinion from the CHMP.

In October 2023, new results of a pooled analysis of long-term extension (LTE) data from the pivotal Phase 3 TRuE-V program assessing OPZELURA cream 1.5% in patients 12 years of age and older with nonsegmental vitiligo who previously experienced limited or no response to treatment at Week 24 were presented at the European Academy of Dermatology and Venereology (EADV) Congress 2023 as a late-breaking oral presentation. These results showed that patients who initially experienced limited or no facial or total body repigmentation at six months achieved improved repigmentation after continued treatment with OPZELURA for up to two years.

In January 2024, Incyte received approval in France to promote and distribute OPZELURA for vitiligo under a process called "Accès Direct." This process is intended to allow for early access to a therapy while a final price is negotiated, which is expected to take up to twelve months.

Clinical Programs in Dermatology

Ruxolitinib cream

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, vitiligo, lichen planus, lichen sclerosus, hidradenitis suppurativa and prurigo nodularis.

In October 2021, we announced the validation of the MAA for ruxolitinib cream as a potential treatment for adolescents and adults (age ≥12 years) with nonsegmental vitiligo with facial involvement.

In November 2022, we initiated two Phase 2 trials evaluating ruxolitinib cream in lichen planus and lichen sclerosus. Lichen planus is a recurrent inflammatory condition affecting the skin and mucosal surfaces and can result in itchy, purple bumps on the skin. Lichen sclerosus is a chronic inflammatory skin disease most commonly affecting women and can result in painful ulcers and intense itching. Two Phase 3 trials evaluating ruxolitinib cream in prurigo nodularis were initiated in 2023. We continue to expand the development of ruxolitinib cream into new indications as part of our efforts to maximize the potential opportunity with ruxolitinib cream.

In July 2023, we announced that the Phase 3 trial (TRuE-AD3) evaluating ruxolitinib cream in pediatric AD patients (age ≥2 and <12) had met its primary endpoint. The study showed that significantly more patients treated with ruxolitinib cream 0.75% and 1.5% achieved Investigator's Global Assessment Treatment Success (IGA-TS) than patients treated with vehicle control. In October 2023, the expanded results from the pivotal Phase 3 TRuE-AD3 were presented at EADV. Again, significantly more patients treated with ruxolitinib cream (0.75% and 1.5%) achieved Investigator's Global Assessment Treatment Success (IGA-TS) than patients treated with vehicle control (non-medicated cream).

In January, 2024, we announced positive topline results from a randomized controlled Phase 2 study evaluating ruxolitinib cream in Hidradenitis Suppurativa (HS). Ruxolitinib 1.5% cream BID met the primary efficacy endpoint as measured by a change from baseline in abscess and nodule count at Week 16 versus placebo in patients with mild to moderate HS. Ruxolitinib cream was well tolerated and consistent with its known safety profile. A Phase 3 study is currently under evaluation.

Povorcitinib

We also are developing povorcitinib (formerly INCB54707), which is an oral small molecule selective JAK1 inhibitor. Povorcitinib is undergoing evaluation in patients with hidradenitis suppurativa (HS), nonsegmental vitiligo, prurigo nodularis (PN), asthma and chronic spontaneous urticaria (CSU).

Hidradenitis Suppurativa. HS is 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 2b trial of povorcitinib was initiated in patients with HS. In August 2022, we presented positive results from the Phase 2 trial of povorcitinib in HS. In December 2022, we initiated two Phase 3 trials (STOP-HS1 and STOP-HS2) in moderate to severe HS.

In February 2023, 52-week results from the Phase 2 study evaluating povorcitinib in HS were presented as an oral presentation at the European Hidradenitis Suppurativa Foundation (EHSF) Annual Meeting. The data demonstrated that longer-term treatment with povorcitinib 75 mg resulted in sustained and durable efficacy across all treatment arms and that importantly, 22-29% of patients achieved HiSCR100, which is defined as a 100% reduction from baseline in total AN count with no increase from baseline in abscess or draining tunnel count.

Nonsegmental Vitiligo. In March 2023, 36-week results from the Phase 2b study evaluating povorcitinib in patients with extensive nonsegmental vitiligo were presented as an oral late-breaking presentation at the American Academy of Dermatology (AAD) Annual Meeting. The data demonstrated that treatment with oral povorcitinib was associated with substantial total body repigmentation in patients with extensive nonsegmental vitiligo, as measured by total Vitiligo Area Scoring Index (T-VASI) scores. Specifically, the study met its primary endpoint, and patients receiving povorcitinib experienced statistically superior improvements in T-VASI at Week 24 compared to placebo.

In October 2023, positive 52-week data from a Phase 2b clinical trial evaluating the safety and efficacy of povorcitinib in adult patients with extensive nonsegmental vitiligo were presented at EADV as a late-breaking oral presentation. Results showed that treatment with oral povorcitinib was associated with substantial total body and facial repigmentation across all treatment groups at Week 52 and further reinforces the efficacy profile and potential of povorcitinib as an oral treatment for patients with extensive nonsegmental vitiligo.

Prurigo Nodularis. In October 2023 we announced that the Phase 2, randomized, double-blind, placebo-controlled, dose ranging study evaluating the efficacy and safety of povorcitinib in participants with PN had met its primary endpoint. A Phase 3 study in PN is being planned.

Asthma and Chronic Spontaneous Urticaria. In July 2023, we initiated two Phase 2 trials evaluating povorcitinib in patients with moderate to severe uncontrolled asthma and in chronic spontaneous urticaria.

IAI and Dermatology Programs	Indication and Phase
Ruxolitinib cream (OPZELURA)[1] (JAK1/JAK2)	Atopic dermatitis: Phase 3 pediatric study (TRuE-AD3) Vitiligo: Approved in the U.S. and Europe Lichen planus: Phase 2 Lichen sclerosus: Phase 2 Hidradenitis suppurativa: Phase 2; Phase 3 being evaluated Prurigo nodularis: Phase 3 (TRuE-PN1, TRuE-PN2)
Ruxolitinib cream + UVB (JAK1/JAK2 + phototherapy)	Vitiligo: Phase 2
Povorcitinib (JAK1)	Hidradenitis suppurativa: Phase 3 (STOP-HS1, STOP-HS2) Vitiligo: Phase 3 (STOP-V1, STOP-V2) Prurigo nodularis: Phase 3 to start in 2024 Asthma: Phase 2 Chronic spontaneous urticaria: Phase 2
INCA034460 (anti-IL-15Rβ)	Vitiligo: Phase 1 initiated

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

Earlier-Stage Development Programs in Dermatology

INCA034460

In November 2022, we acquired Villaris Therapeutics, Inc., an asset-centric biopharmaceutical company focused on the development of novel antibody therapeutics for vitiligo. INCA034460 is a novel, humanized anti-IL-15Rβ monoclonal antibody designed to target and deplete autoreactive tissue resident memory T cells (TRM) that has demonstrated efficacy as a treatment for vitiligo in preclinical models. In July 2023, INCA034460 received Investigational New Drug application (IND) clearance and in October 2023, we announced the first patient had been dosed.

Clinical Programs in Other IAI

In May 2022, we initiated a Phase 2 trial evaluating zilurgisertib (INCB00928) in 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 zilurgisertib as a treatment for patients with FOP.

Other IAI Program	Indication and Phase
Zilurgisertib (ALK2)	Fibrodysplasia ossificans progressiva: Pivotal Phase 2

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 also can 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 safe and effective treatment options for these patients. Rheumatoid arthritis is estimated to affect about 1% of the world's population.

The Phase 3 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 3 trials met their respective primary endpoints.

In January 2016, Lilly submitted a New Drug Application (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 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 2a trial and a Phase 3 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 3 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 3 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. A supplemental New Drug Application (sNDA) for baricitinib was submitted by Lilly for the treatment of patients with moderate to severe 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 AD by three months to allow time for additional data analyses. In July 2021, we and Lilly announced that the FDA will not meet the PDUFA action date for the sNDA for baricitinib for the treatment of adults with moderate to severe AD due to the FDA's ongoing assessment of JAK inhibitors. In January 2022, Lilly provided a regulatory update on the sNDA based on ongoing discussions with the FDA. Lilly announced that alignment with the FDA on the indicated population had not yet been reached and given the FDA's position, there would be the possibility of a Complete Response Letter (CRL).

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.

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 2 results of Lilly's adaptive Phase 2/3 study BRAVE-AA1. In March 2021, we and Lilly announced positive results from BRAVE-AA2, the Phase 3 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 3 portion of BRAVE-AA1. In September 2021, we and Lilly announced detailed results from BRAVE-AA1 and BRAVE-AA2 at the European Academy of Dermatology and Venereology Congress (EADV). The two studies showed statistically significant improvement in scalp hair regrowth across both baricitinib dosing groups when compared to placebo. In March 2022, we and Lilly announced positive 52 week results from BRAVE-AA1 and BRAVE-AA2 at the American Academy of Dermatology (AAD) annual meeting showing 40% of adults saw at least 80% scalp coverage. In June 2022, the FDA approved 2mg, and 4mg doses of OLUMIANT for the treatment of adults with severe alopecia areata, becoming the first and only systemic treatment in the indication. In June 2022, OLUMIANT was approved as a treatment for alopecia areata in Europe and Japan.

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 2 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.

In January 2022, Lilly announced the discontinuation of the Phase 3 development program for baricitinib in SLE based on top-line efficacy results from two pivotal Phase 3 trials (SLE-BRAVE-I and –II). The primary endpoint of SRI-4 response was reached in SLE-BRAVE-I but was not reached in SLE-BRAVE-II and key secondary endpoints were not met in either study.

COVID-19. In May 2020, we amended our agreement with Lilly to enable Lilly to commercialize baricitinib for the treatment of COVID-19. 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 July 2021, we and Lilly announced that the FDA broadened the EUA for baricitinib to allow for treatment with or without remdesivir. The EUA now provides for the use of baricitinib for treatment of COVID-19 in hospitalized adults and pediatric patients two years of age or older requiring supplemental oxygen, non-invasive or invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO). In June 2022, we and Lilly announced the FDA approved baricitinib as OLUMIANT for the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation or ECMO.

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 ≥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. In April 2022, we and Novartis announced a positive opinion from the CHMP based on data from the Phase 2 GEOMETRY mono-1 study showing an overall response rate (ORR) of 51.6% in a cohort evaluating second-line patients only and 44% in all previously-treated patients with advanced non-small cell lung cancer (NSCLC) harboring alterations leading to MET exon 14 skipping.

In June 2022, we and Novartis announced the European Commission approval of capmatinib as TABRECTA as monotherapy treatment of adults with advanced non-small cell lung cancer (NSCLC) harboring alterations leading to mesenchymal-epithelial-transition factor gene (MET) exon 14 (METex14) skipping who require systemic therapy following prior treatment with immunotherapy and/or platinum-based chemotherapy.

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.

Ruxolitinib

Graft-versus-host disease. In March 2022, we and Novartis announced a positive opinion from the CHMP for ruxolitinib in acute and chronic GVHD, based on data from the Phase 3 REACH2 and REACH3 trials. GVHD is a life-threatening complication of stem cell transplants, with no established standard of care in Europe for patients who do not adequately respond to first-line steroid treatment. In May 2022, we and Novartis announced the European Commission approval of ruxolitinib as JAKAVI for the treatment of acute or chronic GVHD in patients aged 12 years and older who have inadequate response to corticosteroids or other systemic therapies. In August 2023, Novartis announced that JAKAVI had been approved in Japan for use in graft-versus-host disease after hematopoietic stem cell transplant.

Partnered Programs	Indication and Phase
Ruxolitinib (JAKAVI)[1] (JAK1/JAK2)	Acute and chronic GVHD: Approved in Europe and Japan
Baricitinib (OLUMIANT)[2] (JAK1/JAK2)	AD: Approved in Europe and Japan Severe alopecia areata (AA): Approved in the U.S., Europe and Japan
Capmatinib (TABRECTA)[3] (MET)	NSCLC (with MET exon 14 skipping mutations): Approved in the U.S., Europe and Japan

[1] ruxolitinib licensed to Novartis outside of the United States for use in hematology and oncology excluding topical administration.
[2] baricitinib licensed to Lilly.
[3] capmatinib licensed to Novartis.

Pending Acquisition

In April 2024, we entered into an agreement and plan of merger with Escient Pharmaceuticals, Inc. ("Escient"), pursuant to which we will acquire Escient. Escient is a clinical-stage drug development company advancing novel small molecule therapeutics for systemic immune and neuro-immune disorders. Escient's clinical development portfolio includes EP262, a first-in-class, potent, highly selective, once-daily small molecule antagonist of Mas-related G protein-coupled receptor X2 (MRGPRX2) and EP547, a first-in-class oral MRGPRX4 antagonist. By blocking MRGPRX2 and degranulation of mast cells, EP262 has the potential to effectively treat multiple mast cell-mediated diseases including atopic dermatitis (AD), chronic inducible urticaria (CIndU) and chronic spontaneous urticaria (CSU). EP262 is in Phase 1b/2 clinical trials for the treatment of AD, CIndU and CSU. EP547 is in a Phase 1b/2 trial for the treatment of cholestatic pruritis and uremic pruritis.

Upon the terms and subject to the conditions set forth in the merger agreement, we will acquire Escient for consideration of $750.0 million plus Escient's net cash remaining at the close of the transaction, subject to adjustments set forth in the merger agreement. The acquisition is subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, among other customary conditions, and will become effective promptly following the satisfaction or waiver of these conditions.

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 at Note 8 of Notes to the 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.

China Medical Systems Holdings Limited

In March 2024, we entered into a collaboration and license agreement with China Medical System Holdings Limited (CMSHL), through a wholly-owned dermatology medical aesthetic subsidiary CMS Skinhealth, for the development and commercialization of povorcitinib, a selective oral JAK1 inhibitor, to research, develop, register and commercialize in mainland China, Hong Kong, Macau, Taiwan and certain countries in Southeast Asia.

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.

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.

Merus

In December 2016, we entered into a Collaboration and License Agreement with 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 ten independent programs.

Syndax

In September 2021, we entered into a Collaboration and License Agreement with Syndax covering the worldwide development and commercialization of SNDX-6352 (axatilimab), Syndax's anti-CSF-1R monoclonal antibody. Axatilimab was granted Orphan Drug Designation by the FDA in March 2021 for the treatment of chronic GVHD and again in April 2021 for the treatment of idiopathic pulmonary fibrosis. Under the terms of this agreement, we received exclusive commercialization rights to axatilimab outside of the United States, and co-commercialization rights in the United States.

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.

For a discussion of our critical accounting policies, refer to "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2023. There have been no significant changes to our critical accounting policies or estimates during the three months ended March 31, 2024.

Recent Accounting Pronouncements and Regulatory Updates

In November 2023, the Financial Accounting Standards Board (the "FASB") issued ASU No. 2023-07, "*Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*." This amended guidance applies to all public entities and aims to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses, to enable investors to develop more decision-useful financial analyses. This guidance is effective for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. We are currently evaluating the impact that ASU No. 2023-07 will have on our annual consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09, "*Income Taxes (Topic 740): Improvements to Income Tax Disclosures*." This amended guidance applies to all entities and broadly aims to enhance the transparency and decision usefulness of income tax disclosures. For public business entities, the amendments in this Update are effective for fiscal years beginning after December 15, 2024. Early adoption is permitted for any annual periods for which financial statements have not been issued or made available for issuance. We are currently evaluating the impact that ASU No. 2023-09 will have on our consolidated financial statements.

In March 2024, the Securities and Exchange Commission (SEC) issued Release Nos. 33-11275; 34-99678 "*The Enhancement and Standardization of Climate-Related Disclosures for Investors*" to require public companies to provide certain climate-related information in their registration statements and annual reports. The compliance dates for the rules amended by this release begin in fiscal year 2025 for large accelerated filers. On April 4, 2024, the SEC issued an order staying the newly adopted rules. We are currently evaluating the impact of this release on our financial disclosures.

Results of Operations

We recorded net income of $169.5 million and basic net income per share of $0.76 and diluted net income per share of $0.75 for the three months ended March 31, 2024, as compared to net income of $21.7 million and basic and diluted net income per share of $0.10 in the corresponding period in 2023.

Revenues

	Three Months Ended March 31,	
	2024	2023
	(in millions)	
JAKAFI revenues, net	$ 571.8	$ 580.0
OPZELURA revenues, net	85.7	56.6
ICLUSIG revenues, net	30.3	27.7
PEMAZYRE revenues, net	17.7	22.5
MINJUVI/MONJUVI revenues, net	23.9	6.5
ZYNYZ revenues, net	0.5	—
Total product revenues, net	729.9	693.3
JAKAVI product royalty revenues	89.6	76.7
OLUMIANT product royalty revenues	30.6	34.1
TABRECTA product royalty revenues	5.2	4.2
PEMAZYRE product royalty revenues	0.6	0.4
Total product royalty revenues	126.0	115.4
Milestone and contract revenues	25.0	—
Total revenues	$ 880.9	$ 808.7

The decrease in JAKAFI net product revenues for the three months ended March 31, 2024 as compared to the corresponding period in 2023 was comprised of a volume decrease of $17.8 million and a price increase of $9.6 million. The JAKAFI net product revenues decrease for the three months ended March 31, 2024 as compared to the corresponding period in 2023 was primarily driven by a decrease in channel inventory. The increase in OPZELURA net product revenues for the three months ended March 31, 2024 as compared to the corresponding period in 2023 was comprised of a volume increase of $26.8 million and a price increase of $2.3 million. The increase in OPZELURA net product revenues for the three months ended March 31, 2024 was driven by growth in new patient starts and refills. The increase in MINJUVI/MONJUVI net product revenues for the three months ended March 31, 2024 was driven by the asset acquisition completed in February 2024, under which we gained exclusive global rights to tafasitamab marketed in the United States as MONJUVI (tafasitamab-cxix). Refer to Note 6 of Notes to the Condensed Consolidated Financial Statements for further information related to the asset acquisition.

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, 2024	Discounts and Distribution Fees	Government Rebates and Chargebacks	Co-Pay Assistance and Other Discounts	Product Returns	Total
Balance at January 1, 2024	$ 20,479	$ 264,422	$ 13,016	$ 11,021	$ 308,938
Allowances for current period sales	32,314	289,203	47,166	3,074	371,757
Allowances for prior period sales	860	(1,637)	(68)	338	(507)
Credits/payments for current period sales	(19,423)	(156,230)	(42,569)	—	(218,222)
Credits/payments for prior period sales	(15,864)	(72,723)	(4,237)	(2,689)	(95,513)
Balance at March 31, 2024	$ 18,366	$ 323,035	$ 13,308	$ 11,744	$ 366,453

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.

We brought a lawsuit against the U.S. Centers for Medicare and Medicaid Services ("CMS") alleging that a recent regulation issued by CMS on the definition of "line extension" for purposes of the Medicaid rebate program is too broad and has the unintended consequence of treating OPZELURA as a "line extension" of JAKAFI under this program. We believe that such a reading would violate CMS's statutory authority and be arbitrary and capricious given that OPZELURA, among other differentiators, is indicated to treat entirely different medical conditions and entirely different patient populations than JAKAFI. As of March 31, 2024, we have accrued approximately $73.7 million within accrued and other current liabilities on the condensed consolidated balance sheet, relating to the incremental rebates that would be owed were OPZELURA considered a line extension of JAKAFI. The impact on OPZELURA gross to net deductions for the quarter ending March 31, 2024 is approximately 7.2%. If OPZELURA is not treated as a line extension of JAKAFI, this would result in a reversal of our accrual and a lower future gross to net deduction for OPZELURA.

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. Our company-sponsored patient savings program in which we provide financial assistance to enable commercially-insured patients to afford their insurance premium and co-pays may fluctuate as the commercial insurance landscape evolves and may impact net revenues, particularly for drugs like OPZELURA. 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. Product royalty revenues on commercial sales of PEMAZYRE by Innovent are based on net sales of licensed products in licensed territories as provided by Innovent.

Our milestone and contract revenues for the three months ended March 31, 2024, was derived from a $25.0 million upfront payment received upon our transfer of functional intellectual property to CMSHL.

Cost of Product Revenues

	Three Months Ended March 31,	
	2024	2023
	(in millions)	
Product costs	$ 27.4	$ 23.5
Salary and benefits related	2.2	2.7
Stock compensation	0.6	0.8
Royalty expense	25.1	24.4
Amortization of definite-lived intangible assets	5.7	5.4
Total cost of product revenues	$ 61.0	$ 56.8

Cost of product revenues includes all product related costs, reserves for obsolescence, employee personnel costs, including stock compensation, for those employees dedicated to the production of our commercial products, royalties under our collaborative agreements and amortization of our licensed intellectual property rights for ICLUSIG and the amortization of capitalized milestone payments. The increase in cost of product revenues for the three months ended March 31, 2024 as compared to the same periods in 2023 was primarily due to growth in net product revenues.

Operating Expenses

Research and development expenses

	Three Months Ended March 31,	
	2024	2023
	(in millions)	
Salary and benefits related	$ 122.7	$ 100.4
Stock compensation	36.8	31.0
Clinical research and outside services	226.6	229.9
Occupancy and all other costs	43.2	45.3
Total research and development expenses	$ 429.3	$ 406.6

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, 2024 as compared to the corresponding period in 2023 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, 2024 as compared to the corresponding period in 2023 was primarily due to differences in the timing of certain expenses. Research and development expenses include upfront and milestone expenses related to our collaborative agreements of $1.0 million and $2.7 million, respectively, for the three months ended March 31, 2024 and 2023. Research and development expenses for the three months ended March 31, 2024 and 2023 were net of $17.1 million and $0.6 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 preclinical 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

	Three Months Ended March 31,	
	2024	2023
	(in millions)	
Salary and benefits related	$ 83.2	$ 72.9
Stock compensation	22.4	21.6
Other contract services and outside costs	194.7	221.1
Total selling, general and administrative expenses	$ 300.3	$ 315.6

The increase in salary and benefits related expense for the three months ended March 31, 2024 as compared to the corresponding period in 2023 was due primarily to increased headcount. This increased headcount was due primarily to the establishment of our dermatology commercial organization. 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 other contract services and outside costs for the three months ended March 31, 2024, as compared to the corresponding period in 2023, was primarily due to the timing of consumer marketing activities and of certain other expenses.

(Gain) loss on 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, 2024 and 2023 was a profit of $0.5 million and a loss of $6.2 million, respectively, which is recorded in (gain) loss on change in fair value of acquisition-related contingent consideration on the condensed consolidated statements of operations. The change in fair value of the contingent consideration during the three months ended March 31, 2024 was due primarily to fluctuations in foreign currency exchange rates impacting future revenue projections of ICLUSIG and the passage of time.

(Profit) and loss sharing under collaboration agreements

Under the former collaboration and license agreement with MorphoSys, which was executed in March 2020 and continued through February 5, 2024 as described further in Note 6 of Notes to the Condensed Consolidated Financial Statements, we and MorphoSys were both responsible for the commercialization efforts of tafasitamab in the United States and shared equally the profits and losses from the co-commercialization efforts. For the period from January 1, 2024 through February 5, 2024, our 50% share of the profits for tafasitamab was $1.0 million, as recorded in (profit) and loss sharing under collaboration agreements on the condensed consolidated statement of operations. For the three months ended March 31, 2023, our 50% share of the profits for tafasitamab was $1.4 million, as recorded in (profit) and loss sharing under collaboration agreements on the condensed consolidated statement of operations.

Interest income and other, net

Interest income and other, net. Interest income and other, net for the three months ended March 31, 2024 and 2023 was $44.7 million and $32.9 million, respectively. The increase in Interest income and other, net for the three months ended March 31, 2024 primarily relates to an increase in interest earned on our cash equivalents and marketable securities generally due to higher interest rates.

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 (losses):

	Three Months Ended March 31,	
	2024	2023
	(in millions)	
Agenus	$ (3.0)	$ (10.6)
Merus	70.2	10.4
MorphoSys	29.9	1.4
Syndax	3.1	(6.2)
Other	(0.3)	(0.3)
Total unrealized gain (loss) on long term investments	$ 99.9	$ (5.3)

Provision for income taxes. The provision for income taxes for the three months ended March 31, 2024 and 2023 was $66.6 million and $30.2 million, respectively.

Our effective tax rate for each of the three months ended March 31, 2024 and 2023 were higher than the U.S. statutory rate primarily due to foreign losses with no associated tax benefit (i.e., full valuation allowance) and an increase in our valuation allowance against certain U.S. federal and state deferred tax assets. This was partially offset by tax rate benefits associated with research and development and orphan drug tax credit generations and the foreign derived intangible income deduction.

Liquidity and Capital Resources

At March 31, 2024, we had available cash, cash equivalents and marketable securities of $3.9 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, 2024 was $218.8 million and net cash used in operating activities for the three months ended March 31, 2023 was $105.6 million. The increase in cash provided by operating activities was due primarily to changes in working capital.

Our investing activities, other than purchases, sales and maturities of marketable securities, have consisted predominantly of capital expenditures and purchases of long term investments. Net cash used in investing activities was $73.1 million for the three months ended March 31, 2024, which represented purchases of marketable securities of $165.8 million, and capital expenditures of $9.5 million, offset in part by the sale and maturities of marketable securities of $102.2 million. Net cash used in investing activities was $28.6 million for the three months ended March 31, 2023, which represented purchases of marketable securities of $54.9 million, payments for intangible assets of $15.0 million, and capital expenditures of $11.9 million, offset in part by the sales and maturities of marketable securities of $53.2 million. In the future, net cash used by investing activities may fluctuate significantly from period to period due to the timing of strategic equity investments, acquisitions, and capital expenditures and maturities/sales and purchases of marketable securities.

Net cash used in financing activities was $12.4 million for the three months ended March 31, 2024, and net cash provided by financing activities was $4.0 million for the three months ended March 31, 2023, respectively, primarily representing cash paid to ARIAD/Takeda for contingent consideration, offset in part by proceeds from the issuance of common stock under our stock plans.

In August 2021, we entered into a $500.0 million, three-year senior unsecured revolving credit facility, which was subsequently amended in May 2023. We may increase the maximum revolving commitments or add one or more incremental term loan facilities, subject to obtaining commitments from any participating lenders and certain other conditions, in an amount not to exceed $250.0 million plus a contingent additional amount that is dependent on our pro forma consolidated leverage ratio. As of March 31, 2024, we had no outstanding borrowings and were in compliance with all covenants under this facility.

Due to the full utilization of our research and development and orphan drug tax credit carryforwards generated in prior years, our U.S. tax liabilities continue to reflect the adverse impacts of the mandatory capitalization and amortization of research and development expenses as required under the Tax Cuts and Jobs Act of 2017, which eliminated the immediate expensing of such expenses.

We believe that our cash flow from operations, together with our cash, cash equivalents and marketable securities and funds available under our revolving credit facility, 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 8 of Notes to the 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 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.

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, 2024, marketable securities were $504.5 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, 2024, 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, 2024, 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. While we also sell our and our licensors' other approved products ICLUSIG, PEMAZYRE, MONJUVI/MINJUVI, OPZELURA and ZYNYZ and our exclusive licensees sell OLUMIANT and TABRECTA, 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 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, as well as whether patients will continue to use JAKAFI;
- 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 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 or in combination with other therapeutic modalities; and
- the effects of a public health pandemic or epidemic such as the COVID-19 pandemic or of adverse geopolitical events, regulatory, legislative or administrative developments.

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, revenues from our other products and our receipt of royalties under our collaboration agreements, including our agreements with Novartis for sales of JAKAVI 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, coverage and reimbursement for our products from government health administration authorities, private health insurers and other organizations, our pricing may be affected and our product sales, results of operations and financial condition could be harmed.

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 these products and the extent to which adequate coverage and 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. 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, MONJUVI/MINJUVI, OPZELURA and ZYNYZ 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.

Governments and other third-party payors continue to pursue initiatives to manage drug costs. Pricing and reimbursement for our products may be adversely affected by a number of factors, including;

- actions of federal, state and foreign governments and other third-party payors to implement or modify laws, regulations or policies addressing payment and reimbursement for drugs;
- pressure by employers on private health insurance plans to reduce costs or moderate cost increases, as well as continued public scrutiny of the price of drugs and other healthcare costs;
- consolidation of third-party payors and continued initiatives of government and other third-party payors to reduce costs by seeking price discounts or rebates, reducing reimbursement rates or imposing restrictions on access to or coverage of particular drugs based on perceived value;
- pressure on healthcare budgets resulting from macroeconomic factors such as inflation, rising interest rates and the economic effects of geopolitical conflicts; and
- the increasing number of hospitals and other covered entities that are eligible to participate in the U.S. 340B drug pricing program, which requires drug manufacturers such as our company to sell drugs to those entities at discounted prices in order for those drugs to be covered by Medicaid.

In many markets outside of the United States, including countries of the EU, drug pricing and reimbursement are subject to government control, and government authorities are making greater efforts to limit or regulate the price of drug products. 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 a drug 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. Some countries set prices by reference to prices in other countries, and countries may refuse to reimburse or may restrict the reimbursed population for a drug product based on their national health technology assessments and cost effectiveness thresholds. In addition, governmental authorities in many countries may reduce prices for approved drug products from previously established prices.

Third-party payors are increasingly challenging the prices charged for medical products and services, and payors and employers are adopting benefit plan changes that shift a greater portion of prescription drug costs to patients. Third party pharmacy benefit managers, or PBMs, other similar organizations and payors can limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication, and to exclude drugs from their formularies in favor of competitor drugs or alternative treatments, or place drugs on formulary tiers with higher patient co-pay obligations, and/or to mandate stricter utilization criteria. Formulary exclusion effectively encourages patients and providers to seek alternative treatments, make a complex and time-intensive request for medical exemptions, or pay 100% of the cost of a drug. In addition, in many instances, certain PBMs, other similar organizations and third party payors may exert negotiating leverage by requiring incremental rebates, discounts or other concessions from manufacturers in order to maintain formulary positions, which could continue to result in higher gross to net deductions for affected products. There has been significant consolidation in the health insurance industry, resulting in large insurers and PBMs exerting greater pressure and leverage in pricing and usage negotiations with drug manufacturers. In this regard, while we have entered into agreements with a number of PBMs, we are in the process of negotiating agreements with additional PBMs and payor accounts to provide rebates to those entities related to formulary coverage for OPZELURA, and we cannot guarantee that we will be able to agree to or maintain acceptable coverage terms with these PBMs and other third party payors. Payors could decide to exclude OPZELURA from formulary coverage lists, impose step edits that require patients to try alternative, including generic, treatments before authorizing payment for OPZELURA, limit the types of diagnoses for which coverage will be provided or impose a moratorium on coverage for products while the payor makes a coverage decision. An inability to maintain adequate formulary positions could increase patient cost-sharing for OPZELURA and cause some patients to determine not to use OPZELURA. Any delays or unforeseen difficulties in reimbursement approvals could limit patient access, depress therapy adherence rates, and adversely impact our ability to successfully commercialize OPZELURA. If we are unsuccessful in obtaining and maintaining broad coverage and reimbursement for OPZELURA, our anticipated revenue from and growth prospects for OPZELURA could be negatively affected.

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, we have provided our products without charge to eligible patients who have no insurance coverage or are underinsured. Substantial support in this manner could harm our profitability in the future. Further, non-profit 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.

Risks related to proposed changes in government regulations and health care reform measures 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. " 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, then our pricing or reimbursement for our products may be affected and our product sales, results of operations or financial condition could be harmed. Our collaborators Novartis and Eli Lilly are affected by similar considerations for the drugs that they market and for which we may receive royalties.

We depend upon a limited number of specialty pharmacies and wholesalers for a significant portion of any revenues from JAKAFI and most of our other drug products, 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 and our other drug products other than OPZELURA primarily to specialty pharmacies and wholesalers. Specialty pharmacies dispense JAKAFI and our other drug products to patients in fulfillment of prescriptions and wholesalers sell JAKAFI and our other drug products to hospitals and physician offices. We do not promote JAKAFI or our other drug products to specialty pharmacies or wholesalers, and they do not set or determine demand for JAKAFI or our other drug products. Our ability to successfully commercialize JAKAFI and our other drug products will depend, in part, on the extent to which we are able to provide adequate distribution of JAKAFI and our other drug products 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 and our other drug products, 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 or our other drug products 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.

We are continuing to establish and maintain sales, marketing and distribution capabilities for OPZELURA. Successful commercialization of our drug candidates for dermatology indications requires us to establish new physician and payor relationships, PBM and pharmacy network relationships, reimbursement strategies and governmental interactions, separate from our existing capabilities for oncology indications. 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. In addition, in September 2021, the FDA updated labeling for JAKAFI and other JAK inhibitor drugs to include warnings of increased risk of major adverse cardiovascular events, thrombosis, and secondary malignancies related to another JAK-inhibitor treating rheumatoid arthritis, a condition for which JAKAFI is not indicated. As part of the FDA labeling update for oral JAK inhibitors in treating inflammatory conditions, class “boxed” warnings were also included in the OPZELURA label. We cannot predict the effects on sales of JAKAFI with the updated warnings or OPZELURA as a result of the “boxed” warnings, but it is possible that future sales of JAKAFI and OPZELURA can be negatively affected, which could have a material and adverse effect on our business, results of operations and prospects.

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, MONJUVI/MINJUVI, OPZELURA and ZYNYZ, the manufacturing, marketing and sale of JAKAFI, PEMAZYRE and OPZELURA and the marketing and sale of ICLUSIG, MONJUVI/MINJUVI and ZYNYZ 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, MONJUVI/MINJUVI, OPZELURA and ZYNYZ.

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 license collaborators in the jurisdictions in which they have 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. Although we believe that our promotional materials for physicians do not constitute improper promotion, the FDA or other agencies may disagree. If the FDA or another agency determines that our promotional materials or other activities constitute improper promotion, it could request that we modify our promotional materials or other activities or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they believe that the alleged improper promotion led to the submission and payment of claims for an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. Even if it is later determined we are not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our position and have to divert significant management resources from other matters.

The European Union and member countries, as well as governmental authorities in other countries, impose similar strict restrictions on the promotion and marketing of drug products. The off-label promotion of medicinal products is prohibited in the EU and in other territories, 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. These Physician Payment 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, and any settlement of such action initiated against us, regardless of the merits, could result in the payment of significant amounts, which could harm our financial condition 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.

Our products compete, and our product candidates may in the future compete, with currently existing therapies, including generic drugs, product candidates currently under development by us and others, or future product candidates, including new chemical entities that may be safer or more effective or more convenient than our products. Any products that we develop may be commercialized in competitive markets, and our competitors, which include large global pharmaceutical and biopharmaceutical companies and smaller research-based biotechnology companies, may succeed in developing products that render our products obsolete or noncompetitive. Many of our competitors, particularly large pharmaceutical and biopharmaceutical companies, have substantially greater financial, operational and human resources than we do. Smaller or earlier stage companies may also prove to be significant competitors, particularly through focused development programs and collaborative arrangements with large, established companies. In addition, many of our competitors deploy more personnel to market and sell their products than we do, and we compete with other companies to recruit, hire, train and retain pharmaceutical sales and marketing personnel. If our sales force and sales support organization are not appropriately resourced and sized to adequately promote our products, the commercial potential of our current and any future products may be diminished. In any event, the commercial potential of our current products and any future products may be reduced or eliminated if our competitors develop or acquire and commercialize generic or branded products that are safer or more effective, are more convenient or are less expensive than our products. See "Item 1. Business —Competition" in our Annual Report on Form 10-K for the year ended December 31, 2023 for additional information regarding the effects of competition. If we are unable to compete successfully, our commercial opportunities will be reduced and our business, results of operations and financial conditions may be materially harmed.

Present and potential competitors for JAKAFI include major pharmaceutical and biotechnology companies, as well as specialty pharmaceutical firms. 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 competitive drug product from another company or 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/MINJUVI 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. Competitors and potential competitors for PEMAZYRE and ZYNYZ include major pharmaceutical and biotechnology companies, as well as specialty pharmaceutical firms.

Competitors for OPZELURA include existing over-the-counter topical treatments, prescription topical treatments, including generic versions, such as tacrolimus, pimecrolimus, topical steroids, and EUCRISA (crisaborole) from Pfizer Inc., as well as oral and injectable therapies such as prednisone and other oral steroids, injectable DUPIXENT (dupilimab) from Sanofi and Regeneron Pharmaceuticals, Inc., and oral CIBINQO (abrocitinib) from Pfizer Inc. and RINVOQ (upadacitinib) from AbbVie Inc. In September 2023, we received a notice letter regarding an ANDA that requested approval to market a generic version of OPZELURA and purported to challenge patents covering ruxolitinib phosphate cream and its uses that expire in 2031 and 2040. The notice letter does not challenge ruxolitinib nor the ruxolitinib phosphate composition of matter patents, providing patent coverage (with pediatric extension) until December 2028. To date, to our knowledge, the FDA has taken no action with respect to this ANDA.

Factors similar to those listed above also apply to our collaborator Novartis for JAKAVI and TABRECTA in jurisdictions in which it has commercialization rights and to our collaborator Lilly for OLUMIANT all jurisdictions. With respect to OLUMIANT, in August 2022 we and Lilly received notice letters with respect to ANDAs that requested approval to market generic versions of OLUMIANT prior to the expiration of the three U.S. Patents that expire in 2030.

OTHER RISKS RELATING TO OUR BUSINESS

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 additional 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 or acquire 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.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Despite investing significant resources, 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. 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. Even if a drug candidate received marketing approval, it may not be able to achieve market acceptance or compete successfully with competitors' products and we may have spent significant amounts of time and money on it without achieving potential returns initially anticipated, which could adversely affect our operating results and financial condition as well as our business plans. 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.

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 and could result in our termination of a drug development program. From time to time we and our collaborators have experienced events that have resulted in delays, setbacks and terminations of drug development programs. 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. In addition, in January 2022, we announced that we withdrew the NDA seeking approval of parsaclisib for the treatment of patients with relapsed or refractory follicular lymphoma, marginal zone lymphoma and mantle cell lymphoma. The decision to withdraw the NDA followed discussions with FDA regarding confirmatory clinical trials that we determined cannot be completed within the time period to support the investment. Also, in March 2023, we received a complete response letter for ruxolitinib extended-release (XR) tablets, which identified additional requirements for 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 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 3 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 Fast Track or 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), these designations 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, do not assure ultimate approval of our product candidate by FDA. For example, in June 2021 we were informed by the FDA that the FDA had extended by three months the review period for the NDA for ruxolitinib cream for atopic dermatitis. Also, in July 2021, we announced that the FDA issued a complete response letter for the BLA of retifanlimab for the treatment of squamous cell carcinoma of the anal canal, in which the FDA stated it cannot approve the BLA and that additional data are needed. In addition, while the FDA had 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, as discussed above we withdrew our NDA seeking approval for treatment of patients with those lymphomas. The FDA has recently increased its attention on mandated confirmatory trials for oncology drug candidates with accelerated approvals, and the logistics, cost and timing required for confirmatory trials may conflict with the investment thesis for drug candidates, resulting in withdrawal of approval applications.

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.

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. For example, the American Rescue Plan Act of 2021 includes a provision that became effective in January 2024 that eliminates the statutory cap on rebates that drug manufacturers pay to Medicaid. It is expected that this provision, as implemented by the Centers for Medicare and Medicaid Services, or CMS, will have the effect of increasing Medicaid rebate liability, particularly in the case of medicines that have experienced price increases at a rate in excess of inflation. Further, in August 2022, the Inflation Reduction Act of 2022 was enacted, which includes provisions allowing the federal government to negotiate prices for certain high-expenditure single source Medicare drugs, to impose penalties and to implement a potential excise tax for manufacturers that fail to comply with the negotiation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law, and to impose rebate liability on manufacturers that take price increases that exceed inflation. The new law also reduced the out-of-pocket prescription drug costs for Medicare Part D beneficiaries, and to help pay for this change in benefit design, the law imposes a new discount program starting in 2025, in which manufacturers pay specified discounts on Medicare Part D utilization of their drugs as a condition of selling such drugs in the Medicare Part D program. The Inflation Reduction Act includes certain exemptions for small biotech drug manufacturers, including Incyte. These exemptions apply on a drug-specific basis, and qualifying drugs will be exempt from possible negotiation through 2028 and subject to reduced discounts that will be phased-in over a number of years under the new Part D benefit. 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 net sales resulting from the Medicare programs and limit our ability to increase the prices that we charge for our drugs. 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. These reforms may affect future investments in our drug development, should the reforms affect our risk-benefit analysis of investing in a drug candidate. Some of these changes and proposed changes could result in reduced reimbursement rates or the elimination of 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 significant legislative activity and proposals from the prior and current Administrations relating to prescription drug prices and reimbursement, any of which, if enacted, could impose downward pressure on 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 ongoing federal congressional inquiries and proposed and enacted federal and state legislation, executive orders and administrative agency rules designed to, among other things, bring more transparency to drug pricing, reduce drug prices, reform government program reimbursement methodologies for prescription drugs, expand access to government-mandated discounted pricing (known as 340B pricing) through broader contract pharmacy arrangements, allow importation of drugs into the United States from other countries, and limit allowable prices for drugs through reference to an average price from foreign markets 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.

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.

In addition, 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 address the cost of government insurance programs, may all result in lower prices for or rejection of our products. Adoption of our products by the medical community and patients 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 certain Asian rights to some of our drug products and clinical stage compounds to other collaborators. 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 have led and could in the future 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, and our other existing collaborations, we 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, MacroGenics, Merus and Syndax Pharmaceuticals, 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, in January 2022, we decided to opt-out of the continued development with Merus of MCLA-145, which was the most advanced compound under our collaboration with Merus, and in 2022 and 2023, we decided to terminate our collaborations with Calithera Biosciences and Syros Pharmaceuticals. If we make or incur contractual obligations to make significant upfront payments in connection with licenses for late-stage drug candidates, 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.

Public health epidemics and pandemics, such as the COVID-19 pandemic, have adversely affected and could in the future adversely affect our business, results of operations, and financial condition.

Our global operations expose us to risks associated with public health epidemics and pandemics, such as the COVID-19 pandemic. The extent to which a public health pandemic and the measures taken to limit the disease's spread can 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 developments, that are highly uncertain, including the duration of the outbreak and any related government actions.

As a result of the COVID-19 pandemic, we experienced, and as a result of future pandemics we may in the future experience disruptions that could severely impact our business, results of operations and financial condition. These disruptions can include the following:

- the imposition of shelter-in-place orders and work-from-home policies that could affect our research and development activities and access to our laboratory space;
- disruptions in our sales and marketing activities;
- negative impacts on the demand for our products as a result of a decrease in patient visits to healthcare professionals and the prioritization of hospital resources for a future pandemic;
- negative impacts on our clinical trials as a result of delays in site initiation, patient screening, patient enrollment, and monitoring and data collection;
- slower response times by the FDA and comparable foreign regulatory agencies for the review and potential approvals of our drug candidate applications; and
- negative impacts on the global supply chain which may affect our ability to obtain sufficient materials for our drug products and product candidates.

Our collaborators could be affected by similar factors as those that have or could affect our business. The ultimate impact of a public health epidemic or pandemic is highly uncertain, but the 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 could have a material adverse impact on our business, results of operations, and financial condition.

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 also may 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, will not cover 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.

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.

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 most of our clinical or commercial products, including JAKAFI, PEMAZYRE, ICLUSIG and OPZELURA, and our drug candidates. Our current manufacturing strategy for these products and drug candidates is to contract with third parties to manufacture the related raw materials, active pharmaceutical ingredient (API), and finished drug product. We do have a biologics production facility located in Yverdon, Switzerland, currently registered for MINJUVI drug substance manufacturing. For ZYNYZ, together with our collaborator MacroGenics, we are responsible for the sourcing and manufacturing of ZYNYZ. While working to increase our own manufacturing capacity through our Swiss bioplant site, we expect to continue to rely on third parties for the manufacture of clinical and commercial supplies of raw materials, API and finished drug product for any drugs that we successfully develop. We also contract with third parties to package and label our products. The FDA requires that the raw materials, API and finished product for drug products such as JAKAFI, PEMAZYRE and OPZELURA and our drug candidates be manufactured according to its current Good Manufacturing Practices regulations, and regulatory authorities in other countries have similar requirements. Failure to comply with 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, initiating product recalls or taking 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 to commercial quantities from clinical quantities. These problems include difficulties with production costs and yields, quality control and assurance and shortages of qualified personnel. To the extent problems such as these are experienced, we could encounter difficulties in supplying sufficient product to meet demand or incur additional costs to remedy the problems or to recall defective products. Any such recall could also harm our sales efforts and our reputation. Our suppliers, which operate in multiple countries around the world, could also experience disruptions in their operations resulting from various factors, including equipment malfunction or failure, regulatory requirements or actions, raw material shortages, labor disputes or shortages, including from the effects of public health pandemics, cyberattacks, natural and other disasters, and wars or other geopolitical events. In addition, one or more of our third party contract manufacturers could be acquired and its contract manufacturing operations could be ceased or curtailed. While our strategy is to maintain at a minimum 24 months stock of ruxolitinib phosphate API, inclusive of finished product, ruxolitinib phosphate might be used by us either to make JAKAFI or OPZELURA 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. Any increases in the cost of our drug candidates or drug products, whether through conditions affecting the cost and availability of raw materials, such as inflation, decreases in available manufacturing capacity, or otherwise, would adversely affect our results of operations.

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 intend to continue to use third-party contract manufacturing organizations for the manufacture of antibodies in conjunction with our manufacturing facility in Switzerland. 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. We may encounter delays and difficulties in scaling up production at our new facility or in obtaining necessary regulatory approvals and registrations to do so.

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, or 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 and in November 2019, the qui tam complaint underlying the DOJ inquiry was unsealed, at which time we learned that a former employee whom we had terminated had made certain allegations relating to the programs described above. While we deny that any improper claims were submitted to government payers, we agreed in May 2021 to settle the matter with the DOJ Civil Division for $12.6 million, plus certain statutory fees. 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 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, February 2024, we entered into a purchase agreement with MorphoSys under which we acquired rights to tafasitamab (MONJUVI/MINJUVI) that resulted in our holding exclusive global development and commercialization rights to tafasitamab. 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. These strategic transactions are complex, time consuming and expensive and entail numerous risks, including:

- unanticipated costs, delays or other operational or financial problems related to integrating the products, product candidates, technologies, business operations, systems, controls and personnel of an acquired company or asset with our company;
- failure to successfully develop and commercialize acquired products, product candidates or technologies or to achieve other strategic objectives;
- delays or inability to progress preclinical programs into clinical development or unfavorable data from clinical trials evaluating acquired or licensed products or product candidates;
- disruption of our ongoing business and diversion of our management's and employees' attention from ongoing development of our existing business and other opportunities and challenges;
- inability to achieve planned synergies or cost savings;
- the potential loss of key employees of an acquired company;
- entry into markets in which we have no or limited direct prior experience or where competitors in such markets have stronger market positions;
- uncertainties in our ability to maintain key business relationships of business we acquire;
- exposure to unknown or contingent liabilities or the incurrence of unanticipated expenses, including those with respect to intellectual property, pre-clinical or clinical data, safety, compliance or internal controls, and including as a result of the failure of the due diligence processes to identify significant problems, liabilities or challenges of an acquired company or asset;
- the risk that acquired businesses may have differing or inadequate cybersecurity and data protection controls; and
- exposure to litigation or other claims in connection with, or inheritance of claims or litigation risk as a result of, the strategic transaction, including claims from terminated employees, customers, former equity holders or other third parties.

Acquisition transactions may be subject to regulatory approvals or other requirements that are not within our control. We may be unable to obtain these regulatory or other approvals, and closing conditions required in connection with our acquisition transactions may be unable to be satisfied or waived, which could result in our inability to complete the planned acquisition transactions. In addition, antitrust scrutiny by regulatory agencies and changes to regulatory approval process in the U.S. and foreign jurisdictions may cause approvals to take longer than anticipated to obtain, not be obtained at all, or contain burdensome conditions such as required divestitures, which may jeopardize, delay or reduce the anticipated benefits of acquisitions to us and could impede the execution of our business strategy.

As a result of these or other problems and risks, businesses, products or technologies we acquire or invest in or obtain licenses to may not produce the revenues, earnings, business synergies or other benefits that we anticipated, within the expected timeframe or at all. As a result, we may incur higher costs and realize lower revenues than we had anticipated. We cannot assure you that any acquisitions or investments we may make in the future will be completed or that, if completed, the acquired business, licenses, investments, products, or technologies will generate sufficient revenue to offset the costs or other negative effects on our business. Other pharmaceutical companies, many of which may have substantially greater resources, compete with us for these opportunities., and we may be unable to effectively advance our business strategy through strategic transactions, which could impair our ability to grow or obtain access to products or technology that could be important to the development of our 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 each of the fiscal quarters in 2022 and in the third quarter of 2023 we recorded unrealized losses related to our investments in our collaboration partners, and we may experience additional losses related to our investments in future period. In addition, if we choose to issue equity securities 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, have opened an office in China and are working with partners in additional markets. 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 inflation, political or economic instability, terrorism and political unrest and geopolitical events;

- public health risks, including epidemics and pandemics, and related effects on new patient starts, clinical trial activity, regulatory agency response times, 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 and unfavorable changes in foreign currency exchange rates may adversely affect our revenues and net income. 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. We have 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.

Business disruptions could seriously harm our operations, future revenues and financial condition and increase our costs and expenses.

Our operations, and those of our CROs, suppliers, and other contractors and consultants, could be subject to geopolitical events, natural disasters, power and other infrastructure failures or shortages, public health pandemics or epidemics, and other natural or man-made disasters or business interruptions. In addition, geopolitical and other events, such as the Russian invasion of Ukraine or the conflicts in the Middle East, could lead to sanctions, embargoes, supply shortages, regional instability, geopolitical shifts, cyberattacks, other retaliatory actions, and adverse effects on macroeconomic conditions, currency exchange rates, and financial markets, which could adversely impact our operations and financial results, as well as those of third parties with whom we conduct business. The occurrence of any of these business disruptions could seriously harm our operations, future revenues and financial condition and increase our costs and expenses. We have engaged CROs to conduct clinical trials outside the United States, including a limited number of trials in Ukraine and Russia. We may not be able to complete any additional dosing or follow-up visits of patients in Ukraine and Russia who are participating in these clinical trials. We may also be unable to ship additional clinical drug and other supplies necessary to complete the clinical trials in Ukraine and Russia. Although the impact of Russia's invasion is highly unpredictable, certain clinical trial activities have already been changed or suspended, and may continue to be changed, suspended or terminated, which could potentially increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

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.

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. 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 OPZELURA and we cannot assure you that we will generate substantial revenues from the drug candidates that we license or develop, including ICLUSIG, PEMAZYRE, MONJUVI/MINJUVI and ZYNYZ, 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, MONJUVI/MINJUVI, OPZELURA and ZYNYZ, 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 could result in increased financing costs due to higher interest rates and 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 short-term instruments, money market funds, U.S. government backed-funds and Treasury securities, which are investment grade and historically have been highly liquid and carried relatively low risk.

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 could result in our recognition of losses on those investments. In addition, to the extent we may seek to sell or otherwise monetize those investments, we may not be able to do so at our desired price or valuation levels, or at all, due to the limited liquidity of some or all of those investments.

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

Changes in tax laws or regulations could adversely affect our results of operations, business and financial condition.

New tax laws or regulations could be enacted at any time, and existing tax laws or regulations could be interpreted, modified or applied in a manner that is adverse to us or our customers, which could adversely affect our results of operations, business and financial condition. For example, beginning in 2022, the Tax Cuts and Jobs Act of 2017 eliminated the option to deduct research and development expenditures for tax purposes in the year incurred and instead requires taxpayers to capitalize and subsequently amortize such expenditures over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. If the requirement to amortize research and development expenditures is not repealed or otherwise modified, it will continue to have an adverse effect on our tax liability, and the amount of that effect could be material. As another example, in August 2022, the Inflation Reduction Act of 2022 was enacted, which, among other things, includes a new 15% alternative minimum tax on the adjusted financial statement income of certain large corporations for tax years beginning after December 31, 2022. Furthermore, the enactment of some or all of the recommendations set forth or that may be forthcoming in the Organization for Economic Co-Operation and Development (OECD) project on "Base Erosion and Profit Shifting" (commonly known as BEPS 2.0) by tax authorities and economic blocs in the countries in which we operate, could unfavorably impact our effective tax rate. Broadly speaking, BEPS 2.0 would make fundamental changes to the international tax system, including with respect to the entitlement to tax global corporate profits and minimum global tax rates. For example, in December 2022, the European Union member states agreed to implement in their domestic tax laws a 15% global minimum tax on the profits of large multinational enterprises with a target effective date for fiscal years beginning on or after December 31, 2023. Although we continue to evaluate and assess the potential impact of the recent U.S. legislation and BEPS 2.0 on us, the minimum tax rules could result in tax increases in both the United States and many foreign jurisdictions where we operate or have a presence. Any new tax legislation or initiatives could not only significantly increase our tax provision, cash tax liabilities, and effective tax rate, but could also significantly increase tax uncertainty due to differing interpretations and increased audit scrutiny.

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, 2023 and the three months ended March 31, 2024 from JAKAVI and OLUMIANT product royalties and, in prior periods, we derived a substantial portion of our revenues 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 a first line therapy, 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." could 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 personal information (including sensitive personal 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 our IT systems and data vulnerable to risks and damages from a variety of sources, including malicious human acts, breaches of security, cyber-attacks, catastrophe or natural disaster, telecommunications or network failures, loss of power or other natural or man-made events. In addition, despite network security and back-up measures, we and our vendors frequently defend against and respond to data security attacks and incidents, and our servers and our vendors' servers are potentially susceptible to physical or electronic break-ins, computer viruses, software vulnerabilities, ransomware attacks and similar disruptive problems. If our business continuity and disaster recovery plans and procedures or those of our vendors, including our CROs and contract manufacturers, were disrupted, inadequate or unsuccessful in the event of a problem, we could experience an interruption of all or a portion of our operations, which could result in significant harm to our business, financial results and reputation. In addition, having a portion of our employees work remotely can strain our IT 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. In particular, we are currently in the process of implementing a new enterprise resource planning system. 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 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. Malicious attacks by third parties are of ever-increasing sophistication and can be made by groups and individuals with a wide range of motives, including nation states, organized criminal groups, "hacktivists" and others acting with malicious intent. 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.

Disruptions or data security breaches within other healthcare companies could also affect our business, results of operations and financial condition. If systems used by healthcare providers, third-party payors and companies in our distribution network such as PBMs, pharmacies and wholesalers are disrupted by a data security breach, the ability to process claims and fulfill prescriptions could be impacted, which could result in adverse effects on our net product revenues.

Further, many countries and jurisdictions in which we work globally have enacted and/or are proposing privacy and data protection laws and regulations which govern the collection and use of personal information and these may impose large fines and penalties for noncompliance. For example in the European Union, under the General Data Protection Regulation, potential fines for noncompliance are up to €20 million or 4% of the annual global revenue, whichever is greater. Further, some jurisdictions provide for private rights of action if data breaches result in the loss or theft of personal data. These laws and regulations may also require, as applicable, that

- we ensure individuals to whom personal information relates are informed about how their personal information is collected and processed;
- keep personal information confidential and secure;
- transfer personal information in a compliant manner;
- respond to requests from individuals about their personal information; and
- inform authorities and individuals as may be applicable about any data breaches.

These obligations may increase our costs of doing business and the varying requirements among all countries and jurisdictions in which we work can complicate our compliance efforts.

Increasing use of social media and new technology, including artificial intelligence software, could give rise to liability, breaches of data security, or reputational damage.

We and our employees increasingly are utilizing social media tools as a means of communication both internally and externally. We also are using new technology on a daily basis to enhance how we work. Despite our efforts to monitor evolving social media communication, our internal guidelines regarding the appropriate use of new technology and applicable and emerging rules, there is risk that the use of these tools by us or our employees may cause us to be found in violation of applicable requirements. In addition, our employees may knowingly or inadvertently make use of these tools in ways that may not comply with our policies 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, 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. Additionally, the use of artificial intelligence based software is increasing in the biopharmaceutical industry. As with many developing technologies, artificial intelligence based software presents risks and challenges that could affect its further development, adoption, and use, which could affect our business. If the analyses that artificial intelligence applications assist in producing are deficient or inaccurate, we could be subjected to competitive harm, potential legal liability, and brand or reputational harm. Use of artificial intelligence based software may also lead to the release of confidential proprietary information, which may impact our ability to realize the benefit of our intellectual property.

Item 5. Other Information

(c) During the three months ended March 31, 2024, the following officers (as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934) of our Company adopted a prearranged trading plan relating to our common stock and intended to satisfy the affirmative defense of Rule 10b5–1(c) under the Securities Exchange Act of 1934:

Steven Stein, our Executive Vice President and Chief Medical Officer, adopted a trading plan on February 20, 2024 providing for the sale of up to an aggregate of 20,147 shares of our common stock until December 31, 2024.

Barry Flannelly, our Executive Vice President and General Manager, North America, adopted a trading plan on February 20, 2024 providing for the sale of up to an aggregate of 52,931 shares of our common stock until December 31, 2024.

Thomas Tray, our Vice President, Chief Accounting Officer, adopted a trading plan on March 7, 2024 providing for the sale of up to an aggregate of 1,093 shares of our common stock until June 28, 2024.

During the three months ended March 31, 2024, no director or officer (as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934) of our Company adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities, whether or not intended to satisfy the affirmative defense conditions of Rule 10b5-1(c), other than as set forth above.

Item 6. Exhibits

Exhibit Number	Description of Document
10.1	Incyte Corporation 2024 Inducement Stock Incentive Plan (incorporated by reference to Exhibit 99.1 to the Company's Registration Statement on Form S-8 (File No. 333-277043)).
10.2	Form of Global Nonstatutory Stock Option Agreement for Executive Officers under the Incyte Corporation 2024 Inducement Stock Incentive Plan (incorporated by reference to Exhibit 99.2 to the Company's Registration Statement on Form S-8 (File No. 333-277043)).
10.3	Form of Global Restricted Stock Unit Agreement under the Incyte Corporation 2024 Inducement Stock Incentive Plan (incorporated by reference to Exhibit 99.3 to the Company's Registration Statement on Form S-8 (File No. 333-277043)).
10.4	Form of Performance Share Award Agreement under the Incyte Corporation 2024 Inducement Stock Incentive Plan (incorporated by reference to Exhibit 99.4 to the Company's Registration Statement on Form S-8 (File No. 333-277043)).
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 – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL 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: April 30, 2024

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

Dated: April 30, 2024

By: /s/ CHRISTIANA STAMOULIS
Christiana Stamoulis
Executive Vice President and Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

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.

/s/ HERVÉ HOPPENOT

Hervé Hoppenot
Chief Executive Officer

April 30, 2024

Exhibit 31.2

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.

/s/ CHRISTIANA STAMOULIS

Christiana Stamoulis
Chief Financial Officer
April 30, 2024

Exhibit 32.1

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, 2024, 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
April 30, 2024

Exhibit 32.2

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, 2024, 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
April 30, 2024