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): February 7, 2023

INCYTE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**001-12400**	**94-3136539**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

1801 Augustine Cut-Off Wilmington, DE	**19803**
(Address of principal executive offices)	(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 February 7, 2023, Incyte Corporation issued a press release announcing financial results for its fourth fiscal quarter and year ended December 31, 2022. 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 February 7, 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: February 7, 2023

INCYTE CORPORATION

By: /s/ Christiana Stamoulis

Christiana Stamoulis

Executive Vice President and
Chief Financial Officer

Exhibit 99.1

FOR IMMEDIATE RELEASE

Incyte Reports 2022 Fourth Quarter and Year-end Financial Results, Provides 2023 Financial Guidance and Updates on Key Clinical Programs

- *Total FY'22 net product revenues grew 18% to $2.75 billion; total FY'22 revenues of $3.4 billion (+14% Y/Y)*
- *Jakafi® (ruxolitinib) net revenues of $647 million (+9% Y/Y) in Q4'22 and $2.41 billion (+13%) in FY'22; Jakafi net revenues guidance range of $2.53 - $2.63 billion for FY 2023*
- *Opzelura™ (ruxolitinib) Cream net revenues of $61 million in Q4'22 and $129 million in FY'22, driven by strong demand in atopic dermatitis, a successful launch in vitiligo and broadening formulary access*

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

WILMINGTON, Del. – February 7, 2023 – Incyte (Nasdaq:INCY) today reports 2022 fourth quarter financial results, provides 2023 financial guidance and provides a status update on the Company's clinical development portfolio.

"We are entering 2023 with significant momentum, following a year of strong commercial performance and progress of several important mid-to-late stage programs across our pipeline. Opzelura has now become the market share leader among branded agents for new atopic dermatitis patients and the adoption in vitiligo has been strong," said Hervé Hoppenot, Chief Executive Officer, Incyte. "We are well positioned for strong growth with our current product portfolio and we expect to deliver many important updates this year as we continue to execute on our growth and diversification strategy."

Portfolio Updates

MPNs and GVHD – key highlights

LIMBER (Leadership In MPNs and GVHD BEyond Ruxolitinib) program: Important LIMBER updates were presented at the American Society of Hematology (ASH) Annual Meeting in December 2022:

- **Parsaclisib + ruxolitinib in myelofibrosis (MF):** Final results from the Phase 2 trial in MF patients with a suboptimal response to ruxolitinib demonstrated additional spleen volume response and symptom improvement with the addition of parsaclisib. Add-on parsaclisib was generally well-tolerated. A Phase 3 trial evaluating parsaclisib as an add-on to ruxolitinib in suboptimal responders is ongoing with results expected at the end of 2023.
- **Zilurgisertib (ALK2) ± ruxolitinib in MF:** Initial results from the Phase 1 study evaluating zilurgisertib as monotherapy or in combination with ruxolitinib in patients with anemia due to MF were presented, establishing proof of mechanism in improving anemia. Updated combination data with ruxolitinib are expected later this year.
- **INCA33989 (mCALR) in MF and essential thrombocythemia (ET):** A novel anti-mutant calreticulin (mCALR) monoclonal antibody was unveiled during the ASH plenary session. These data highlight Incyte's discovery capabilities and research progress in MF and ET; two patient populations where 25-35% of patients have a CALR mutation. INCA33989 is expected to enter the clinic later this year.

Ruxolitinib extended release (XR) formulation: The New Drug Application (NDA) was accepted by the U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) target action date of March 23, 2023.

Axatilimab in chronic graft-versus-host disease (GVHD): In December, Syndax and Incyte announced that results from the Phase 1/2 trial of axatilimab in patients with recurrent or refractory chronic GVHD following two or more prior lines of therapy were published in the *Journal of Clinical Oncology.* The data demonstrate that treatment with axatilimab resulted in an overall response rate (ORR) by cycle 7, day 1 of 67% across all patients. AGAVE-201, a global pivotal Phase 2 trial of axatilimab in patients with cGVHD, is ongoing with results expected mid-2023. A Phase 1/2 combination trial of axatilimab with ruxolitinib in patients with newly-diagnosed cGVHD is expected to initiate later this year.

Jakafi patent extension: Incyte was granted pediatric exclusivity which adds six months to the expiration for all ruxolitinib patents, thereby extending the patent expiry for Jakafi through December 2028.

	Indication and status
Ruxolitinib XR (QD) (JAK1/JAK2)	Myelofibrosis, polycythemia vera and GVHD: NDA under review
Ruxolitinib + parsaclisib (JAK1/JAK2 + PI3Kδ)	Myelofibrosis: Phase 3 (first-line therapy) (LIMBER-313) Myelofibrosis: Phase 3 (suboptimal responders to ruxolitinib) (LIMBER-304)
Ruxolitinib + INCB57643 (JAK1/JAK2 + BET)	Myelofibrosis: Phase 2
Ruxolitinib + zilurgisertib (JAK1/JAK2 + ALK2)	Myelofibrosis: Phase 2
Ruxolitinib + CK0804[1] (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 + axatilimab[2] (JAK1/JAK2 + anti-CSF-1R)	Chronic GVHD (newly diagnosed): Phase 1/2 in preparation

[1] Development collaboration with Cellenkos, Inc.
[2] Clinical development of axatilimab in GVHD conducted in collaboration with Syndax Pharmaceuticals.

Other Hematology/Oncology – key highlights

Oral PD-L1: In November, data from Incyte's oral, small molecule PD-L1 program, including Phase 1 data evaluating the safety and tolerability of INCB99280 and INCB99318, were presented at the Society for Immunotherapy of Cancer (SITC) meeting. Both INCB99280 and INCB99318 demonstrated clinical activity with tumor shrinkage and were generally well-tolerated. Updated data are expected later in 2023.

INCB99280 (Oral PD-L1) + adagrasib ($KRAS^{G12C}$): In November, Incyte and Mirati announced a clinical trial collaboration and supply agreement to investigate the combination of INCB99280 and adagrasib, a $KRAS^{G12C}$ selective inhibitor, in patients with $KRAS^{G12C}$-mutated solid tumors. We expect to initiate a Phase 1/1b trial evaluating the combination this year.

	Indication and status
Pemigatinib (Pemazyre®) (FGFR1/2/3)	Myeloid/lymphoid neoplasms (MLN): approved by FDA Cholangiocarcinoma (CCA): Phase 3 (FIGHT-302) Glioblastoma: Phase 2 (FIGHT-209) Non-small cell lung cancer (NSCLC): Phase 2 (FIGHT-210)
Tafasitamab (Monjuvi®/Minjuvi®)[1] (CD19)	Relapsed or refractory diffuse large B-cell lymphoma (DLBCL): Phase 2 (L-MIND); Phase 3 (B-MIND) First-line DLBCL: Phase 3 (*frontMIND*) Relapsed or refractory follicular lymphoma (FL) and relapsed or refractory marginal zone lymphoma (MZL): Phase 3 (*inMIND*)
Parsaclisib (PI3Kδ)	Warm autoimmune hemolytic anemia: Phase 3 (PATHWAY)
Retifanlimab[2] (PD-1)	Squamous cell anal cancer (SCAC): Phase 3 (POD1UM-303) MSI-high endometrial cancer: Phase 2 (POD1UM-101, POD1UM-204) Merkel cell carcinoma: Phase 2 (POD1UM-201) Non-small cell lung cancer (NSCLC): Phase 3 (POD1UM-304)
INCB99280 (Oral PD-L1)	Solid tumors: Phase 1 $KRAS^{G12C}$-mutated solid tumors: Phase 1/1b in combination with adagrasib, in preparation
INCB99318 (Oral PD-L1)	Solid tumors: Phase 1

[1] Development of tafasitamab in collaboration with MorphoSys.
[2] Retifanlimab licensed from MacroGenics.

Inflammation and Autoimmunity (IAI) – key highlights

Dermatology

Opzelura growth coming from both atopic dermatitis (AD) and vitiligo in the U.S.: More than 84,000 units of Opzelura were shipped in the fourth quarter of 2022 driven by strong growth in new patient starts across AD and vitiligo, as well as broadening formulary coverage. Refills grew across both indications, helping drive net product revenues to $61 million, a growth of 61% versus the third quarter. Additionally, in late 2022, Incyte received an issued patent and allowed claims directed to the treatments of atopic dermatitis and vitiligo, respectively, with expiration dates of 2040.

Ruxolitinib cream in pediatric AD: A Phase 3 trial of ruxolitinib cream in pediatric AD is ongoing, with results expected by end of year. There are an estimated 2 million pediatric AD patients ages 2 to 11 in the U.S.

Ruxolitinib cream in vitiligo in Europe: A marketing authorization application (MAA) is under review at the European Medicines Agency (EMA), with the Committee for Medicinal Products for Human Use (CHMP) opinion expected in the first half of 2023.

Ruxolitinib cream in other indications: Incyte continues to expand the development of ruxolitinib cream into new indications to maximize the opportunity with Opzelura. In December, a Phase 2 trial evaluating ruxolitinib cream in mild to moderate hidradenitis suppurativa (HS) was initiated. Two Phase 2 trials in lichen planus (LP) and lichen sclerosus (LS) are ongoing. There are no topical therapies approved in hidradenitis suppurativa, lichen planus or lichen sclerosus.

Povorcitinib in multiple indications: In December, two Phase 3 trials (STOP-HS1 and STOP-HS2) in moderate to severe HS were initiated. Additionally, two Phase 2 trials in vitiligo and prurigo nodularis are ongoing, with results expected in 2023.

	Indication and status
Ruxolitinib cream (Opzelura™)[1] (JAK1/JAK2)	AD: Phase 3 pediatric study (TRuE-AD3) Vitiligo: Phase 3 (TRuE-V1, TRuE-V2); approved by FDA; MAA under review Lichen planus: Phase 2 Lichen sclerosus: Phase 2 Hidradenitis suppurativa: Phase 2
Ruxolitinib cream + UVB (JAK1/JAK2 + phototherapy)	Vitiligo: Phase 2
Povorcitinib (JAK1)	Hidradenitis suppurativa: Phase 2b; Phase 3 (STOP-HS1, STOP-HS2) Vitiligo: Phase 2 Prurigo nodularis: Phase 2
Auremolimab (anti-IL-15Rβ)	Vitiligo: Phase 1 in preparation

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

Discovery and early development – key highlights

Incyte's portfolio of other earlier-stage clinical candidates is below.

Modality	Candidates
Small molecules	INCB81776 (AXL/MER), INCB106385 (A2A/A2B), INCB123667 (CDK2)
Monoclonal antibodies	INCAGN1876 (GITR)[1], INCAGN2385 (LAG-3)[1], INCAGN2390 (TIM-3)[1], INCA00186 (CD73), INCA33989 (mCALR)
Bi-specific antibodies	INCA32459 (LAG-3xPD-1)[2]

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

Partnered – key highlights

	Indication and status
Ruxolitinib[1] (JAK1/JAK2)	Acute and chronic GVHD: approved in Europe; J-NDA under review
Baricitinib[2] (JAK1/JAK2)	AD: approved in Europe and Japan Severe AA: approved in the U.S., Europe and Japan
Capmatinib[3] (MET)	NSCLC (with MET exon 14 skipping mutations): approved in the U.S., Europe and Japan

[1] ruxolitinib licensed to Novartis ex-US for use in hematology and oncology excluding topical administration.
[2] baricitinib 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 licensed to Novartis.

2022 Fourth Quarter and Year-end Financial Results

The financial measures presented in this press release for the quarter and year ended December 31, 2022 and 2021 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 December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
Total GAAP revenues	$ 926,700	$ 862,853	$ 3,394,635	$ 2,986,267
Total GAAP operating income	70,093	110,734	579,440	585,777
Total Non-GAAP operating income	152,503	166,013	801,545	825,032
GAAP provision (benefit) for income taxes	52,154	(443,831)	188,456	(378,137)
GAAP net income	28,461	563,851	340,660	948,581
Non-GAAP net income	139,661	22,565	622,676	611,978
GAAP basic EPS	$ 0.13	$ 2.55	$ 1.53	$ 4.30
Non-GAAP basic EPS	$ 0.63	$ 0.10	$ 2.80	$ 2.78
GAAP diluted EPS	$ 0.13	$ 2.54	$ 1.52	$ 4.27
Non-GAAP diluted EPS	$ 0.62	$ 0.10	$ 2.78	$ 2.76

Revenue Details

Revenue Details
(unaudited, in thousands)

	Three Months Ended December 31,		% Change (as reported)	% Change (constant currency)[1]	Twelve Months Ended December 31,		% Change (as reported)	% Change (constant currency)[1]
	2022	2021			2022	2021		
Net product revenues:								
Jakafi	$ 647,493	$ 592,370	9 %	9 %	$ 2,409,225	$ 2,134,508	13 %	13 %
Iclusig	27,616	27,039	2 %	8 %	105,838	109,395	(3 %)	8 %
Pemazyre	23,016	19,607	17 %	37 %	83,445	68,531	22 %	26 %
Minjuvi	4,809	4,354	10 %	54 %	19,654	4,910	300 %	350 %
Opzelura	61,281	4,668	NM	NM	128,735	4,668	NM	NM
Total net product revenues	764,215	648,038	18 %	19 %	2,746,897	2,322,012	18 %	19 %
Royalty revenues:								
Jakavi	91,189	95,696	(5 %)	10 %	331,575	337,991	(2 %)	11 %
Olumiant	35,858	66,000	(46 %)	(31 %)	134,547	220,875	(39 %)	(32 %)
Tabrecta	4,233	3,119	36 %	NA	15,411	10,389	48 %	NA
Pemazyre	1,205	—	NM	NM	1,205	—	NM	NM
Total royalty revenues	132,485	164,815	(20 %)		482,738	569,255	(15 %)	
Total net product and royalty revenues	896,700	812,853	10 %		3,229,635	2,891,267	12 %	
Milestone and contract revenues	30,000	50,000	(40 %)	(40 %)	165,000	95,000	74 %	74 %
Total GAAP revenues	$ 926,700	$ 862,853	7 %		$ 3,394,635	$ 2,986,267	14 %	

NM = not meaningful
NA = not available
[1] Percentage change in constant currency is calculated using 2021 foreign exchange rates to recalculate 2022 results.

Product and Royalty Revenues Product and royalty revenues for the quarter and year ended December 31, 2022 increased over the prior year comparative periods as a result of net product revenues increasing 18% for both periods year-over-year, primarily driven by increases in Jakafi and Opzelura net product revenues. Jakafi net product revenues for the year ended December 31, 2022 increased 13% over the prior year comparative period, primarily driven by growth in patient demand across all indications. Jakavi and Olumiant royalties for the year 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 December 31,		%	Twelve Months Ended December 31,		%
	2022	2021	Change	2022	2021	Change
GAAP cost of product revenues	$ 59,163	$ 43,874	35 %	$ 206,997	$ 150,991	37 %
Non-GAAP cost of product revenues[1]	53,022	37,886	40 %	182,737	127,749	43 %
GAAP research and development	501,360	472,827	6 %	1,585,936	1,458,179	9 %
Non-GAAP research and development[2]	469,048	442,693	6 %	1,473,420	1,343,863	10 %
GAAP selling, general and administrative	272,819	226,202	21 %	1,002,140	739,560	36 %
Non-GAAP selling, general and administrative[3]	253,209	208,718	21 %	928,960	652,604	42 %
GAAP loss on change in fair value of acquisition-related contingent consideration	24,347	1,673	1355 %	12,149	14,741	(18 %)
Non-GAAP loss on change in fair value of acquisition-related contingent consideration[4]	—	—	— %	—	—	— %
GAAP (profit) and loss sharing under collaboration agreements	(1,082)	7,543	(114 %)	7,973	37,019	(78 %)

[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 and legal settlements.
[4] Non-GAAP loss on change in fair value of acquisition-related contingent consideration is null.

Research and development expenses GAAP and Non-GAAP research and development expense for the quarter ended December 31, 2022 increased 6% and for the year ended December 31, 2022 increased 9% and 10%, respectively, compared to the same periods in 2021 primarily due to continued investment in our late stage development assets and the $70 million upfront payment made as part of the Villaris acquisition.

Selling, general and administrative expenses GAAP and Non-GAAP selling, general and administrative expenses for the quarter ended December 31, 2022 increased 21% and for the year ended December 31, 2022 increased 36% and 42%, respectively, compared to the same periods in 2021, primarily due to expenses related to our dermatology commercial organization and activities to support the launch of Opzelura for the treatments of atopic dermatitis and vitiligo.

Other Financial Information

Operating income GAAP and Non-GAAP operating income for the year ended December 31, 2022 decreased 1% and 3%, respectively, compared to the same period in 2021, primarily due to expenses related to our dermatology commercial organization and activities to support the launch of Opzelura for the treatments of atopic dermatitis and vitiligo.

Cash, cash equivalents and marketable securities position As of December 31, 2022 and 2021, cash, cash equivalents and marketable securities totaled $3.2 billion and $2.3 billion, respectively.

2023 Financial Guidance

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

[1]Pemazyre in the U.S., EU and Japan and Iclusig and Minjuvi in the EU.
[2]Adjusted 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, 13735569.

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, 13735569.

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.

About Jakafi® (ruxolitinib)
Jakafi is a first-in-class JAK1/JAK2 inhibitor approved by the U.S. FDA for treatment of chronic GVHD after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.

Jakafi is also indicated for treatment of polycythemia vera (PV) in adults who have had an inadequate response to or are intolerant of hydroxyurea, in adults with intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF and for treatment of steroid-refractory acute GVHD in adult and pediatric patients 12 years and older.

Jakafi is marketed by Incyte in the United States and by Novartis as Jakavi® (ruxolitinib) outside the United States. Jakafi is a registered trademark of Incyte Corporation. Jakavi is a registered trademark of Novartis AG in countries outside the United States.

About Opzelura™ (ruxolitinib) Cream
Opzelura, a novel cream formulation of Incyte's selective JAK1/JAK2 inhibitor ruxolitinib, is the first and only topical JAK inhibitor approved for use in the United States, indicated for the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older and 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 October 2021, Incyte announced the validation of the European Marketing Authorization Application (MAA) for ruxolitinib cream as a potential treatment for adolescents and adults (age >12 years) with non-segmental vitiligo with facial involvement.

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

Opzelura is a trademark of Incyte.

About Monjuvi®/Minjuvi® (tafasitamab)
Tafasitamab is a humanized Fc-modified cytolytic 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 approval, 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 Corporation.

[*] 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.

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 growth and diversification; Incyte's financial guidance for 2023, including its expectations regarding sales of Jakafi; expectations with regard to Incyte's NDA submission in the U.S. for once-daily ruxolitinib; expectations with respect to demand for and uptake of Opzelura, including expectations for broadening formulary coverage; the marketing authorization application for ruxolitinib cream in vitiligo under review at the European Medicines Agency; the potential for ruxolitinib cream to expand into other indications; 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; expectations regarding ongoing clinical trials and clinical trials to be initiated, including the LIMBER program, INCA33989 (mCALR) in MF and essential thrombocythemia, axatilimab in GVHD, 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; 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. 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 December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
	GAAP		GAAP	
Revenues:				
Product revenues, net	$ 764,215	$ 648,038	$ 2,746,897	$ 2,322,012
Product royalty revenues	132,485	164,815	482,738	569,255
Milestone and contract revenues	30,000	50,000	165,000	95,000
Total revenues	926,700	862,853	3,394,635	2,986,267
Costs and expenses:				
Cost of product revenues (including definite-lived intangible amortization)	59,163	43,874	206,997	150,991
Research and development	501,360	472,827	1,585,936	1,458,179
Selling, general and administrative	272,819	226,202	1,002,140	739,560
Loss on change in fair value of acquisition-related contingent consideration	24,347	1,673	12,149	14,741
(Profit) and loss sharing under collaboration agreements	(1,082)	7,543	7,973	37,019
Total costs and expenses	856,607	752,119	2,815,195	2,400,490
Income from operations	70,093	110,734	579,440	585,777
Other income (expense), net	26,637	5,716	39,932	10,647
Interest expense	(667)	(752)	(2,666)	(1,908)
Unrealized (loss) gain on long term investments	(15,448)	4,322	(87,590)	(24,072)
Income before provision (benefit) for income taxes	80,615	120,020	529,116	570,444
Provision (benefit) for income taxes	52,154	(443,831)	188,456	(378,137)
Net income	$ 28,461	$ 563,851	$ 340,660	$ 948,581
Net income per share:				
Basic	$ 0.13	$ 2.55	$ 1.53	$ 4.30
Diluted	$ 0.13	$ 2.54	$ 1.52	$ 4.27
Shares used in computing net income per share:				
Basic	222,615	220,984	222,004	220,428
Diluted	224,840	221,989	223,958	222,074

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

	December 31, 2022	December 31, 2021
ASSETS		
Cash, cash equivalents and marketable securities	$ 3,238,965	$ 2,348,192
Accounts receivable	644,879	616,300
Property and equipment, net	739,310	723,920
Finance lease right-of-use assets, net	26,298	27,548
Inventory	120,959	56,938
Prepaid expenses and other assets	194,144	165,302
Long term investments	133,676	221,266
Other intangible assets, net	129,219	150,755
Goodwill	155,593	155,593
Deferred income tax asset	457,941	467,538
Total assets	$ 5,840,984	$ 4,933,352
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 1,216,603	$ 885,081
Finance lease liabilities	33,262	34,267
Acquisition-related contingent consideration	221,000	244,000
Stockholders' equity	4,370,119	3,770,004
Total liabilities and stockholders' equity	$ 5,840,984	$ 4,933,352

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
GAAP Net Income	$ 28,461	$ 563,851	$ 340,660	$ 948,581
Adjustments[1]*:*				
Non-cash stock compensation from equity awards (R&D)[2]	32,312	30,134	112,516	114,316
Non-cash stock compensation from equity awards (SG&A)[2]	19,610	17,484	73,180	66,984
Non-cash stock compensation from equity awards (COGS)[2]	757	604	2,724	1,706
Non-cash interest[3]	143	109	431	181
Changes in fair value of equity investments[4]	15,448	(4,322)	87,590	24,072
Amortization of acquired product rights[5]	5,384	5,384	21,536	21,536
Loss on change in fair value of contingent consideration[6]	24,347	1,673	12,149	14,741
Legal settlements[7]	—	—	—	19,972
Non-operating tax adjustments[8]	—	(568,988)	—	(568,988)
Tax effect of Non-GAAP pre-tax adjustments[9]	13,199	(23,364)	(28,110)	(31,123)
Non-GAAP Net Income	$ 139,661	$ 22,565	$ 622,676	$ 611,978
Non-GAAP net income per share:				
Basic	$ 0.63	$ 0.10	$ 2.80	$ 2.78
Diluted	$ 0.62	$ 0.10	$ 2.78	$ 2.76
Shares used in computing Non-GAAP net income per share:				
Basic	222,615	220,984	222,004	220,428
Diluted	224,840	221,989	223,958	222,074

[1] Included within the Milestone and contract revenues line item in the Condensed Consolidated Statements of Operations (in thousands) for the three and twelve months ended December 31, 2022 are milestones of $30,000 and $165,000, respectively, earned from our collaborative partners, as compared to milestones of $50,000 and $95,000, respectively, for the three and twelve months ended December 31, 2021. Included within the Research and development expenses line item in the Condensed Consolidated Statements of Operations (in thousands) for the three and twelve months ended December 31, 2022 are upfront consideration and milestones of $70,000 and $125,950, respectively, related to our collaborative partners, as compared to upfront consideration and milestones of $128,152 and $148,985, respectively, for the three and twelve months ended December 31, 2021.
[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) gain 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] As included within Selling, general and administrative expenses line item in the Condensed Consolidated Statements of Operations.
[8] Included within the Provision (benefit) for income taxes line item in the Condensed Consolidated Statements of Operations is portions of the provision for income taxes that are not associated with normal, recurring operations. For the three and twelve months ended December 31, 2021 (in thousands), the company recorded a one-time non-cash benefit from income taxes of $568,988 related to the release of its valuation allowance on the majority of its U.S. deferred tax assets.
[9] Income tax effects of Non-GAAP pre-tax adjustments are calculated using the applicable statutory tax rate for the jurisdictions in which the charges are incurred, while taking into consideration any valuation allowances against related deferred tax assets. The tax benefit for the three months ended December 31, 2022 includes a true up from the interim quarters related to valuation allowances against deferred tax assets associated with the loss on equity investments.