
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 2, 2023

INCYTE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of
Incorporation)

001-12400
(Commission File Number)

94-3136539
(I.R.S. Employer
Identification No.)

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

19803
(Zip Code)

(302) 498-6700
(Registrant's telephone number,
including area code)

N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240-13e-4(c))

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

Title of each class	Trading Symbol	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 is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b—2 of the Securities Exchange Act of 1934 (§ 240.12b—2 of this chapter).

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.

Item 2.02 Results of Operations and Financial Condition.

On May 2, 2023, Incyte Corporation issued a press release announcing financial results for its first fiscal quarter ended March 31, 2023. The full text of the press release is furnished as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) **Exhibits.**

Exhibits	Description
99.1	Press release issued by Incyte Corporation dated May 2, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

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 hereunto duly authorized.

Date: May 2, 2023

INCYTE CORPORATION

By: /s/ Christiana Stamoulis

Christiana Stamoulis

Executive Vice President and
Chief Financial Officer



FOR IMMEDIATE RELEASE

Incyte Reports 2023 First Quarter Financial Results and Provides Updates on Key Clinical Programs

- Total net product revenues of \$693 million in Q1'23 (+14% Y/Y)
- Jakafi® (ruxolitinib) net product revenues of \$580 million (+7% Y/Y) in Q1'23; raising the bottom end of full year guidance to new range of \$2.55 - \$2.63 billion for FY 2023
- Opzelura® (ruxolitinib) cream approved as the first and only treatment for repigmentation of nonsegmental vitiligo in Europe; continued strong U.S. launch in atopic dermatitis and vitiligo
- Multiple positive data readouts from dermatology portfolio at AAD and EHSF 2023

– **Conference Call and Webcast Scheduled Today at 8:00 a.m. ET**

WILMINGTON, Del. – May 2, 2023 – Incyte (Nasdaq:INCY) today reports 2023 first quarter financial results, and provides a status update on the Company's clinical development portfolio.

"Our first quarter results demonstrate continued year-over-year double-digit revenue growth driven by Jakafi, which grew across all indications, and Opzelura, which is on track to become one of the most successful dermatology launches in recent years. In addition, we further expanded our commercial portfolio with several regulatory approvals including Opzelura for vitiligo in Europe." said Hervé Hoppenot, Chief Executive Officer, Incyte. "Furthermore, in Q1 we made a decision to focus our development efforts on eight programs that have high potential value for us and discontinued six other programs. This allows us to optimize our allocation of resources on programs that can have a high impact for patients and for Incyte."

Key Product Sales Performance

Jakafi:

Net product revenues of \$580 million:

- Net product revenues grew 7% compared with the first quarter of 2022, driven by strong underlying patient demand growth (+7% Y/Y) including an 8% growth in new patients. Total patients grew across myelofibrosis (MF), polycythemia vera (PV) and graft-versus-host disease (GVHD).
- Net product revenues were unfavorably impacted by:
 - Higher gross-to-net deductions, compared to fourth quarter of 2022, as a result of the Medicare coverage gap and higher commercial patient deductibles at the beginning of the plan year, as well as an increase in 340B orders.
 - Lower than normal levels of channel inventory at the end of Q1, representing an \$11 million impact.

Opzelura:

Net product revenues of \$57 million:

- Net product revenues grew 343% compared with the first quarter of 2022, driven by growth in patient demand and expansion in payer coverage as the launch in atopic dermatitis (AD) and vitiligo continues.
- Compared to the fourth quarter of 2022, net product revenues were unfavorably impacted by:
 - Increase in co-pay assistance due to higher commercial patient deductibles at the beginning of the plan year, consistent with first quarter dynamics and higher Medicaid utilization volume.
 - Acceleration of refills in December 2022 driven by patient demand in advance of annual deductible reset or health plan changes that negatively impacted refills during the months of January and February this year.

Pipeline Updates

MPNs and GVHD – key highlights

LIMBER (Leadership In MPNs and GVHD BEyond Ruxolitinib): Our LIMBER development program encompasses multiple monotherapy and combination strategies, with the goal of improving upon the standard of care in MF, PV, GVHD and now, essential thrombocythemia (ET).

- Combination trials of **ruxolitinib BID with zilurgisertib (ALK2)** and **INCB57643 (BET)** are ongoing and progressing well.
- In early development, **INCA33989 (mCALR)** is on track for initiating first-in-human study in MF and ET in 2023. Additionally, a Phase 1 study evaluating ruxolitinib BID in combination with Cellenkos' **CK0804** in MF is continuing to recruit patients.
- AGAVE-201, a global pivotal Phase 2 trial of **axatilimab** in patients with cGVHD is ongoing and results are on track for mid-2023. A Phase 1/2 combination trial of axatilimab in combination with ruxolitinib is being planned.
- The Phase 3 LIMBER-304 trial, evaluating **parsaclisib in combination with ruxolitinib BID** in suboptimal responders in MF and the Phase 3 LIMBER-313 trial, evaluating **parsaclisib in combination with ruxolitinib BID** in first-line MF, were discontinued following results of interim analyses that indicated that the studies were unlikely to meet their primary endpoints in the intent-to-treat patient population. The studies were not stopped due to safety.
- The U.S. Food and Drug Administration (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. Incyte will work with the FDA to determine appropriate next steps.

Indication and status

Ruxolitinib XR (QD) (JAK1/JAK2)	Myelofibrosis, polycythemia vera and GVHD
Ruxolitinib + zilurgesertib (JAK1/JAK2 + ALK2)	Myelofibrosis: Phase 2
Ruxolitinib + INCB57643 (JAK1/JAK2 + BET)	Myelofibrosis: Phase 2
Ruxolitinib + CK0804¹ (JAK1/JAK2 + CB-Tregs)	Myelofibrosis: Phase 1 (LIMBER-TREG108)
Axatilimab (anti-CSF-1R)²	Chronic GVHD: Pivotal Phase 2 (third-line plus therapy) (AGAVE-201)
Ruxolitinib + axatilimab² (JAK1/JAK2 + anti-CSF-1R)	Chronic GVHD: Phase 1/2 in preparation
INCA33989 (mCALR)	Myelofibrosis, essential thrombocythemia: Entering clinic in 2023

¹ Development collaboration with Cellenkos, Inc.

² Clinical development of axatilimab in GVHD conducted in collaboration with Syndax Pharmaceuticals.

Other Hematology/Oncology – key highlights

Zynyz™ (retifanlimab-dlwr) approved for Merkel cell carcinoma in the U.S.: Zynyz, a humanized monoclonal antibody targeting programmed death receptor-1 (PD-1), received accelerated approval for the treatment of adults with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC) in the U.S. This represents the first regulatory approval for Incyte's PD-1 inhibitor, which is also being evaluated in pivotal trials in non-small cell lung cancer (NSCLC) and squamous cell carcinoma of the anal canal (SCAC).

Monjuvi® (tafasitamab-cxix)/Minjuvi® (tafasitamab): Minjuvi continues to launch in new ex-US markets, having gained reimbursement in two additional countries this quarter, bringing the total of launch markets to six. At the American Association for Cancer Research (AACR), final five-year follow-up data from the Phase 2 L-MIND study were presented, which showed that Monjuvi plus lenalidomide followed by Monjuvi monotherapy provided prolonged, durable responses in adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL).

Pemazyre® (pemigatinib) continues to expand in ex-U.S. markets in cholangiocarcinoma and myeloproliferative neoplasms (MLNs): Pemazyre was approved in Japan by the Japanese Ministry of Health, Labour and Welfare (MHLW) for the treatment of MLNs with FGFR1 fusion. MLNs are a rare, aggressive group of cancers characterized by an over-production of myeloid cells, or bone tissue, with the tendency to rapidly progress to an acute myeloid leukemia (AML). The launch of Pemazyre in cholangiocarcinoma (CCA) is ongoing in 10 key markets in Europe. In clinical development, FIGHT-210, evaluating pemigatinib in NSCLC, was discontinued.

Parsaclisib in warm autoimmune hemolytic anemia (wAIHA): Based on the challenging regulatory landscape associated with the PI3K class, development of parsaclisib in wAIHA has been discontinued.

Indication and status

Pemigatinib (Pemazyre®) (FGFR1/2/3)	Myeloid/lymphoid neoplasms (MLN): approved in the U.S. and Japan Cholangiocarcinoma (CCA): Phase 3 (FIGHT-302) Glioblastoma: Phase 2 (FIGHT-209)
Tafasitamab (Monjuvi®/Minjuvi®)¹ (CD19)	Relapsed or refractory diffuse large B-cell lymphoma (DLBCL): Phase 3 (B-MIND) First-line DLBCL: Phase 3 (<i>frontMIND</i>) Relapsed or refractory follicular lymphoma (FL) and relapsed or refractory marginal zone lymphoma (MZL): Phase 3 (<i>inMIND</i>)
Retifanlimab (Zynyz™)² (PD-1)	Merkel cell carcinoma: 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: Phase 1 KRAS ^{G12C} -mutated solid tumors: Phase 1/1b in combination with adagrasib ³ , in preparation
INCB99318 (Oral PD-L1)	Solid tumors: Phase 1

¹ Development of tafasitamab in collaboration with MorphoSys.

² Retifanlimab licensed from MacroGenics.

³ Clinical trial collaboration and supply agreement with Mirati Therapeutics.

Inflammation and Autoimmunity (IAI) – key highlights

Dermatology

Opzelura

- **Opzelura approved for vitiligo in Europe:** Opzelura was approved by the European Commission for the treatment of non-segmental vitiligo with facial involvement in adults and adolescents 12 years of age and older. The EC decision is based on data from two pivotal Phase 3 clinical trials (TRuE-V1 and -V2), which showed treatment with Opzelura resulted in significant improvements in facial and total body repigmentation versus vehicle at Week 24 and among completers of an open-label extension at Week 52. Opzelura was well-tolerated with no serious treatment-related adverse events related to ruxolitinib cream.
- **Opzelura 104-week safety and efficacy data in vitiligo provide insights into the value of long-term treatment:** 104-week results from the long-term extension of the Phase 3 TRuE-V study were presented at the American Academy of Dermatology (AAD) Annual Meeting. The data demonstrated that many patients who achieved a high level of facial repigmentation (\geq F-VASI90) at Week 52 were able to maintain durable response one year following withdrawal of treatment. In patients who did not achieve \geq F-VASI90 at Week 52 and continued treatment with Opzelura, improvements in facial and total body repigmentation, as shown by greater proportions of patients reaching F-VASI75 and T-VASI50, were observed through Week 104.
- **Ruxolitinib cream in pediatric atopic dermatitis (AD):** A Phase 3 trial of ruxolitinib cream in pediatric AD has completed enrollment with results expected by end of year. There are an estimated 2-3 million pediatric AD patients (ages 2-11) in the United States.
- **Ruxolitinib cream in other indications:** Incyte continues to expand the development of ruxolitinib cream into new indications as we seek to maximize the potential opportunity with the franchise. Phase 2 trials evaluating ruxolitinib cream in mild to moderate hidradenitis suppurativa (HS), lichen planus (LP) and lichen sclerosus (LS) are ongoing. Additionally, two Phase 3 trials evaluating ruxolitinib cream in prurigo nodularis (PN) were initiated.

Povorcitinib

- **Phase 2 results in hidradenitis suppurativa:** 52-week results from the Phase 2 study evaluating povorcitinib (15mg QD, 45mg QD, 75mg QD) in HS were presented as an oral presentation at the European Hidradenitis Suppurativa Foundation (EHSF) Annual Meeting. The data demonstrated that continuation of treatment with povorcitinib 75 mg resulted in sustained and durable efficacy across all treatment arms, and importantly, 22-29% of patients treated for 52-weeks achieved HiSCR100, which is defined as a 100% reduction from baseline in total abscess and nodule (AN) count with no increase from baseline in abscess or draining tunnel count. Povorcitinib is currently in two Phase 3 studies in moderate to severe HS.
- **Phase 2 results in vitiligo:** 36-week results from the Phase 2b study evaluating povorcitinib in patients with extensive 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 (povorcitinib 15 mg, -19.1%; 45 mg, -17.8%; 75 mg, -15.7% vs. placebo, +2.3%; least squares mean [LSM] difference, P<0.01). Incyte plans to move into Phase 3 development for povorcitinib in vitiligo, pending FDA regulatory discussions.
- **Studies planned for asthma and chronic spontaneous urticaria:** Incyte announced the expansion of povorcitinib development into other inflammatory and autoimmune diseases, including planning for two Phase 2 trials in asthma and chronic spontaneous urticaria.

	Indication and status
Ruxolitinib cream (Opzelura®)¹ (JAK1/JAK2)	AD: Phase 3 pediatric study (TRuE-AD3) Vitiligo: Phase 3 (TRuE-V1, TRuE-V2); approved in the U.S. and Europe Lichen planus: Phase 2 Lichen sclerosus: Phase 2 Hidradenitis suppurativa: Phase 2 Prurigo nodularis: Phase 3 initiated (TRuE-PN1, TRuE-PN2)
Ruxolitinib cream + UVB (JAK1/JAK2 + phototherapy)	Vitiligo: Phase 2
Povorcitinib (JAK1)	Hidradenitis suppurativa: Phase 2b; Phase 3 (STOP-HS1, STOP-HS2) Vitiligo: Phase 2; Phase 3 planned Prurigo nodularis: Phase 2 Asthma: PoC planned Chronic spontaneous urticaria: PoC planned
Auremolimab (anti-IL-15Rβ)	Vitiligo: Phase 1 in preparation

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

Discovery and other early development – key highlights

INCB123667 (CDK2) oral presentation at the American Association for Cancer Research (AACR) 2023: INCB123667 is a selective and potent CDK2 kinase inhibitor, 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. At AACR, Incyte presented data demonstrating INCB123667 exhibited significant single-agent activity in vivo in CCNE1^{high} breast cancer xenograft and patient-derived xenograft models. INCB123667 is currently 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.

INCA33890 (TGFβR2xPD-1) in clinical development: INCA33890 is a TGFβR2xPD1 bispecific antibody which has been engineered to avoid the known toxicity of broad TGFβ pathway blockade. INCA33890 has higher affinity for PD1 than TGFβR2, and blocks TGFβ-signaling specifically in cells co-expressing PD-1, thus potentially sparing tissues where TGFβ-signaling is important for normal function. Preclinical in vivo data presented at AACR show that INCA33890 has a greater anti-tumor effect than either individual benchmark antibodies or a simple combination of these.

Development of the adenosine program (including INCB106385 and INCA00186), INCAGN1876 (GITR) and INCB81776 (AXL/MER) has been discontinued based on early efficacy data.

Modality	Candidates
Small molecules	INCB123667 (CDK2)
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.

² Development in collaboration with Merus

Partnered – key highlights

	Indication and status
Ruxolitinib¹ (JAK1/JAK2)	Acute and chronic GVHD: approved in Europe; J-NDA under review
Baricitinib² (JAK1/JAK2)	AD: approved in Europe and Japan Severe AA: approved in the U.S., Europe and Japan
Capmatinib³ (MET)	NSCLC (with MET exon 14 skipping mutations): approved in the U.S., Europe and Japan

¹ Ruxolitinib (Jakavi®) licensed to Novartis ex-U.S. for use in hematology and oncology excluding topical administration.

² Baricitinib (Olumiant®) licensed to Lilly: approved as Olumiant in multiple territories globally for certain patients with moderate-to-severe rheumatoid arthritis; approved as Olumiant in EU and Japan for certain patients with atopic dermatitis.

³ Capmatinib (Tabrecta®) licensed to Novartis.

2023 First Quarter Financial Results

The financial measures presented in this press release for the three months ended March 31, 2023 and 2022 have been prepared by the Company in accordance with U.S. Generally Accepted Accounting Principles (“GAAP”), unless otherwise identified as a Non-GAAP financial measure. Management believes that Non-GAAP information is useful for investors, when considered in conjunction with Incyte’s GAAP disclosures. Management uses such information internally and externally for establishing budgets, operating goals and financial planning purposes. These metrics are also used to manage the Company’s business and monitor performance. The Company adjusts, where appropriate, for expenses in order to reflect the Company’s core operations. The Company believes these adjustments are useful to investors by providing an enhanced understanding of the financial performance of the Company’s core operations. The metrics have been adopted to align the Company with disclosures provided by industry peers.

Non-GAAP information is not prepared under a comprehensive set of accounting rules and should only be used in conjunction with and to supplement Incyte’s operating results as reported under GAAP. Non-GAAP measures may be defined and calculated differently by other companies in our industry.

As changes in exchange rates are an important factor in understanding period-to-period comparisons, Management believes the presentation of certain revenue results on a constant currency basis in addition to reported results helps improve investors’ ability to understand its operating results and evaluate its performance in comparison to prior periods. Constant currency information compares results between periods as if exchange rates had remained constant period over period. The Company calculates constant currency by calculating current year results using prior year foreign currency exchange rates and generally refers to such amounts calculated on a constant currency basis as excluding the impact of foreign exchange or being on a constant currency basis. These results should be considered in addition to, not as a substitute for, results reported in accordance with GAAP. Results on a constant currency basis, as the Company presents them, may not be comparable to similarly titled measures used by other companies and are not measures of performance presented in accordance with GAAP.

Financial Highlights

Financial Highlights (unaudited, in thousands, except per share amounts)

	Three Months Ended March 31,	
	2023	2022
Total GAAP revenues	\$ 808,673	\$ 733,235
Total GAAP operating income	24,770	116,540
Total Non-GAAP operating income	89,729	172,147
GAAP net income	21,703	37,992
Non-GAAP net income	84,577	122,867
GAAP basic EPS	\$ 0.10	\$ 0.17
Non-GAAP basic EPS	\$ 0.38	\$ 0.56
GAAP diluted EPS	\$ 0.10	\$ 0.17
Non-GAAP diluted EPS	\$ 0.37	\$ 0.55

Revenue Details

Revenue Details (unaudited, in thousands)

	Three Months Ended March 31,		% Change (as reported)	% Change (constant currency) ¹
	2023	2022		
Net product revenues:				
Jakafi	\$ 579,969	\$ 544,464	7 %	7 %
Iclusig	27,685	26,069	6 %	12 %
Pemazyre	22,475	18,032	25 %	29 %
Minjuvi	6,556	4,502	46 %	51 %
Opzelura	56,552	12,754	343 %	343 %
Total net product revenues	693,237	605,821	14 %	15 %
Royalty revenues:				
Jakavi	76,692	70,867	8 %	16 %
Olumiant	34,155	48,064	(29 %)	(16 %)
Tabrecta	4,177	3,483	20 %	NA
Pemazyre	412	—	NM	NM
Total royalty revenues	115,436	122,414	(6 %)	
Total net product and royalty revenues	808,673	728,235	11 %	
Milestone and contract revenues	—	5,000	(100 %)	(100 %)
Total GAAP revenues	\$ 808,673	\$ 733,235	10 %	

NM = not meaningful

NA = not available

¹Percentage change in constant currency is calculated using 2022 foreign exchange rates to recalculate 2023 results.

Product and Royalty Revenues Product and royalty revenues for the three months ended March 31, 2023 increased 11% over the prior year comparative period as a result of net product revenues increasing 14% year-over-year, primarily driven by increases in Jakafi and Opzelura net product revenues. The increase in Jakafi net product revenues was primarily driven by growth in patient demand across all indications and was partially offset by higher gross-to-net deductions for Medicare and commercial co-pay assistance consistent with historical prior years' first quarters, as well as an increase in 340B volumes. The quarter was also impacted by lower weeks on hand channel inventory than normal due to timing of certain customer purchases. Opzelura net product revenues for the quarter were \$57 million, representing a 343% increase year-over-year driven by increased patient demand and expanded coverage. The quarter was negatively impacted by an increase in co-pay assistance due to higher commercial patient deductibles at the beginning of the plan year and higher Medicaid utilization volume. In addition, volume was negatively impacted by an acceleration of refills in December 2022 driven by patient demand in advance of annual deductible reset or health plan changes. Jakafi and Olumiant royalties for the quarter were impacted by unfavorable changes in foreign currency exchange rates, while Olumiant royalties were also impacted by a decrease in net product sales of Olumiant for use as a treatment for COVID-19.

Operating Expenses

Operating Expense Summary (unaudited, in thousands)

	Three Months Ended March 31,		% Change
	2023	2022	
GAAP cost of product revenues	\$ 56,822	\$ 42,614	33 %
Non-GAAP cost of product revenues ¹	50,669	36,619	38 %
GAAP research and development	406,641	353,373	15 %
Non-GAAP research and development ²	375,620	327,045	15 %
GAAP selling, general and administrative	315,606	209,584	51 %
Non-GAAP selling, general and administrative ³	294,017	192,682	53 %
GAAP loss on change in fair value of acquisition-related contingent consideration	6,196	6,382	(3 %)
Non-GAAP loss on change in fair value of acquisition-related contingent consideration ⁴	—	—	— %
GAAP (profit) and loss sharing under collaboration agreements	(1,362)	4,742	(129 %)

¹ Non-GAAP cost of product revenues excludes the amortization of licensed intellectual property for Iclusig relating to the acquisition of the European business of ARIAD Pharmaceuticals, Inc. and the cost of stock-based compensation.

² Non-GAAP research and development expenses exclude the cost of stock-based compensation.

³ Non-GAAP selling, general and administrative expenses exclude the cost of stock-based compensation.

⁴ Non-GAAP loss on change in fair value of acquisition-related contingent consideration is null.

Cost of product revenues GAAP and Non-GAAP cost of product revenues for three months ended March 31, 2023 increased 33% and 38%, respectively, compared to the same period in 2022 primarily due to product related costs for our commercial products including Opzelura.

Research and development expenses GAAP and Non-GAAP research and development expense for three months ended March 31, 2023 increased 15%, compared to the same period in 2022 primarily due to continued investment in our late stage development assets and timing of certain expenses.

Selling, general and administrative expenses GAAP and Non-GAAP selling, general and administrative expenses for the three months ended March 31, 2023 increased 51% and 53%, respectively, compared to the same period in 2022, primarily due to expenses related to promotional activities to support the launch of Opzelura for the treatments of atopic dermatitis and vitiligo and timing of certain expenses.

Other Financial Information

Operating income GAAP and Non-GAAP operating income for the three months ended March 31, 2023 decreased 79% and 48%, respectively, compared to the same period in 2022, primarily due to expenses related to promotional activities to support the launch of Opzelura for the treatments of atopic dermatitis and vitiligo and timing of certain expenses.

Cash, cash equivalents and marketable securities position As of March 31, 2023 and December 31, 2022, cash, cash equivalents and marketable securities totaled \$3.1 billion and \$3.2 billion, respectively. The decrease from December 31, 2022 is due a reduction of our accounts payable balance at March 31, 2023.

2023 Financial Guidance

Incyte is tightening its full year 2023 guidance for Jakafi net product revenues as a result of its strong first quarter performance. Guidance does not include revenue from any potential new product launches or the impact of any potential future strategic transactions. Incyte's guidance is summarized below.

	Current	Previous
Jakafi net product revenues	\$2.55 - \$2.63 billion	\$2.53 - \$2.63 billion
Other Hematology/Oncology net product revenues ⁽¹⁾	\$215 - \$225 million	Unchanged
GAAP Cost of product revenues	7 – 8% of net product revenues	Unchanged
Non-GAAP Cost of product revenues ⁽²⁾	6 – 7% of net product revenues	Unchanged
GAAP Research and development expenses	\$1,610 - \$1,650 million	Unchanged
Non-GAAP Research and development expenses ⁽³⁾	\$1,485 - \$1,520 million	Unchanged
GAAP Selling, general and administrative expenses	\$1,050 - \$1,150 million	Unchanged
Non-GAAP Selling, general and administrative expenses ⁽³⁾	\$965 - \$1,060 million	Unchanged

¹Pemazyre in the U.S., EU and Japan and Iclusig and Minjuvi in the EU.

²Adjusted to exclude the amortization of licensed intellectual property for Iclusig relating to the acquisition of the European business of ARIAD Pharmaceuticals, Inc. and the estimated cost of stock-based compensation.

³ Adjusted to exclude the estimated cost of stock-based compensation.

Conference Call and Webcast Information

Incyte will hold a conference call and webcast this morning at 8:00 a.m. ET. To access the conference call, please dial 877-407-3042 for domestic callers or 201-389-0864 for international callers. When prompted, provide the conference identification number, 13737924.

If you are unable to participate, a replay of the conference call will be available for 90 days. The replay dial-in number for the United States is 877-660-6853 and the dial-in number for international callers is 201-612-7415. To access the replay you will need the conference identification number, 13737924.

The conference call will also be webcast live and can be accessed at investor.incyte.com.

About Incyte

Incyte is a Wilmington, Delaware-based, global biopharmaceutical company focused on finding solutions for serious unmet medical needs through the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit Incyte.com and follow [@Incyte](https://twitter.com/Incyte).

About Jakafi® (ruxolitinib)

Jakafi® (ruxolitinib) is a JAK1/JAK2 inhibitor approved by the U.S. FDA for treatment of polycythemia vera (PV) in adults who have had an inadequate response to or are intolerant of hydroxyurea; intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF in adults; steroid-refractory acute GVHD in adult and pediatric patients 12 years and older; and chronic GVHD after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.

Jakafi is a registered trademark of Incyte.

About Opzelura® (ruxolitinib) Cream 1.5%

Opzelura, a novel cream formulation of Incyte's selective JAK1/JAK2 inhibitor ruxolitinib, approved by the U.S. Food & Drug Administration for the topical treatment of nonsegmental vitiligo in patients 12 years of age and older, is the first and only treatment for repigmentation approved for use in the United States. Opzelura is also approved in the U.S. 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. Use of Opzelura in combination with therapeutic biologics, other JAK inhibitors, or potent immunosuppressants, such as azathioprine or cyclosporine, is not recommended.

In Europe, Opzelura (ruxolitinib) cream 15mg/g is approved for the treatment of non-segmental vitiligo with facial involvement in adults and adolescents from 12 years of age.

Incyte has worldwide rights for the development and commercialization of ruxolitinib cream, marketed in the United States as Opzelura.

Opzelura and the Opzelura logo are registered trademarks of Incyte.

About Monjuvi®/Minjuvi® (tafasitamab)

Tafasitamab is a humanized Fc-modified CD19 targeting immunotherapy. In 2010, MorphoSys licensed exclusive worldwide rights to develop and commercialize tafasitamab from Xencor, Inc. Tafasitamab incorporates an XmAb® engineered Fc domain, which mediates B-cell lysis through apoptosis and immune effector mechanism including Antibody-Dependent Cell-Mediated Cytotoxicity (ADCC) and Antibody-Dependent Cellular Phagocytosis (ADCP).

In the United States, Monjuvi® (tafasitamab-cxix) is approved by the U.S. Food and Drug Administration in combination with lenalidomide for the treatment of adult patients with relapsed or refractory DLBCL not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT). This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

In Europe, Minjuvi® (tafasitamab) received conditional marketing authorization in combination with lenalidomide, followed by Minjuvi® monotherapy, for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are not eligible for autologous stem cell transplant (ASCT).

Tafasitamab is being clinically investigated as a therapeutic option in B-cell malignancies in several ongoing combination trials.

Minjuvi® and Monjuvi® are registered trademarks of MorphoSys AG. Tafasitamab is co-marketed by Incyte and MorphoSys under the brand name Monjuvi® in the U.S., and marketed by Incyte under the brand name Minjuvi® in Europe and Canada.

XmAb® is a registered trademark of Xencor, Inc.

About Pemazyre® (pemigatinib)

Pemazyre is a kinase inhibitor indicated in the United States for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test*. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Pemazyre is also the first targeted treatment approved for use in the United States for treatment of adults with relapsed or refractory myeloid/lymphoid neoplasms (MLNs) with FGFR1 rearrangement.

In Japan, Pemazyre is approved for the treatment of patients with unresectable biliary tract cancer (BTC) with a fibroblast growth factor receptor 2 (FGFR2) fusion gene, worsening after cancer chemotherapy.

In Europe, Pemazyre is approved for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy.

Pemazyre is a potent, selective, oral inhibitor of FGFR isoforms 1, 2 and 3 which, in preclinical studies, has demonstrated selective pharmacologic activity against cancer cells with FGFR alterations.

Pemazyre is marketed by Incyte in the United States, Europe and Japan.

Pemazyre is a trademark of Incyte.

* Pemazyre® (pemigatinib) [Package Insert]. Wilmington, DE: Incyte; 2020.

About Iclusig® (ponatinib) tablets

Ponatinib (Iclusig®) targets not only native BCR-ABL but also its isoforms that carry mutations that confer resistance to treatment, including the T315I mutation, which has been associated with resistance to other approved TKIs.

In the EU, Iclusig is approved for the treatment of adult patients with chronic phase, accelerated phase or blast phase chronic myeloid leukemia (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 Philadelphia-chromosome positive acute lymphoblastic leukemia (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.

[Click here](#) to view the Iclusig EU Summary of Medicinal Product Characteristics.

Incyte has an exclusive license from Takeda Pharmaceuticals International AG to commercialize ponatinib in the European Union and 29 other countries, including Switzerland, UK, Norway, Turkey, Israel and Russia. Iclusig is marketed in the U.S. by Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceutical Company Limited.

About Zynyz™ (retifanlimab-dlwr)

Zynyz (retifanlimab-dlwr), is an intravenous PD-1 inhibitor indicated in the U.S. for the treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC). This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Zynyz is marketed by Incyte in the U.S. In 2017, Incyte entered into an exclusive collaboration and license agreement with MacroGenics, Inc. for global rights to retifanlimab.

Zynyz is a trademark of Incyte.

Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this release contain predictions, estimates and other forward-looking statements, including any discussion of the following: Incyte's potential for continued performance and growth; Incyte's financial guidance for 2023, including its expectations regarding sales of Jakafi; expectations with respect to demand for and uptake of Opzelura; the potential for ruxolitinib cream to expand into other indications; expectations regarding the potential and progress of programs in our pipeline and the delivery of same; expectations regarding ongoing clinical trials and clinical trials to be initiated, including the LIMBER program, INCA33989 (mCALR) in MF and ET, a Phase 1 study evaluating ruxolitinib BID in combination with Cellenkos' CK0804 in MF, axatilimab in cGVHD (alone and in combination with ruxolitinib), Incyte's oral PD-L1 program, a phase 3 trial of ruxolitinib cream in pediatric AD, phase 2 and 3 trials of povorcitinib in multiple indications and a phase 1 trial of auremolimab in vitiligo; our and our collaborators' potential for receiving additional regulatory approvals within the next 1-2 years and the corresponding potential for launches of new products and/or indications; Incyte's plan to work with the FDA to determine next steps for ruxolitinib extended-release (XR) tablets for once-daily (QD) use; expectations regarding ongoing launches by us and our collaborators; and our expectations regarding 2023 newsflow items.

These forward-looking statements are based on Incyte's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: further research and development and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials and the ability to enroll subjects in accordance with planned schedules; the effects of the COVID 19 pandemic and measures to

address the pandemic on Incyte's clinical trials, supply chain and other third-party providers, sales and marketing efforts and business, development and discovery operations; determinations made by the FDA, EMA, and other regulatory agencies; Incyte's dependence on its relationships with and changes in the plans of its collaboration partners; the efficacy or safety of Incyte's products and the products of Incyte's collaboration partners; the acceptance of Incyte's products and the products of Incyte's collaboration partners in the marketplace; market competition; unexpected variations in the demand for Incyte's products and the products of Incyte's collaboration partners; the effects of announced or unexpected price regulation or limitations on reimbursement or coverage for Incyte's products and the products of Incyte's collaboration partners; sales, marketing, manufacturing and distribution requirements, including Incyte's and its collaboration partners' ability to successfully commercialize and build commercial infrastructure for newly approved products and any additional products that become approved; greater than expected expenses, including expenses relating to litigation or strategic activities; variations in foreign currency exchange rates; and other risks detailed in Incyte's reports filed with the Securities and Exchange Commission, including its annual report for the year ended December 31, 2022. Incyte disclaims any intent or obligation to update these forward-looking statements.

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

	Three Months Ended March 31,	
	2023	2022
	GAAP	
Revenues:		
Product revenues, net	\$ 693,237	\$ 605,821
Product royalty revenues	115,436	122,414
Milestone and contract revenues	—	5,000
Total revenues	808,673	733,235
Costs and expenses:		
Cost of product revenues (including definite-lived intangible amortization)	56,822	42,614
Research and development	406,641	353,373
Selling, general and administrative	315,606	209,584
Loss on change in fair value of acquisition-related contingent consideration	6,196	6,382
(Profit) and loss sharing under collaboration agreements	(1,362)	4,742
Total costs and expenses	783,903	616,695
Income from operations	24,770	116,540
Interest income and other, net	32,873	1,260
Interest expense	(469)	(680)
Unrealized loss on long term investments	(5,318)	(46,585)
Income before provision for income taxes	51,856	70,535
Provision for income taxes	30,153	32,543
Net income	\$ 21,703	\$ 37,992
Net income per share:		
Basic	\$ 0.10	\$ 0.17
Diluted	\$ 0.10	\$ 0.17
Shares used in computing net income per share:		
Basic	222,960	221,326
Diluted	225,589	222,950

INCYTE CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

	March 31, 2023	December 31, 2022
ASSETS		
Cash, cash equivalents and marketable securities	\$ 3,112,712	\$ 3,238,965
Accounts receivable	623,788	644,879
Property and equipment, net	741,701	739,310
Finance lease right-of-use assets, net	25,849	26,298
Inventory	157,564	120,959
Prepaid expenses and other assets	216,694	194,144
Long term investments	128,313	133,676
Other intangible assets, net	140,658	129,219
Goodwill	155,593	155,593
Deferred income tax asset	494,751	457,941
Total assets	<u>\$ 5,797,623</u>	<u>\$ 5,840,984</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	\$ 1,084,207	\$ 1,216,603
Finance lease liabilities	32,848	33,262
Acquisition-related contingent consideration	218,000	221,000
Stockholders' equity	4,462,568	4,370,119
Total liabilities and stockholders' equity	<u>\$ 5,797,623</u>	<u>\$ 5,840,984</u>

INCYTE CORPORATION
RECONCILIATION OF GAAP NET (LOSS) INCOME TO SELECTED NON-GAAP ADJUSTED INFORMATION
(unaudited, in thousands, except per share amounts)

	Three Months Ended March 31,	
	2023	2022
GAAP Net Income	\$ 21,703	\$ 37,992
<i>Adjustments¹:</i>		
Non-cash stock compensation from equity awards (R&D) ²	31,021	26,328
Non-cash stock compensation from equity awards (SG&A) ²	21,589	16,902
Non-cash stock compensation from equity awards (COGS) ²	769	611
Non-cash interest ³	108	108
Changes in fair value of equity investments ⁴	5,318	46,585
Amortization of acquired product rights ⁵	5,384	5,384
Loss on change in fair value of contingent consideration ⁶	6,196	6,382
Tax effect of Non-GAAP pre-tax adjustments ⁷	(7,511)	(17,425)
Non-GAAP Net Income	\$ 84,577	\$ 122,867
Non-GAAP net income per share:		
Basic	\$ 0.38	\$ 0.56
Diluted	\$ 0.37	\$ 0.55
Shares used in computing Non-GAAP net income per share:		
Basic	222,960	221,326
Diluted	225,589	222,950

¹ Included within the Milestone and contract revenues line item in the Condensed Consolidated Statements of Operations (in thousands) for the three months ended March 31, 2023 and 2022 are milestones of \$0 and \$5,000, respectively, earned from our collaborative partners. Included within the Research and development expenses line item in the Condensed Consolidated Statements of Operations (in thousands) for the three months ended March 31, 2023 and 2022 are upfront consideration and milestones of \$2,700 and \$20,000, respectively, related to our collaborative partners.

² As included within the Cost of product revenues (including definite-lived intangible amortization) line item; the Research and development expenses line item; and the Selling, general and administrative expenses line item in the Condensed Consolidated Statements of Operations.

³ As included within the Interest expense line item in the Condensed Consolidated Statements of Operations.

⁴ As included within the Unrealized loss on long term investments line item in the Condensed Consolidated Statements of Operations.

⁵ As included within the Cost of product revenues (including definite-lived intangible amortization) line item in the Condensed Consolidated Statements of Operations. Acquired product rights of licensed intellectual property for Iclusig is amortized utilizing a straight-line method over the estimated useful life of 12.5 years.

⁶ As included within the Loss on change in fair value of acquisition-related contingent consideration line item in the Condensed Consolidated Statements of Operations.

⁷ Income tax effects of Non-GAAP pre-tax adjustments are calculated using an estimated annual effective tax rate, taking into consideration any permanent items and valuation allowances against related deferred tax assets.