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): October 29, 2024

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 October 29, 2024, Incyte Corporation issued a press release announcing financial results for its third fiscal quarter ended September 30, 2024. 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 October 29, 2024.
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: October 29, 2024

INCYTE CORPORATION

By: /s/ Christiana Stamoulis

Christiana Stamoulis

Executive Vice President and
Chief Financial Officer

Exhibit 99.1

FOR IMMEDIATE RELEASE

Incyte Reports 2024 Third Quarter Financial Results and Provides Updates on Key Clinical Programs

- *Total revenues of $1,138 million in the third quarter (Q3'24) (+24% Y/Y)*
- *Jakafi® (ruxolitinib) net product revenues of $741 million in Q3'24 (+16% Y/Y); raising full year 2024 Jakafi guidance to a new range of $2,740 - $2,770 million*
- *Opzelura® (ruxolitinib) cream net product revenues of $139 million in Q3'24 (+52% Y/Y); launch momentum continues in the U.S. supported by reimbursement expansion in Europe*
- *Niktimvo™ (axatilimab-csfr) approved by FDA for the treatment of chronic graft-versus-host disease after failure of at least two prior lines of systemic therapy in adult and pediatric patients*
- *Regulatory and development progress with supplemental New Drug Application (sNDA) for ruxolitinib cream in pediatric atopic dermatitis filed and positive data presented for CDK2 inhibitor, retifanlimab and tafasitamab*

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

WILMINGTON, Del. – October 29, 2024 – Incyte (Nasdaq:INCY) today reports 2024 third quarter financial results, and provides a status update on the Company's clinical development portfolio.

"In the third quarter of 2024, we delivered significant achievements, including strong revenue growth for both Jakafi® (ruxolitinib) and Opzelura® (ruxolitinib) cream, and the advancement of our clinical pipeline highlighted by the submission to the FDA of the supplemental New Drug Application (sNDA) for ruxolitinib cream in pediatric atopic dermatitis and several key data readouts including CDK2i, retifanlimab, tafasitamab, povorcitinib and ruxolitinib cream, which all hold near to mid-term launch potential. Additionally, in August, the FDA approved Niktimvo™ (axatilimab-csfr) for patients with chronic graft-versus-host disease, after failure of two prior lines of therapy, making it the first anti-CSF-1R antibody approved to target the inflammation and fibrosis associated with chronic GVHD," said Hervé Hoppenot, Chief Executive Officer, Incyte. "We are on track to achieve over ten impactful launches by 2030."

Key Recent Company Updates

- In October, the sNDA submission for ruxolitinib cream in pediatric atopic dermatitis was filed with the FDA with approval anticipated in the second half of 2025.
- In October, Opzelura was granted a Notice of Compliance by Health Canada for the topical treatment of both mild to moderate atopic dermatitis and nonsegmental vitiligo in patients 12 years of age and older.
- In September, Incyte presented late-breaking Phase 3 results for retifanlimab (Zynyz®) and initial data from the Phase 1 CDK2 inhibitor program at the 2024 European Society for Medical Oncology (ESMO) Congress.

- Featured during the Presidential Symposium, the Phase 3 POD1UM-303/InterAACT2 trial for retifanlimab met the primary endpoint of progression free survival (PFS) and demonstrated improvement across secondary endpoints in patients with squamous cell anal carcinoma (SCAC) receiving retifanlimab in combination with platinum-based chemotherapy (carboplatin-paclitaxel). Incyte plans to file a supplemental Biologics License Application (sBLA) for retifanlimab in SCAC by the end of 2024. A potential approval in 2025 could represent the first PD-(L)1 antibody for patients with SCAC.

- Phase 1 data of INCB123667, a highly selective and potentially first-in-class CDK2 inhibitor, were presented demonstrating single-agent antitumor activity across a range of doses and regimens, notably in patients with ovarian cancer and endometrial cancer whose tumors overexpress Cyclin E1. The Phase 1 trial of INCB123667 in combination with other agents is ongoing. Incyte plans to initiate a pivotal trial in ovarian cancer in 2025.

- In August, Incyte and its partner Syndax announced the U.S. Food and Drug Administration (FDA) approval of Niktimvo™ (axatilimab-csfr), an anti-CSF-1R antibody, for the treatment of chronic graft-versus-host disease (GVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric patients. Niktimvo is the first approved anti-CSF-1R antibody targeting the drivers of inflammation and fibrosis seen in chronic GVHD. In September, Incyte and Syndax announced the *New England Journal of Medicine* publication of data from the pivotal AGAVE-201 trial of Niktimvo in chronic GVHD and the addition of Niktimvo to the NCCN Clinical Practice Guidelines in Oncology for the treatment of chronic GVHD.

- In August, Incyte announced positive topline results from the Phase 3 clinical study evaluating tafasitamab (Monjuvi®) in relapsed or refractory follicular lymphoma (FL). The pivotal Phase 3 inMIND trial met the primary endpoint of PFS by investigator assessment in FL. The trial also met key secondary endpoints. No new safety signals with tafasitamab were observed. The full dataset is anticipated to be presented at an upcoming medical meeting in 2024 and Incyte expects to file an sBLA for tafasitamab in combination with lenalidomide and rituximab in FL by the end of 2024.

Jakafi:

Net product revenues for the third quarter 2024 of $741 million (+16% Y/Y):

- Net product revenues were primarily driven by patient demand, which increased 10% in the third quarter of 2024 versus the same quarter in the prior year, with growth across all indications.

Opzelura:

Net product revenues for the third quarter 2024 of $139 million (+52% Y/Y):

- Net product revenues of $119 million in the third quarter of 2024 in the U.S. were primarily driven by patient demand and refills in both atopic dermatitis (AD) and vitiligo.

- Net product revenues of $20 million in the third quarter of 2024 ex-U.S. were primarily driven by sales in Germany and France.

Additional Pipeline Updates

Myeloproliferative Neoplasms (MPNs) and Graft-Versus-Host Disease (GVHD) – key highlights

- A bioequivalence study of ruxolitinib extended-release (XR) is enrolling. The data are anticipated in the first half of 2025.

- A Phase 2 trial evaluating the safety and efficacy of axatilimab in combination with ruxolitinib in patients with newly diagnosed chronic GVHD is enrolling.

- Trials of ruxolitinib twice daily (BID) with BETi and zilurgisertib are ongoing. Additional data for BETi and zilurgisertib are anticipated in the fourth quarter of 2024.

- The Phase 1 studies evaluating mCALR and JAK2V617Fi are ongoing and enrolling patients. Initial data for both studies are anticipated in 2025.

MPN and GVHD Programs	Indication and status
Ruxolitinib XR (QD) (JAK1/JAK2)	Myelofibrosis, polycythemia vera and GVHD
Ruxolitinib + zilurgisertib (JAK1/JAK2 + ALK2i)	Myelofibrosis: Phase 2
Ruxolitinib + INCB57643 (JAK1/JAK2 + BETi)	Myelofibrosis: Phase 2
Ruxolitinib + axatilimab[1] (JAK1/JAK2 + anti-CSF-1R)	Chronic GVHD: Phase 2
Steroids + axatilimab[1] (Steroids + anti-CSF-1R)	Chronic GVHD: Phase 3 in preparation
INCA33989 (mCALR)	Myelofibrosis, essential thrombocythemia: Phase 1
INCB160058 (JAK2V617Fi)	Myelofibrosis: Phase 1

[1] Clinical development of axatilimab in GVHD conducted in collaboration with Syndax Pharmaceuticals.

Other Hematology/Oncology – key highlights

- Following the announcement of the positive topline results from the Phase 3 study evaluating retifanlimab, a humanized monoclonal antibody targeting programmed cell death receptor-1 (PD-1), in non-small cell lung cancer (NSCLC), Incyte anticipates sharing the full dataset at an upcoming medical meeting in the fourth quarter of 2024.

- The Phase 3 study evaluating tafasitamab in first-line diffuse large B-cell lymphoma (DLBCL) is ongoing. The Phase 3 data are anticipated in the first half of 2025.

- The Phase 1 studies evaluating KRASG12D and TGFßR2×PD-1 are ongoing and enrolling patients. Initial data for both studies are anticipated in 2025.

Heme/Oncology Programs	Indication and status
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): Phase 3 (*in*MIND)
Retifanlimab (Zynyz®)[1] (PD-1)	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)
INCB123667 (CDK2i)	Solid tumors with Amplification/ Overexpression of CCNE1: Phase 1
INCB161734 (KRASG12D)	Advanced metastatic solid tumors with a KRASG12D mutation: Phase 1
INCA33890 (TGFßR2×PD-1)[2]	Advanced or metastatic solid tumors: Phase 1

[1] Retifanlimab licensed from MacroGenics.
[2] Development in collaboration with Merus.

Inflammation and Autoimmunity (IAI) – key highlights

Ruxolitinib Cream

- In September 2024, Incyte presented multiple datasets for ruxolitinib cream at the 2024 European Academy of Dermatology and Venereology (EADV) Congress including late-breaking oral presentations for vitiligo, atopic dermatitis, hidradenitis suppurativa (HS) and lichen planus.

- Two Phase 3 trials (TRuE-PN1 and TRuE-PN2) evaluating ruxolitinib cream in prurigo nodularis (PN) are ongoing. The Phase 3 data are anticipated in the first half of 2025.

- The Phase 3 trial for ruxolitinib cream in mild to moderate HS is on track to initiate in the first half of 2025 following achieving alignment on the study design with FDA. Ruxolitinib cream has the potential to provide a new therapeutic option for the approximately 150,000 mild to moderate HS patients in the U.S.

Povorcitinib (INCB54707)

- In September 2024, Incyte presented long-term extension data at the 2024 EADV Congress from the Phase 2 randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of povorcitinib in patients with PN. In October 2024, two Phase 3 studies (STOP-PN1 and STOP-PN2) evaluating povorcitinib versus placebo were initiated and are enrolling.

- The Phase 3 studies of povorcitinib in patients with hidradenitis suppurativa (STOP-HS1 and STOP-HS2) are enrolling well with data anticipated in the first quarter of 2025.

- Two Phase 2 trials evaluating povorcitinib in asthma and chronic spontaneous urticaria (CSU) are enrolling. Data for CSU are anticipated in the first half of 2025 and data in asthma are anticipated in the second half of 2025.

INCB000262 (MRGPRX2)

- Three clinical studies evaluating INCB000262 in CSU (Phase 2), chronic inducible urticaria (CIndu) (Phase 1b) and atopic dermatitis (AD) (Phase 2a) are ongoing. Data for all three studies are anticipated in the first quarter of 2025.

INCB000547 (MRGPRX4)

- The phase 2 clinical study evaluating MRGPRX4 in cholestatic pruritus is ongoing with data expected in the first quarter of 2025.

IAI and Dermatology Programs	Indication and status
Ruxolitinib cream (Opzelura®)[1] (JAK1/JAK2)	Atopic dermatitis: Phase 3 pediatric study (TRuE-AD3) Hidradenitis suppurativa: Phase 2; Phase 3 expected to initiate in 2025 Prurigo nodularis: Phase 3 (TRuE-PN1, TRuE-PN2)
Povorcitinib (JAK1)	Hidradenitis suppurativa: Phase 3 (STOP-HS1, STOP-HS2) Vitiligo: Phase 3 (STOP-V1, STOP-V2) Prurigo nodularis: Phase 3 (STOP-PN1, STOP-PN2) Asthma: Phase 2 Chronic spontaneous urticaria: Phase 2
INCB000262 (MRGPRX2)	Chronic spontaneous urticaria: Phase 2 Chronic inducible urticaria: Phase 1b Atopic dermatitis: Phase 2a
INCB000547 (MRGPRX4)	Cholestatic pruritus: Phase 2a
INCA034460 (anti-CD122)	Vitiligo: Phase 1

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

Other

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

2024 Third Quarter Financial Results

The financial measures presented in this press release for the three and nine months ended September 30, 2024 and 2023 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Total GAAP revenues	$ 1,137,871	$ 919,025	$ 3,062,519	$ 2,682,308
Total GAAP operating income (loss)	146,085	214,705	(240,147)	433,255
Total Non-GAAP operating income	255,236	273,294	37,618	625,081
GAAP net income (loss)	106,456	171,269	(168,597)	396,520
Non-GAAP net income (loss)	209,651	248,719	(53,762)	556,325
GAAP basic EPS	$ 0.55	$ 0.76	$ (0.80)	$ 1.77
Non-GAAP basic EPS	$ 1.09	$ 1.11	$ (0.25)	$ 2.49
GAAP diluted EPS[1]	$ 0.54	$ 0.76	$ (0.80)	$ 1.76
Non-GAAP diluted EPS[1]	$ 1.07	$ 1.10	$ (0.25)	$ 2.46

[1] All stock options and stock awards were excluded from the diluted share calculation for the nine months ended September 30, 2024 because their effect would have been anti-dilutive, as we were in a net loss position.

Revenue Details

Revenue Details
(unaudited, in thousands)

	Three Months Ended September 30,		% Change (as reported)	% Change (constant currency)[1]	Nine Months Ended September 30,		% Change (as reported)	% Change (constant currency)[1]
	2024	2023			2024	2023		
Net product revenues:								
Jakafi	$ 741,181	$ 636,252	16 %	16 %	$ 2,018,993	$ 1,898,605	6 %	6 %
Opzelura	139,272	91,836	52 %	51 %	346,691	228,621	52 %	52 %
Iclusig	29,745	27,721	7 %	6 %	86,950	84,493	3 %	2 %
Pemazyre	20,661	18,942	9 %	9 %	58,606	62,989	(7 %)	(7 %)
Minjuvi/ Monjuvi	31,439	8,348	277 %	276 %	86,429	28,063	208 %	208 %
Zynyz	694	98	608 %	608 %	1,812	668	171 %	171 %
Total net product revenues	962,992	783,197	23 %	23 %	2,599,481	2,303,439	13 %	13 %
Royalty revenues:								
Jakavi	115,741	96,551	20 %	20 %	304,653	263,691	16 %	16 %
Olumiant	34,796	29,615	17 %	22 %	97,087	95,779	1 %	5 %
Tabrecta	5,928	4,139	43 %	NA	16,460	13,115	26 %	NA
Pemazyre	414	523	(21 %)	NM	1,838	1,284	43 %	NM
Total royalty revenues	156,879	130,828	20 %		420,038	373,869	12 %	
Total net product and royalty revenues	1,119,871	914,025	23 %		3,019,519	2,677,308	13 %	
Milestone and contract revenues	18,000	5,000	260 %	260 %	43,000	5,000	760 %	760 %
Total GAAP revenues	$ 1,137,871	$ 919,025	24 %		$ 3,062,519	$ 2,682,308	14 %	

NM = not meaningful
NA = not applicable
[1] Percentage change in constant currency is calculated using 2023 foreign exchange rates to recalculate 2024 results.

Product and Royalty Revenues Total net product and royalty revenues for the quarter and nine months ended September 30, 2024 increased 23% and 13%, respectively, over the prior year comparative periods, primarily driven by the following:

- For the quarter ended September 30, 2024, Jakafi net product revenue increased 16% primarily driven by a 10% increase in total demand. Channel inventory at the end of the third quarter of 2024 was within the normal range. For the nine months ended September 30, 2024, Jakafi net product revenue increased 6% primarily driven by a 7% increase in total demand.

- For the quarter and nine months ended September 30, 2024, Opzelura net product revenue increased 52% due to continued growth in new patient starts and refills in the U.S. and increased contribution from Europe, driven by continued uptake in Germany and the launch in France.

- For the quarter and nine months ended September 30, 2024, Minjuvi/Monjuvi net product revenue increased 277% and 208%, respectively, following the acquisition of the exclusive global rights to tafasitamab in February 2024.

- For the quarter ended September 30, 2024, total royalty revenues grew by 20%, driven by 20% and 17% growth in Jakavi and Olumiant royalty revenues, respectively. For the nine months ended September 30, 2024, total royalty revenues grew by 12%, driven primarily by 16% growth in Jakavi royalty revenues.

Operating Expenses

Operating Expense Summary
(unaudited, in thousands)

	Three Months Ended September 30,		%	Nine Months Ended September 30,		%
	2024	2023	Change	2024	2023	Change
GAAP cost of product revenues	$ 85,993	$ 60,091	43 %	$ 223,583	$ 185,239	21 %
Non-GAAP cost of product revenues[1]	79,981	53,914	48 %	205,839	166,733	23 %
GAAP research and development	573,174	375,709	53 %	2,140,814	1,183,100	81 %
Non-GAAP research and development[2]	525,343	348,868	51 %	2,002,870	1,092,409	83 %
GAAP selling, general and administrative	309,209	267,893	15 %	915,447	867,428	6 %
Non-GAAP selling, general and administrative[3]	277,311	241,896	15 %	817,217	798,943	2 %
GAAP loss (gain) on change in fair value of acquisition-related contingent consideration	23,410	(426)	(5595 %)	23,847	14,144	69 %
Non-GAAP loss (gain) on change in fair value of acquisition-related contingent consideration[4]	—	—	— %	—	—	— %
GAAP loss and (profit) sharing under collaboration agreements	—	1,053	— %	(1,025)	(858)	19 %

[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, MorphoSys transition costs, and Escient acquisition related compensation expense related to cash settled unvested Escient equity awards and severance payments.
[3] Non-GAAP selling, general and administrative expenses exclude the cost of stock-based compensation, MorphoSys transition costs, Escient acquisition related compensation expense related to cash settled unvested Escient equity awards and severance payments, and asset impairments.
[4] Non-GAAP (gain) 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 the quarter and nine months ended September 30, 2024 increased 43% and 48%, and 21% and 23%, respectively, compared to the same periods in 2023 primarily due to growth in net product revenues, increased royalty expense and increased manufacturing related costs.

Research and development expenses GAAP and Non-GAAP research and development expense for the quarter ended September 30, 2024 increased 53% and 51%, respectively, compared to the same period in 2023 primarily due to the $100.0 million milestone payment made to MacroGenics during the third quarter of 2024 and continued investment in our late stage development assets. Excluding upfront and milestone payments and Escient severance payments, research and development expense for the quarter ended September 30, 2024 increased 26% compared to the same period in 2023 due to continued investment in our late stage development assets, additional expenses resulting from the Escient acquisition, and timing of certain expenses. For the nine months ended September 30, 2024, excluding upfront and milestone payments and the Escient acquisition related compensation expense and severance payments, research and development expense increased 15% compared to the same period in 2023 due to continued investment in our late stage development assets, additional expenses resulting from the Escient acquisition, and timing of certain expenses.

Selling, general and administrative expenses GAAP and Non-GAAP selling, general and administrative expenses for the quarter ended September 30, 2024 increased 15% compared to the same period in 2023 primarily due to timing of consumer marketing activities and of certain other expenses.

GAAP and Non-GAAP selling, general and administrative expenses for the nine months ended September 30, 2024 increased 6% and 2%, respectively, compared to the same period in 2023 primarily due to $22.0 million of Escient acquisition related compensation expense including severance payments and timing of consumer marketing activities and of certain other expenses. Excluding the Escient acquisition related compensation expense and severance payments, selling, general and administrative expenses for the nine months ended September 30, 2024 increased 3% compared to the same period in 2023.

Other Financial Information

Change in fair value of acquisition-related contingent consideration The change in fair value of contingent consideration during the quarter ended September 30, 2024, compared to the same period in 2023, was primarily due to fluctuations in foreign currency exchange rates impacting future revenue projections of Iclusig.

Operating income GAAP and Non-GAAP operating income for the three months ended September 30, 2024 decreased 32% and 7%, respectively, compared to the same period in 2023, driven primarily by the $100.0 million milestone payment made to MacroGenics during the third quarter of 2024. Excluding upfront and milestone payments and Escient severance payments, operating income for the three months ended September 30, 2024 increased 14% compared to the same period in 2023 primarily driven by growth in net product revenue.

GAAP and Non-GAAP operating income for the nine months ended September 30, 2024 decreased 155% and 94%, respectively, compared to the same period in 2023, driven primarily by the $679.4 million of expense relating to the IPR&D assets acquired in the Escient acquisition, $36.3 million of Escient acquisition related compensation expense and severance payments, and the $100.0 million milestone payment made to MacroGenics during the third quarter of 2024. Excluding upfront and milestone payments and the Escient acquisition related compensation expense and severance payments, operating income for the nine months ended September 30, 2024 increased 29% compared to the same period in 2023 primarily driven by growth in net product revenue.

Cash, cash equivalents and marketable securities position As of September 30, 2024 and December 31, 2023, cash, cash equivalents and marketable securities totaled $1.8 billion and $3.7 billion, respectively. The decrease in cash, cash equivalents and marketable securities during 2024 was driven primarily by the $2.0 billion share repurchase completed during June 2024, and the total cash consideration paid to Escient shareholders of $783 million, partially offset by proceeds of sales of equity investments during the nine months ended September 30, 2024.

2024 Financial Guidance

Incyte is raising its full year 2024 Jakafi revenue guidance, as well as updating its full year 2024 Other Hematology/Oncology revenue guidance. In addition, Incyte is updating the full year research and development guidance to include the $100 million milestone payment to MacroGenics. The full year GAAP and Non-GAAP research and development guidance now includes $791 million in one-time expenses related to the $691 million of upfront consideration recorded for the acquisition of Escient Pharmaceuticals and the $100 million milestone payment to MacroGenics. Incyte is also maintaining its full year 2024 cost of product revenue and selling general and administrative guidance. Incyte's guidance is summarized below. The guidance does not include revenue from any potential new product launches or the impact of one-time items and any potential future strategic transactions.

	Current	Previous
Jakafi net product revenues	$2,740 - $2,770 million	$2,710 - $2,750 million
Other Hematology/Oncology net product revenues[(1)]	$310 - $320 million	$325 - $360 million
GAAP Cost of product revenues	Unchanged	7 – 8% of net product revenues
Non-GAAP Cost of product revenues[(2)]	Unchanged	6 – 7% of net product revenues
GAAP Research and development expenses	$2,545 - $2,590 million	$2,445 - $2,490 million
Non-GAAP Research and development expenses[(3)]	$2,395 - $2,435 million	$2,295 - $2,335 million
GAAP Selling, general and administrative expenses	Unchanged	$1,210 - $1,240 million
Non-GAAP Selling, general and administrative expenses[(3)]	Unchanged	$1,115 - $1,140 million

[1]Pemazyre in the U.S., EU and Japan; Monjuvi and Zynyz in the U.S.; 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 and Escient acquisition related 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, 13749146.

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, 13749146.

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

About Incyte
A global biopharmaceutical company on a mission to *Solve On*., Incyte follows the science to find solutions for patients with unmet medical needs. Through the discovery, development and commercialization of proprietary therapeutics, Incyte has established a portfolio of first-in-class medicines for patients and a strong pipeline of products in Oncology and Inflammation & Autoimmunity. Headquartered in Wilmington, Delaware, Incyte has operations in North America, Europe and Asia.

For additional information on Incyte, please visit Incyte.com or follow us on social media: LinkedIn, X, Instagram, Facebook, YouTube.

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
Opzelura® (ruxolitinib) Cream, 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® (tafasitamab-cxix)
Monjuvi® (tafasitamab-cxix) is a humanized Fc-modified cytolytic CD19 targeting monoclonal antibody. 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). MorphoSys and Incyte entered into: (a) in January 2020, a collaboration and licensing agreement to develop and commercialize tafasitamab globally; and (b) in February 2024, an agreement whereby Incyte obtained exclusive rights to develop and commercialize tafasitamab globally.

Following accelerated approval by the U.S. Food and Drug Administration in July 2020, Monjuvi® (tafasitamab-cxix) is being commercialized in the United States by Incyte. In Europe, Minjuvi® (tafasitamab) received conditional Marketing Authorization from the European Medicines Agency in August 2021.

XmAb® is a registered trademark of Xencor, Inc.

Monjuvi, Minjuvi, the Minjuvi and Monjuvi logos and the “triangle” design are (registered) trademarks of Incyte.

About Pemazyre® (pemigatinib)
Pemazyre® (pemigatinib) 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
Iclusig® (ponatinib) 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) 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 press 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 2024, including its expectations regarding sales of Jakafi; expectations regarding demand for and sales of Opzelura, among other products; expectations regarding reimbursement for Opzelura in Europe; expectations regarding the potential and progress of our pipeline, including expectations for ruxolitinib cream, ruxolitinib extended-release (XR), povorcitinib, INCB000262, INCB000547, axatilimab, mCALR, JAK2V617Fi, retifanlimab, tafasitamab, INCB123667, BETi, zilurgisertib, KRASG12D and our TGFβ program; Incyte's ability to develop new transformative therapies to treat myeloid disease and cure MPNs; expectations regarding ongoing clinical trials and clinical trials to be initiated; expectations regarding data flow/readouts; expectations regarding regulatory filings, potential regulatory approvals and potential product launches; and expectations regarding 2024 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 possibility that results of clinical trials will be negative and/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; determinations made by 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 supply of and/or 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 quarterly report on form 10-Q for the quarter ended June 30, 2024. 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	GAAP		GAAP	
Revenues:				
Product revenues, net	$ 962,992	$ 783,197	$ 2,599,481	$ 2,303,439
Product royalty revenues	156,879	130,828	420,038	373,869
Milestone and contract revenues	18,000	5,000	43,000	5,000
Total revenues	1,137,871	919,025	3,062,519	2,682,308
Costs, expenses and other:				
Cost of product revenues (including definite-lived intangible amortization)	85,993	60,091	223,583	185,239
Research and development	573,174	375,709	2,140,814	1,183,100
Selling, general and administrative	309,209	267,893	915,447	867,428
Loss (gain) on change in fair value of acquisition-related contingent consideration	23,410	(426)	23,847	14,144
Loss and (profit) sharing under collaboration agreements	—	1,053	(1,025)	(858)
Total costs, expenses and other	991,786	704,320	3,302,666	2,249,053
Income (loss) from operations	146,085	214,705	(240,147)	433,255
Interest income and other, net	24,195	46,371	118,708	121,912
Interest expense	(774)	(623)	(1,861)	(1,747)
Realized and unrealized (loss) gain on equity investments	(12,982)	(26,654)	126,206	9,839
Income before provision for income taxes	156,524	233,799	2,906	563,259
Provision for income taxes	50,068	62,530	171,503	166,739
Net income (loss)	$ 106,456	$ 171,269	$ (168,597)	$ 396,520
Net income (loss) per share:				
Basic	$ 0.55	$ 0.76	$ (0.80)	$ 1.77
Diluted	$ 0.54	$ 0.76	$ (0.80)	$ 1.76
Shares used in computing net income (loss) per share:				
Basic	192,629	224,078	211,763	223,428
Diluted	195,838	226,167	211,763	225,756

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

	September 30, 2024	December 31, 2023
ASSETS		
Cash, cash equivalents and marketable securities	$ 1,771,344	$ 3,656,043
Accounts receivable	758,450	743,557
Property and equipment, net	773,102	751,513
Finance lease right-of-use assets, net	25,072	25,535
Inventory	368,416	269,937
Prepaid expenses and other assets	247,243	236,782
Short and long term equity investments	30,910	187,716
Other intangible assets, net	119,994	123,545
Goodwill	155,593	155,593
Deferred income tax asset	762,310	631,886
Total assets	$ 5,012,434	$ 6,782,107
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 1,602,059	$ 1,347,669
Finance lease liabilities	32,155	32,601
Acquisition-related contingent consideration	207,000	212,000
Stockholders' equity	3,171,220	5,189,837
Total liabilities and stockholders' equity	$ 5,012,434	$ 6,782,107

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
GAAP Net Income (Loss)	$ 106,456	$ 171,269	$ (168,597)	$ 396,520
Adjustments[1]*:*				
Non-cash stock compensation from equity awards (R&D)[2]	45,808	26,841	117,141	90,691
Non-cash stock compensation from equity awards (SG&A)[2]	31,486	20,366	75,607	62,854
Non-cash stock compensation from equity awards (COGS)[2]	628	793	1,592	2,354
Non-cash interest[3]	81	108	333	355
Realized and unrealized gain on equity investments[4]	12,982	26,654	(126,206)	(9,839)
Amortization of acquired product rights[5]	5,384	5,384	16,152	16,152
Loss (gain) on change in fair value of contingent consideration[6]	23,410	(426)	23,847	14,144
Asset impairment[7]	—	5,631	—	5,631
MorphoSys transition costs[8]	132	—	7,084	—
Escient acquisition related compensation expense[9]	2,303	—	36,342	—
Tax effect of Non-GAAP pre-tax adjustments[10]	(19,019)	(7,901)	(37,057)	(22,537)
Non-GAAP Net Income (Loss)	$ 209,651	$ 248,719	$ (53,762)	$ 556,325
Non-GAAP net income (loss) per share:				
Basic	$ 1.09	$ 1.11	$ (0.25)	$ 2.49
Diluted[11]	$ 1.07	$ 1.10	$ (0.25)	$ 2.46
Shares used in computing Non-GAAP net income (loss) per share:				
Basic	192,629	224,078	211,763	223,428
Diluted[11]	195,838	226,167	211,763	225,756

[1] Included within the Milestone and contract revenues line item in the Condensed Consolidated Statements of Operations (in thousands) for the three and nine months ended September 30, 2024 are milestones of $18,000 and $43,000, respectively, earned from our collaborative partners, as compared to $5,000 of milestones earned for both the three and nine months ended September 30, 2023. Included within the Research and development expenses line item in the Condensed Consolidated Statements of Operations (in thousands) for the three and nine months ended September 30, 2024 are upfront consideration and milestones of $100,000 and $101,414, respectively, related to our collaborative partners as compared to upfront consideration and milestones of $2,950 and $12,650, respectively, for the three and nine months ended September 30, 2023.

[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 Realized and unrealized gain on equity 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 (gain) on change in fair value of acquisition-related contingent consideration line item in the Condensed Consolidated Statements of Operations.

[7] As included within the Selling, general and administrative expenses line item in the Condensed Consolidated Statements of Operations.

[8] Included within the Research and development line item in the Condensed Consolidated Statements of Operations (in thousands) is $226 and $6,489 for the three and nine months ended September 30, 2024, respectively, and included within the Selling, general and administrative expenses line item in the Condensed Consolidated Statements of Operations (in thousands) is a benefit of $94 and expense of $595 for the three and nine months ended September 30, 2024, respectively. MorphoSys transition costs primarily represent employee related costs to transition research and development and selling, general and administrative activities to us under the former collaboration agreement with MorphoSys.

[9] Included within the Research and development line item in the Condensed Consolidated Statements of Operations (in thousands) is $1,797 and $14,314, respectively, for the three and nine months ended September 30, 2024, and included within the Selling, general and administrative expenses line item in the Condensed Consolidated Statements of Operations (in thousands) is $506 and $22,028, respectively, for the three and nine months ended September 30, 2024. Escient acquisition related compensation expense represents non-recurring charges associated with (i) cash settled unvested Escient equity awards in connection with the acquisition, and (ii) severance payments to former Escient employees.

[10] 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.

[11] All stock options and stock awards were excluded from the diluted share calculation for the nine months ended September 30, 2024 because their effect would have been anti-dilutive, as we were in a Non-GAAP net loss position.