Incyte Reports Third Quarter 2025 Financial Results and Provides Business Updates

October 28, 2025

Total revenues of $1.37 billion in the third quarter of 2025, reflecting 20% growth compared to the third quarter of 2024

Jakafi® (ruxolitinib) net product revenue of $791 million, an increase of 7% compared to the same period in 2024

Opzelura® (ruxolitinib) cream net product revenue of $188 million, an increase of 35% compared to the prior year period

Hematology-Oncology portfolio net product revenues of $171 million, including Niktimvo ™ (axatilimab-csfr) net revenue of $46 million

Raises 2025 full year net product revenue guidance to $4.23 - $4.32 billion

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

WILMINGTON, Del.--(BUSINESS WIRE)--Oct. 28, 2025-- Incyte (Nasdaq:INCY) today reported financial results for the third quarter of 2025 and provided a business update.

“Our third-quarter results demonstrate strong growth across our product portfolio, with net product revenues increasing 19% year-over-year, which highlights the momentum in our business and effective commercial execution,” said Bill Meury, President and Chief Executive Officer, Incyte. “We are taking a deliberate approach to pipeline prioritization. We are actively reviewing our R&D efforts and focusing on high-value programs that are scientifically differentiated, address unmet medical needs, and have the potential to significantly drive Incyte’s next phase of growth."

Third Quarter 2025 Results

- **Total revenues:** Total revenues were $1.37 billion, an increase of 20% compared to the third quarter of 2024, primarily driven by an increase in total net product revenues. Total net product revenue for the third quarter of 2025 was $1.15 billion, an increase of 19%. The increase was primarily related to patient demand for Jakafi® (ruxolitinib) across all indications and strong uptake of the initial launch of Niktimvo ™ (axatilimab-csfr).
- **Cost of product revenues:** GAAP and non-GAAP cost of product revenues were $99.0 million and $92.7 million, an increase of 15% and 16%, respectively, compared to the prior year period.
- **Research and development (R&D) expenses:** GAAP and non-GAAP R&D expenses were $506.6 million and $467.0 million, a decrease of 12% and 11%, respectively, compared to the prior year period.
- **Selling, general and administrative (SG&A) expenses:** GAAP and non-GAAP SG&A expenses were $329.1 million and $308.0 million, an increase of 6% and 11%, respectively, compared to the prior year period.
- **Cash, cash equivalents and marketable securities position:** As of September 30, 2025 and December 31, 2024, cash, cash equivalents and marketable securities totaled $2.9 billion and $2.2 billion, respectively.

Full-year 2025 Financial Guidance

- The Company is raising its full-year 2025 net product revenue guidance to $4.23 - $4.32 billion to account for higher demand for Jakafi and other hematology and oncology marketed products. The update includes raised guidance for Jakafi to $3.050 - $3.075 billion, as well as other hematology and oncology marketed products to $550 - $575 million. The Opzelura® (ruxolitinib) cream revenue guidance of $630 - $670 million is maintained.
- The Company reiterates its guidance for GAAP and non-GAAP cost of product revenues, R&D, and SG&A expenses for full year 2025, which reflects the continued investment in mid- and late-stage clinical development programs and commercial capabilities.

Key Business Updates

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

- The Company is on track to submit ruxolitinib extended-release (XR) bioequivalence data to the U.S. Food and Drug Administration (FDA) in the fourth quarter.
- Results from the Phase 1 trial evaluating INCA033989, an investigational mutant calreticulin (mutCALR) selective monoclonal antibody, in mutCALR positive patients with myelofibrosis (MF) are expected in the second half of 2025. The Phase 1 results will include safety and efficacy data evaluating INCA033989 as a monotherapy in patients who are resistant, refractory or intolerant to JAK inhibitor treatment, as well as data evaluating INCA033989 as a combination therapy with ruxolitinib in patients who are exhibiting a suboptimal response to ruxolitinib monotherapy.

Hematology/Oncology

- In October, results from the Phase 1 trial evaluating INCA33890 (TGFBR2xPD-1 bispecific antibody) in solid tumors were presented at the European Society for Medical Oncology (ESMO) Congress. In the trial, INCA33890 demonstrated a manageable tolerability profile and clinical efficacy across multiple tumors, including microsatellite stable colorectal cancer (MSS CRC) patients with and without active liver metastases. Based on these initial findings, the Company plans to initiate a registrational program evaluating INCA33890 in MSS CRC in 2026.
- Preliminary results from the Phase 1 trial evaluating INCB161734 ($KRAS^{G12D}$ selective inhibitor) were presented at the ESMO Congress in October. In the trial, INCB161734 demonstrated a manageable safety profile and clinical efficacy in heavily pretreated pancreatic ductal adenocarcinoma (PDAC) patients with a $KRAS^{G12D}$ mutation. Evaluation of INCB161734 in PDAC patients as a monotherapy, and in combination with chemotherapy, is ongoing and will support potential future development efforts.
- A Phase 2 trial evaluating INCB123667 (CDK2i) in patients with platinum-resistant ovarian cancer (PROC) with Cyclin E1 overexpression was initiated in the third quarter.
- The Phase 3 study evaluating tafasitamab (Monjuvi®) as first-line treatment for diffuse large B-cell lymphoma (DLBCL) is ongoing, with data anticipated around year-end 2025.

Inflammation and Autoimmunity (IAI)

Ruxolitinib cream

- In September, the FDA approved the supplemental New Drug Application (sNDA) for Opzelura for pediatric atopic dermatitis (AD). Opzelura is now indicated for the short-term and non-continuous chronic treatment of mild to moderate AD in non-immunocompromised adult and pediatric patients two years of age and older whose disease is not well controlled with topical prescription therapies, or when those therapies are not recommended.
- In October, Phase 3 results from the TRuE-AD4 trial evaluating Opzelura in patients with moderate AD were presented at the International Symposium on Atopic Dermatitis (ISAD). Results from the study demonstrated that by Week 8, treatment with Opzelura significantly improved the clinical signs of AD, rapidly improved itch, improved quality of life measures and was well tolerated in adults with moderate AD who had an inadequate response, intolerance or contraindication to topical corticosteroid (TCS)s and topical calcineurin inhibitor (TCI)s.
- The Company anticipates filing a Type-II variation application for ruxolitinib cream 1.5% for the treatment of adults with moderate AD in the European Union (EU) by year-end 2025.

Povorcitinib

- In September, longer-term data for povorcitinib were presented at the European Association of Dermatology and Venereology (EADV) which demonstrated continued clinically meaningful and statistically significant improvements in patients with active moderate to severe hidradenitis suppurativa (HS).
- Regulatory submissions for povorcitinib in moderate to severe HS in the EU and the U.S. are anticipated by year end 2025 and early 2026, respectively.
- Data from the Phase 3 studies evaluating povorcitinib in prurigo nodularis (PN) and vitiligo, as well as data from the Phase 2 proof-of-concept trial in asthma, are anticipated in 2026.

Corporate and Business Development Updates

- The Company strengthened its executive leadership team through the appointment of Soni Basi as Executive Vice President and Chief Human Resources Officer and Dave Gardner as Executive Vice President and Chief Strategy Officer in the third quarter.
- Based on ongoing pipeline prioritization efforts, the Company has paused further development of the INCA034460 (anti-CD122) and INCB57643 (BET inhibitor) programs, as well as the development of povorcitinib in chronic spontaneous urticaria (CSU).
- The Company announced a strategic partnership with Enable Injections, Inc., to develop and commercialize specific assets in Incyte's portfolio, including INCA033989, with Enable's enFuse ® on-body delivery system. Under the terms of the agreement, Incyte will obtain a worldwide, exclusive license to use the enFuse technology with INCA033989 in essential thrombocythemia (ET) and MF, with the potential to expand to additional assets and indications.

2025 Third Quarter Financial Results

The financial measures presented in this press release for the three and nine months ended September 30, 2025 and 2024 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,	
	2025	2024	2025	2024
Total GAAP revenues	$ 1,365,980	$ 1,137,871	$ 3,634,407	$ 3,062,519
Total GAAP operating income (loss)	443,518	146,085	1,179,000	(240,147)
Total Non-GAAP operating income	498,296	255,236	1,164,516	37,618
GAAP net income (loss)	424,169	106,456	987,371	(168,597)
Non-GAAP net income (loss)	455,972	209,651	997,358	(53,762)
GAAP basic EPS	$ 2.17	$ 0.55	$ 5.08	$ (0.80)
Non-GAAP basic EPS	$ 2.33	$ 1.09	$ 5.13	$ (0.25)
GAAP diluted EPS[1]	$ 2.11	$ 0.54	$ 4.95	$ (0.80)
Non-GAAP diluted EPS[1]	$ 2.26	$ 1.07	$ 5.00	$ (0.25)

[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]
	2025	2024			2025	2024		
Net product revenues:								
Jakafi	$ 791,071	$ 741,181	7%	NA	$ 2,264,271	$ 2,018,993	12%	NA
Opzelura	187,968	139,272	35%	33%	471,172	346,691	36%	35%
Iclusig	37,582	29,745	26%	19%	99,855	86,950	15%	11%
Pemazyre	22,741	20,661	10%	9%	63,373	58,606	8%	8%
Minjuvi/ Monjuvi	41,990	31,439	34%	32%	102,672	86,429	19%	18%
Niktimvo	45,830	—	NM	NA	95,597	—	NM	NA
Zynyz	22,674	694	3,167%	NA	34,604	1,812	1,810%	NA
Total net product revenues	1,149,856	962,992	19%	19%	3,131,544	2,599,481	20%	20%
Royalty revenues:								
Jakavi	125,645	115,741	9%	4%	327,504	304,653	8%	5%
Olumiant	37,111	34,796	7%	4%	101,393	97,087	4%	5%
Tabrecta	6,513	5,928	10%	NA	19,558	16,460	19%	NA
Other	1,855	414	348%	NA	4,408	1,838	140%	NA
Total royalty revenues	171,124	156,879	9%		452,863	420,038	8%	
Total net product and royalty revenues	1,320,980	1,119,871	18%		3,584,407	3,019,519	19%	
Milestone and contract revenues	45,000	18,000	150%	150%	50,000	43,000	16%	16%
Total GAAP revenues	$ 1,365,980	$ 1,137,871	20%		$ 3,634,407	$ 3,062,519	19%	

NM = not meaningful
NA = not applicable
[1] Percentage change in constant currency is calculated using 2024 foreign exchange rates to recalculate 2025 results.

Product and Royalty Revenues Total net product revenues for the quarter ended September 30, 2025 increased 19% over the prior year comparative period.

- Jakafi net product revenue increased 7% in the third quarter of 2025 versus the prior year comparable period to $791 million, primarily driven by a 10% increase in paid demand across all indications. Jakafi inventory levels were within normal range at the end of the third quarter of 2025.
- Opzelura net product revenue increased 35% in the third quarter of 2025 versus the prior year comparable period to $188 million driven by increased patient demand and refills in both atopic dermatitis (AD) and vitiligo. Opzelura inventory levels were within normal range at the end of the third quarter of 2025.
- Niktimvo net product revenue increased 27% versus the second quarter of 2025 to $46 million driven by strong uptake following the product launch in the first quarter of 2025.
- Total net product and royalty revenues for the quarter ended September 30, 2025 increased 18% over the prior year comparative period.

Operating Expenses

Operating Expense Summary
(unaudited, in thousands)

	Three Months Ended September 30,		%	Nine Months Ended September 30,		%
	2025	2024	Change	2025	2024	Change
GAAP cost of product revenues	$ 99,001	$ 85,993	15%	$ 250,955	$ 223,583	12%
Non-GAAP cost of product revenues[1]	92,694	79,981	16%	232,183	205,839	13%
Contract dispute settlement	—	—	NM	(242,251)	—	NM
Non-GAAP contract dispute settlement[2]	—	—	NM	—	—	NM
GAAP research and development	506,584	573,174	(12%)	1,438,780	2,140,814	(33%)
Non-GAAP research and development[3]	466,950	525,343	(11%)	1,322,605	2,002,870	(34%)
GAAP selling, general and administrative	329,081	309,209	6%	985,794	915,447	8%
Non-GAAP selling, general and administrative[4]	308,040	277,311	11%	915,103	817,217	12%
GAAP (gain) loss on change in fair value of acquisition-related contingent consideration	(12,204)	23,410	NM	22,129	23,847	NM
Non-GAAP (gain) loss on change in fair value of acquisition-related contingent consideration	—	—	NM	—	—	NM
GAAP (profit) and loss sharing under collaboration agreements	—	—	NM	—	(1,025)	NM

NM = not meaningful

[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 contract dispute settlement excludes the contract dispute settlement reached with Novartis.
[3] 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.
[4] Non-GAAP selling, general and administrative 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.

Cost of product revenues GAAP and Non-GAAP cost of product revenues for the quarter ended September 30, 2025 were $99.0 million and $92.7 million, an increase of 15% and 16%, respectively, compared to the same period in 2024, primarily driven by growth in net product revenues, the Niktimvo profit share and increased manufacturing related costs, partially offset by the impact of the contract dispute settlement with Novartis.

Research and development expenses GAAP and Non-GAAP research and development expenses for the quarter ended September 30, 2025 were $506.6 million and $467.0 million, a decrease of 12% and 11%, respectively, compared to the same period in 2024, primarily due to the $100 million milestone payment made to MacroGenics during the third quarter of 2024. Excluding upfront and milestone payments and Escient severance payments, research and development expenses for the quarter ended September 30, 2025 increased 7% compared to the same period in 2024 primarily driven by continued investment in our late stage development assets.

Selling, general and administrative expenses GAAP and Non-GAAP selling, general and administrative expenses for the quarter ended September 30, 2025 were $329.1 million and $308.0 million, an increase of 6% and 11%, respectively, compared to the same period in 2024, primarily due to international marketing activities to support product launches.

Other Financial Information

Contract dispute settlement In May 2025, Incyte and Novartis entered into a settlement agreement with respect to litigation relating to the duration of royalty payments owed under the Collaboration and License Agreement between Incyte and Novartis. We recorded $242.2 million in contract dispute settlement on the condensed consolidated statement of operations for the nine months ended September 30, 2025, representing the difference between the accrued royalties and the total amount paid by us to Novartis.

Change in fair value of acquisition-related contingent consideration The change in fair value of contingent consideration during the quarter ended September 30, 2025, compared to the same period in 2024, was primarily due to updated projections of future net revenues of Iclusig, including the impacts from fluctuations in foreign currency exchange rates.

Operating income GAAP and Non-GAAP operating income for the quarter ended September 30, 2025 increased 204% and 95%, respectively, compared to the same period in 2024, driven primarily by growth in net product revenues and the $100 million milestone payment made to MacroGenics during the third quarter of 2024.

Cash, cash equivalents and marketable securities position As of September 30, 2025 and December 31, 2024, cash, cash equivalents and marketable securities totaled $2.9 billion and $2.2 billion, respectively.

2025 Financial Guidance

Incyte's guidance for the fiscal year 2025 is summarized below. Incyte is raising its full year 2025 net product revenue guidance to $4.23 - $4.32 billion to account for higher demand for Jakafi and other hematology and oncology marketed products. The update includes raised guidance for Jakafi to $3.050 - $3.075 billion, as well as other hematology and oncology marketed products to $550 - $575 million. Incyte is reaffirming its guidance across all other categories.

	Current	Previous
Jakafi net product revenues	$3,050 - $3,075 million	$3,000 - $3,050 million
Opzelura net product revenues	Unchanged	$630 - $670 million
Other oncology net product revenues[(1)]	$550 - $575 million	$500 - $520 million
GAAP Cost of product revenues	Unchanged	8.0% - 9.0% of net product revenues
Non-GAAP Cost of product revenues[(2)]	Unchanged	7.0% - 8.0% of net product revenues
GAAP Research and development expenses	Unchanged	$1,965 - $1,995 million
Non-GAAP Research and development expenses[(3)]	Unchanged	$1,815 - $1,840 million
GAAP Selling, general and administrative expenses	Unchanged	$1,280 - $1,310 million
Non-GAAP Selling, general and administrative expenses[(3)]	Unchanged	$1,160 - $1,185 million

[1]Pemazyre in the U.S., EU and Japan; Niktimvo, 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.

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, 13756261.

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, 13756261.

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's unique expertise in medicinal chemistry and biology has enabled us to establish 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 the 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. FDA 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 AD in non-immunocompromised patients 2 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. 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). Incyte licenses exclusive worldwide rights to develop and commercialize tafasitamab from Xencor, Inc.

In the U.S., Monjuvi is approved by the U.S. FDA in combination with lenalidomide and rituximab for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL).

Monjuvi is not indicated and is not recommended for the treatment of patients with relapsed or refractory marginal zone lymphoma outside of controlled clinical trials.

Additionally, Monjuvi received accelerated approval in the United States in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT). In Europe, Minjuvi® (tafasitamab) received conditional Marketing Authorization from the European Medicines Agency in combination with lenalidomide, followed by Minjuvi monotherapy, for the treatment of adult patients with relapsed or refractory DLBCL who are not eligible for ASCT.

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 an 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 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 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.

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 tyrosine kinase inhibitors.

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 a humanized monoclonal antibody targeting programmed death receptor-1 (PD-1), indicated in combination with carboplatin and paclitaxel (platinum-based chemotherapy) for the first-line treatment of adult patients with inoperable locally recurrent or metastatic SCAC and as a single agent for the treatment of adult patients with locally recurrent or metastatic SCAC with disease progression or intolerance to platinum-based chemotherapy in the U.S.

Zynyz is also indicated for the treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC) in the U.S. 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 United States. In 2017, Incyte entered into an exclusive collaboration and license agreement with MacroGenics, Inc. for global rights to retifanlimab.

Zynyz is a registered trademark of Incyte.

About Niktimvo™ (axatilimab-csfr)

Niktimvo™ (axatilimab-csfr) is a first-in-class colony stimulating factor-1 receptor (CSF-1R)-blocking antibody approved for use in the U.S. for the treatment of chronic GVHD after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg (88.2 lbs).

In 2016, Syndax licensed exclusive worldwide rights to develop and commercialize axatilimab from UCB. In September 2021, Syndax and Incyte entered into an exclusive worldwide co-development and co-commercialization license agreement for axatilimab in chronic GVHD and any future indications.

Axatilimab is being studied in frontline combination trials in chronic GVHD – a Phase 2 combination trial with ruxolitinib (NCT06388564) and a Phase 3 combination trial with steroids (NCT06585774) are underway. Axatilimab is also being studied in an ongoing Phase 2 trial in patients with idiopathic pulmonary fibrosis (NCT06132256).

Niktimvo is a trademark of Incyte.

All other trademarks are the property of their respective owners.

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 strategic priorities and its plans for executing on same; Incyte's financial guidance for 2025, including its expectations regarding sales of and demand for Jakafi and Opzelura; expected revenue contribution from Niktimvo and other hematology and oncology products; Incyte's potential for continued performance and growth; expectations regarding regulatory submissions, approvals and launches of ruxolitinib XR, ruxolitinib cream in Europe and povorcitinib; the potential and progress of programs in our pipeline, including povorcitinib, our TGFBR2xPD1 bispecific (INCA33890), our KRASG12D inhibitor (INCB161734) and INCA033989; ongoing clinical trials and clinical trials to be initiated; expectations regarding discussions with regulators, regulatory submissions and regulatory approvals; and 2025 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; 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 on form 10-K for the year ended December 31, 2024. Incyte disclaims any intent or obligation to update these forward-looking statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
	GAAP		GAAP	
Revenues:				
Product revenues, net	$ 1,149,856	$ 962,992	$ 3,131,544	$ 2,599,481
Product royalty revenues	171,124	156,879	452,863	420,038

Milestone and contract revenues	45,000	18,000	50,000	43,000
Total revenues	1,365,980	1,137,871	3,634,407	3,062,519
Costs, expenses and other:				
Cost of product revenues (including definite-lived intangible amortization)	99,001	85,993	250,955	223,583
Contract dispute settlement	—	—	(242,251)	—
Research and development	506,584	573,174	1,438,780	2,140,814
Selling, general and administrative	329,081	309,209	985,794	915,447
(Gain) loss on change in fair value of acquisition-related contingent consideration	(12,204)	23,410	22,129	23,847
(Profit) and loss sharing under collaboration agreements	—	—	—	(1,025)
Total costs, expenses and other	922,462	991,786	2,455,407	3,302,666
Income (loss) from operations	443,518	146,085	1,179,000	(240,147)
Interest income	26,781	19,266	74,846	107,512
Interest expense	(592)	(774)	(1,846)	(1,861)
Gain (loss) on equity investments	8,558	(12,982)	3,064	126,206
Other, net	4,043	4,929	19,446	11,196
Income before provision for income taxes	482,308	156,524	1,274,510	2,906
Provision for income taxes	58,139	50,068	287,139	171,503
Net income (loss)	$ 424,169	$ 106,456	$ 987,371	$ (168,597)
Net income (loss) per share:				
Basic	$ 2.17	$ 0.55	$ 5.08	$ (0.80)
Diluted	$ 2.11	$ 0.54	$ 4.95	$ (0.80)
Shares used in computing net income (loss) per share:				
Basic	195,670	192,629	194,459	211,763
Diluted	201,429	195,838	199,405	211,763

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

	September 30, 2025	December 31, 2024
ASSETS		
Cash, cash equivalents and marketable securities	$ 2,929,820	$ 2,158,092
Accounts receivable	895,890	853,154
Property and equipment, net	798,634	763,411
Finance lease right-of-use assets, net	28,155	30,803
Inventory	449,957	407,199
Prepaid expenses and other assets	402,878	181,382
Equity investments	21,870	18,814
Other intangible assets, net	119,421	113,803
Goodwill	155,593	155,593
Deferred income tax asset	528,138	762,071
Total assets	$ 6,330,356	$ 5,444,322
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 1,459,790	$ 1,765,733
Finance lease liabilities	35,372	37,961
Acquisition-related contingent consideration	184,000	193,000
Stockholders' equity	4,651,194	3,447,628
Total liabilities and stockholders' equity	$ 6,330,356	$ 5,444,322

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,	
	2025	2024	2025	2024
GAAP Net Income (Loss)	$ 424,169	$ 106,456	$ 987,371	$ (168,597)
Adjustments[1]*:*				
Non-cash stock compensation from equity awards (R&D)[2]	39,634	45,808	114,058	117,141
Non-cash stock compensation from equity awards (SG&A)[2]	21,041	31,486	70,511	75,607
Non-cash stock compensation from equity awards (COGS)[2]	923	628	2,620	1,592
Non-cash interest[3]	82	81	245	333
(Gain) loss on equity investments[4]	(8,558)	12,982	(3,064)	(126,206)
Amortization of acquired product rights[5]	5,384	5,384	16,152	16,152
(Gain) loss on change in fair value of contingent consideration[6]	(12,204)	23,410	22,129	23,847
Contract dispute settlement[7]	—	—	(242,251)	—
MorphoSys transition costs[8]	—	132	—	7,084
Escient acquisition related compensation expense[9]	—	2,303	2,297	36,342
Tax effect of Non-GAAP pre-tax adjustments[10]	(14,499)	(19,019)	27,290	(37,057)
Non-GAAP Net Income (Loss)	$ 455,972	$ 209,651	$ 997,358	$ (53,762)
Non-GAAP net income (loss) per share:				
Basic	$ 2.33	$ 1.09	$ 5.13	$ (0.25)
Diluted[11]	$ 2.26	$ 1.07	$ 5.00	$ (0.25)
Shares used in computing Non-GAAP net income (loss) per share:				
Basic	195,670	192,629	194,459	211,763
Diluted[11]	201,429	195,838	199,405	211,763

[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, 2025 are milestones of $45,000 and $50,000 earned from our collaborative partners, as compared to $18,000 and $43,000 of milestones earned for the three and nine months ended September 30, 2024. 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, 2025 are upfront consideration and milestones of $100 and $28,150, respectively, related to our collaborative partners as compared to upfront consideration and milestones of $100,000 and $101,414, respectively, for the three and nine months ended September 30, 2024.

[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 Gain (loss) 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 (Gain) loss on change in fair value of acquisition-related contingent consideration line item in the Condensed Consolidated Statements of Operations.

[7] As included within the Contract dispute settlement 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 $0 and $2,117 for the three and nine months ended September 30, 2025, and included within the Selling, general and administrative expenses line item in the Condensed Consolidated Statements of Operations is $0 and $180 for the three and nine months ended September 30, 2025. 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 ended September 30, 2024 because their effect would have been anti-dilutive, as we were in a net loss position.

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