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

April 30, 2024

*– Total revenues of $881 million in the first quarter (Q1'24) (+9% Y/Y)*

*– Jakafi® (ruxolitinib) net product revenues of $572 million in Q1'24, total paid patients increased +5% Y/Y; reiterating full year 2024 guidance of $2,690 - $2,750 million*

*– Opzelura® (ruxolitinib) net product revenues of $86 million (+52% Y/Y) in Q1'24; continued uptake in atopic dermatitis (AD) and vitiligo*

*– Incyte to acquire Escient Pharmaceuticals and its pipeline of first-in-class oral MRGPR antagonists with the potential to treat multiple mast cell-mediated diseases*

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

WILMINGTON, Del.--(BUSINESS WIRE)--Apr. 30, 2024-- Incyte (Nasdaq:INCY) today reports 2024 first quarter financial results, and provides a status update on the Company's clinical development portfolio.

"In the first quarter of 2024, total revenues grew 9% year-over-year driven by patient demand growth in the U.S. for Opzelura® (ruxolitinib) cream and Jakafi® (ruxolitinib). As anticipated, the revenue growth during the quarter was offset by an inventory drawdown for Jakafi and the typical first quarter net pricing dynamics," said Hervé Hoppenot, Chief Executive Officer, Incyte. "We made important progress with our clinical pipeline including the initiation of two Phase 1 studies evaluating our JAK2V617F inhibitor and KRASG12D inhibitor. We also recently announced an agreement to acquire Escient Pharmaceuticals, pending the appropriate regulatory review process. Escient's lead compound EP262, is a first-in-class, potent, highly selective, once-daily small molecule designed to block mast cell activation, independent from IgE. We believe this novel mechanism has broad clinical utility in a number of conditions including chronic spontaneous urticaria (CSU), chronic inducible urticaria (CIndU) and other diseases."

**Key First Quarter 2024 Company Updates**

- In February 2024, Incyte announced that the U.S. Food and Drug Administration (FDA) accepted for Priority Review the Biologics License Application (BLA) for axatilimab, 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 February 2024, Incyte entered into an asset purchase agreement with MorphoSys AG which gave Incyte exclusive global rights for tafasitamab, a humanized Fc-modified CD19-targeting immunotherapy marketed in the U.S. as Monjuvi® (tafasitamab-cxix) and outside of the U.S. as Minjuvi® (tafasitamab).
- In March 2024, multiple abstracts featuring data from Incyte's dermatology portfolio were presented at the 2024 American Academy of Dermatology (AAD) Annual Meeting, including two late-breaking oral presentations for ruxolitinib cream (Opzelura) in hidradenitis suppurativa (HS) and povorcitinib in prurigo nodularis (PN).
- In April 2024, Incyte and China Medical System Holdings Limited announced the Companies entered into a Collaboration and License Agreement, through a wholly-owned dermatology medical aesthetic subsidiary CMS Skinhealth, for the development and commercialization of povorcitinib, a selective oral JAK1 inhibitor, in Mainland China, Hong Kong, Macau, Taiwan Region and eleven Southeast Asian countries.
- In April 2024, Incyte and Escient Pharmaceuticals, a clinical-stage drug development company advancing novel small molecule therapeutics for systemic immune and neuro-immune disorders, entered into a definitive agreement under which Incyte has agreed to acquire Escient and its clinical development portfolio, including EP262, a first-in-class, potent, highly selective, once-daily small molecule antagonist of Mas-related G protein-coupled receptor (MRGPRX2) and EP547, a first-in-class oral MRGPRX4 antagonist. Under the terms of the agreement, Incyte will acquire Escient and its assets for $750 million plus Escient's net cash remaining at the close of the transaction, subject to customary adjustments. The acquisition is subject to clearance under the Hart-Scott-Rodino Act, among other customary conditions, and will become effective promptly following the satisfaction or waiver of these conditions.

***Jakafi:***

**Net product revenues for the first quarter 2024 of $572 million (-1% Y/Y):**

- Total paid patients increased 5% in the first quarter of 2024 versus the same quarter in the prior year, with growth across all indications and leading to the highest quarterly paid patient demand for Jakafi since launch.
- Patients on free drug in the fourth quarter of 2023 gradually returned to paid demand during the first quarter of 2024; as a result, the percent of patients on free drug returned to more normalized levels during the first quarter of 2024.
- Channel inventory at the end of the first quarter of 2024 decreased by approximately $55 million versus the fourth quarter of 2023.

**Opzelura:**

**Net product revenues for the first quarter 2024 of $86 million (+52% Y/Y):**

- Net product revenues growth in the first quarter of 2024 were driven by patient demand, refills and expansion in payer coverage as the launch in atopic dermatitis (AD) and vitiligo continues.
- Net product revenues of $6 million in the first quarter of 2024 in Europe where the launch is ongoing in Germany, Austria and initial uptake has begun in France.

**Additional Pipeline Updates**

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

- Combination trials of ruxolitinib twice daily (BID) with zilurgisertib (INCB000928) and BETi (INCB057643) are ongoing and continue to enroll. A Phase 3 study for BETi is anticipated to initiate in the second half of 2024 and clinical proof-of-concept for zilurgisertib is anticipated by mid-2024.
- The Phase 1 studies evaluating INCA033989 (mCALR) and INCB100658 (JAK2V617F) are ongoing and enrolling patients.

| MPN and GVHD Programs | Indication and status |
|---|---|
| **Ruxolitinib XR (QD) (JAK1/JAK2)** | Myelofibrosis, polycythemia vera and GVHD |
| **Ruxolitinib + zilurgisertib (JAK1/JAK2 + ALK2)** | Myelofibrosis: Phase 2 |
| **Ruxolitinib + INCB57643 (JAK1/JAK2 + BET)** | Myelofibrosis: Phase 2 |
| **Ruxolitinib + CK0804[1] (JAK1/JAK2 + CB-Tregs)** | Myelofibrosis: Phase 1 |
| **Axatilimab (anti-CSF-1R)[2]** | Chronic GVHD: Pivotal Phase 2 (third-line plus therapy) (AGAVE-201); BLA under review in the U.S. |
| **Ruxolitinib + axatilimab[2] (JAK1/JAK2 + anti-CSF-1R)** | Chronic GVHD: Phase 2 in preparation |
| **Steroids + axatilimab[2] (Steroids + anti-CSF-1R)** | Chronic GVHD: Phase 3 in preparation |
| **INCA033989 (mCALR)** | Myelofibrosis, essential thrombocythemia: Phase 1 |
| **INCB160058 (JAK2V617Fi)** | Phase 1 |

[1] Development collaboration with Cellenkos, Inc.

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

***Other Hematology/Oncology – key highlights***

- In January 2024, Incyte highlighted promising early clinical efficacy data for its selective small molecule inhibitor of CDK2 (INCB123667), which demonstrated its potential use as monotherapy or combination therapy for late-stage cancers. In a Phase 1 study of INCB123667, early clinical activity was observed with several partial responses (PR) achieved in patients with amplification/over expression of CCNE1, a cell cycle regulator and potential predictive biomarker. Tumor shrinkage was observed across multiple tumor types, including CCNE1+ patients with ovarian cancer. The safety profile of INCB123667 aligns with the mechanism of action. Additional data is expected to be presented in 2024.
- In April 2024, Incyte presented new preclinical data at the American Association for Cancer Research (AACR) Annual Meeting 2024 highlighting its KRASG12D inhibitor (INCB161734). INCB161734 is a potent, selective, and orally bioavailable KRAS G12D inhibitor which is efficacious against KRAS G12D mutant tumors in preclinical models. The potential benefit of INCB161734 for patients with KRAS G12D mutant disease is under investigation in an ongoing Phase 1 study. The KRASG12D mutation is found in 40% of pancreatic ductal adenocarcinoma patients, 15% of colorectal cancer patients, and 5% of non-small cell lung cancer patients and with no approved G12D-targeting agents, represents a significant medical need.

| Oncology Programs | Indication and status |
|---|---|
| **Pemigatinib (Pemazyre®) (FGFR1/2/3)** | Myeloid/lymphoid neoplasms (MLN): approved in the U.S. and Japan<br>Cholangiocarcinoma (CCA): Phase 3 (FIGHT-302) |
| **Tafasitamab (Monjuvi®/Minjuvi®) (CD19)** | Relapsed or refractory diffuse large B-cell lymphoma (DLBCL): Phase 3 (B-MIND)<br>First-line DLBCL: Phase 3 (*front*MIND)<br>Relapsed or refractory follicular lymphoma (FL) and relapsed or refractory marginal zone lymphoma (MZL): Phase 3 (*in*MIND) |

| | |
|---|---|
| **Retifanlimab (Zynyz®)[1] (PD-1)** | Merkel cell carcinoma (MCC): approved in the U.S.<br>Squamous cell anal cancer (SCAC): Phase 3 (POD1UM-303)<br>Non-small cell lung cancer (NSCLC): Phase 3 (POD1UM-304)<br>MSI-high endometrial cancer: Phase 2 (POD1UM-101, POD1UM-204) |
| **INCB99280 (Oral PD-L1)** | Solid tumors (combination): Phase 1<br>Solid tumors (monotherapy): Phase 2<br>Cutaneous squamous cell carcinoma (cSCC): Phase 2 |
| **INCB99318 (Oral PD-L1)** | Solid tumors: Phase 1 |
| **INCB123667 (CDK2i)** | Solid tumors with Amplification/ Overexpression of CCNE1: Phase 1 |
| **INCB161734 (KRASG12D)** | Advanced metastatic solid tumors with a KRAS G12D mutation: Phase 1 |

[1] Retifanlimab licensed from MacroGenics.

***Inflammation and Autoimmunity (IAI) – key highlights***

**Dermatology**

**Opzelura**

- In March 2024, Incyte presented data at the 2024 AAD Annual Meeting from its randomized, placebo-controlled, Phase 2 study evaluating the safety and efficacy of ruxolitinib cream (Opzelura®) in adults with mild/moderate HS. At Week 16, patients receiving ruxolitinib cream 1.5% twice daily (BID) had significantly greater decreases from baseline versus placebo in total abscess and inflammatory nodule (AN) count, the primary endpoint of the study. The overall safety profile of ruxolitinib cream was consistent with previous data, and no new safety signals were observed. A Phase 3 study is currently being evaluated.
- Ruxolitinib cream in other indications: Phase 2 studies in lichen planus and lichen sclerosus have completed enrollment. Two Phase 3 trials evaluating ruxolitinib cream in PN are ongoing.

**Povorcitinib (INCB54707)**

- The Phase 2, randomized, double-blind, placebo-controlled, dose ranging study evaluating the efficacy and safety of povorcitinib in participants with PN were presented at the 2024 AAD Annual Meeting with the study meeting its primary and secondary endpoints following 16 weeks of treatment across all dosing groups, reinforcing povorcitinib's potential role in treating PN. A Phase 3 study in PN is being planned.
- Asthma and chronic spontaneous urticaria: Two Phase 2 trials in asthma and chronic spontaneous urticaria are enrolling.

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

[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 |

***Discovery and other early development***

| Modality | Candidates |
|---|---|
| **Monoclonal antibodies** | INCAGN2385 (LAG-3)[1], INCAGN2390 (TIM-3)[1] |
| **Bi-specific antibodies** | INCA32459 (LAG-3xPD-1)[2], INCA33890 (TGFβR2xPD-1)[2] |

[1] Discovery collaboration with Agenus.

[2] Development in collaboration with Merus.

***Partnered***

| Partnered Programs | Indication and Phase |
|---|---|
| **Ruxolitinib (Jakavi®)[1] (JAK1/JAK2)** | Acute and chronic GVHD: Approved in Europe and Japan |
| **Baricitinib (Olumiant®)[2] (JAK1/JAK2)** | AD: Approved in Europe and Japan<br>Severe alopecia areata (AA): Approved in the U.S., Europe and Japan |
| **Capmatinib (Tabrecta®)[3] (MET)** | NSCLC (with MET exon 14 skipping mutations): Approved in the U.S., Europe and Japan |

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

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

[3] Capmatinib (Tabrecta®) licensed to Novartis.

**2024 First Quarter Financial Results**

The financial measures presented in this press release for the three months ended March 31, 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 March 31, | |
|---|---|---|
| | **2024** | **2023** |
| Total GAAP revenues | $ 880,889 | $ 808,673 |
| Total GAAP operating income | 91,898 | 24,770 |
| Total Non-GAAP operating income | 161,183 | 89,729 |
| GAAP net income | 169,548 | 21,703 |
| Non-GAAP net income | 145,269 | 84,577 |
| GAAP basic EPS | $ 0.76 | $ 0.10 |
| Non-GAAP basic EPS | $ 0.65 | $ 0.38 |
| GAAP diluted EPS | $ 0.75 | $ 0.10 |

| | | |
|---|---|---|
| Non-GAAP diluted EPS | $ 0.64 | $ 0.37 |

**Revenue Details**

**Revenue Details**
**(unaudited, in thousands)**

| | Three Months Ended March 31, | | % Change (as reported) | % Change (constant currency)[1] |
|---|---|---|---|---|
| | 2024 | 2023 | | |
| Net product revenues: | | | | |
| Jakafi | $ 571,839 | $ 579,969 | (1%) | (1%) |
| Opzelura | 85,724 | 56,552 | 52% | 51% |
| Iclusig | 30,343 | 27,685 | 10% | 8% |
| Pemazyre | 17,676 | 22,475 | (21%) | (22%) |
| Minjuvi/Monjuvi | 23,874 | 6,556 | 264% | 262% |
| Zynyz | 467 | — | NM | NM |
| Total net product revenues | 729,923 | 693,237 | 5% | 5% |
| Royalty revenues: | | | | |
| Jakavi | 89,595 | 76,692 | 17% | 19% |
| Olumiant | 30,589 | 34,155 | (10%) | (8%) |
| Tabrecta | 5,234 | 4,177 | 25% | NA |
| Pemazyre | 548 | 412 | 33% | NM |
| Total royalty revenues | 125,966 | 115,436 | 9% | |
| Total net product and royalty revenues | 855,889 | 808,673 | 6% | |
| Milestone and contract revenues | 25,000 | — | NM | NM |
| Total GAAP revenues | $ 880,889 | $ 808,673 | 9% | |

NM = not meaningful

NA = not available

[1] Percentage change in constant currency is calculated using 2023 foreign exchange rates to recalculate 2024 results.

**Product and Royalty Revenues** Product revenues and product and royalty revenues for the quarter ended March 31, 2024 increased 5% and 6%, respectively, over the prior year comparative period, primarily driven by a 52% year-over-year increase in Opzelura net product revenue due to the growth in new patient starts and refills, an increase in Minjuvi/Monjuvi net product revenues, following the acquisition of the exclusive global rights to tafasitamab in February 2024, and an increase in Jakavi royalty revenues.

**Operating Expenses**

**Operating Expense Summary**
**(unaudited, in thousands)**

| | Three Months Ended March 31, | | % Change |
|---|---|---|---|
| | 2024 | 2023 | |
| GAAP cost of product revenues | $ 60,956 | $ 56,822 | 7% |
| Non-GAAP cost of product revenues[1] | 54,959 | 50,669 | 8% |
| GAAP research and development | 429,260 | 406,641 | 6% |
| Non-GAAP research and development[2] | 388,437 | 375,620 | 3% |
| GAAP selling, general and administrative | 300,256 | 315,606 | (5%) |
| Non-GAAP selling, general and administrative[3] | 277,335 | 294,017 | (6%) |
| GAAP (gain) loss on change in fair value of acquisition-related contingent consideration | (456) | 6,196 | (107%) |
| Non-GAAP (gain) loss on change in fair value of acquisition-related contingent consideration[4] | — | — | —% |
| GAAP (profit) and loss sharing under collaboration agreements | (1,025) | (1,362) | (25%) |

[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 and MorphoSys transition costs.

[3] Non-GAAP selling, general and administrative expenses exclude the cost of stock-based compensation and MorphoSys transition costs.

[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 ended March 31, 2024 increased 7% and 8%, respectively, compared to the same period in 2023 primarily due to growth in net product revenues.

**Research and development expenses** GAAP and Non-GAAP research and development expense for the quarter ended March 31, 2024 increased 6% and 3%, respectively, compared to the same period in 2023 primarily due to 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 March 31, 2024 decreased 5% and 6%, respectively, compared to the same period in 2023 primarily due to the timing of consumer marketing activities and of certain other expenses.

**Other Financial Information**

**Change in fair value of acquisition-related contingent consideration** The change in fair value of contingent consideration during the quarter ended March 31, 2024, compared to the same periods in 2023, was due primarily 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 March 31, 2024 increased 271% and 80%, respectively, compared to the same period in 2023, driven by growth in total revenues and stable operating expenses.

**Cash, cash equivalents and marketable securities position** As of March 31, 2024 and December 31, 2023, cash, cash equivalents and marketable securities totaled $3.9 billion and $3.7 billion, respectively.

**2024 Financial Guidance**

Incyte is maintaining its full year 2024 revenue and expense guidance. Incyte's guidance is summarized below. Guidance does not include revenue from any potential new product launches or the impact of the acquisition of Escient Pharmaceuticals or any other potential future strategic transactions.

| | **Guidance** |
|---|---|
| Jakafi net product revenues | $2,690 - $2,750 million |
| Other Hematology/Oncology net product revenues[(1)] | $325 - $360 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 | $1,720 - $1,760 million |
| Non-GAAP Research and development expenses[(3)] | $1,580 - $1,615 million |
| GAAP Selling, general and administrative expenses | $1,210 - $1,240 million |
| Non-GAAP Selling, general and administrative expenses[(3)] | $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.

**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, 13745743.

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, 13745743.

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 1.5%**

Opzelura, a novel cream formulation of Incyte's selective JAK1/JAK2 inhibitor ruxolitinib, approved by the U.S. Food & Drug Administration for the topical treatment of nonsegmental vitiligo in patients 12 years of age and older, is the first and only treatment for repigmentation approved for use in the United States. Opzelura is also approved in the U.S. for the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis (AD) in non-immunocompromised patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies, or when those therapies are not advisable. Use of Opzelura in combination with therapeutic biologics, other JAK inhibitors, or potent immunosuppressants, such as azathioprine or cyclosporine, is not recommended.

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

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

Opzelura and the Opzelura logo are registered trademarks of Incyte**.**

**About Monjuvi® (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 trademarks of Incyte.

**About Pemazyre® (pemigatinib)**

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

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

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

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

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

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

Pemazyre is a trademark of Incyte.

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

**About Iclusig® (ponatinib) tablets**

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

In the EU, Iclusig is approved for the treatment of adult patients with chronic phase, accelerated phase or blast phase chronic myeloid leukemia (CML) who are resistant to dasatinib or nilotinib; who are intolerant to dasatinib or nilotinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation, or the treatment of adult patients with Philadelphia-chromosome positive acute lymphoblastic leukemia (Ph+ ALL) who are resistant to dasatinib; who are intolerant to dasatinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation.

**Click here** to view the Iclusig EU Summary of Medicinal Product Characteristics.

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

**About Zynyz® (retifanlimab-dlwr)**

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

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

Zynyz is a trademark of Incyte.

**Forward-Looking Statements**

Except for the historical information set forth herein, the matters set forth in this release contain predictions, estimates and other forward-looking statements, including any discussion of the following: Incyte's potential for continued performance and growth; Incyte's financial guidance for 2024, including its expectations regarding sales of Jakafi; expectations regarding demand for and sales of Opzelura, among other products; expectations regarding Incyte's acquisition of Escient and the potential of Escient's pipeline; expectations regarding the potential and progress of programs in our pipeline; expectations regarding ongoing clinical trials and clinical trials to be initiated, including a phase 3 study for BETi and a clinical proof-of-concept for zilurgisertib, a phase 3 trial of povorcitinib in prurigo nodularis, and various additional clinical trials across our MPH/GVHD, oncology, IAI and dermatology programs; expectations regarding data readouts; our expectations regarding regulatory filings; and our 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 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, 2023. 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 March 31, | |
|---|---|---|
| | **2024** | **2023** |
| | **GAAP** | |
| Revenues: | | |
| Product revenues, net | $ 729,923 | $ 693,237 |
| Product royalty revenues | 125,966 | 115,436 |
| Milestone and contract revenues | 25,000 | — |
| Total revenues | 880,889 | 808,673 |
| Costs, expenses and other: | | |
| Cost of product revenues (including definite-lived intangible amortization) | 60,956 | 56,822 |
| Research and development | 429,260 | 406,641 |
| Selling, general and administrative | 300,256 | 315,606 |
| (Gain) loss on change in fair value of acquisition-related contingent consideration | (456) | 6,196 |
| (Profit) and loss sharing under collaboration agreements | (1,025) | (1,362) |
| Total costs, expenses and other | 788,991 | 783,903 |
| Income from operations | 91,898 | 24,770 |
| Interest income and other, net | 44,744 | 32,873 |
| Interest expense | (430) | (469) |
| Unrealized gain (loss) on long term investments | 99,947 | (5,318) |

| | | |
|---|---|---|
| Income before provision for income taxes | 236,159 | 51,856 |
| Provision for income taxes | 66,611 | 30,153 |
| Net income | $ 169,548 | $ 21,703 |
| | | |
| Net income per share: | | |
| Basic | $ 0.76 | $ 0.10 |
| Diluted | $ 0.75 | $ 0.10 |
| | | |
| Shares used in computing net income per share: | | |
| Basic | 224,484 | 222,960 |
| Diluted | 227,219 | 225,589 |

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

| | March 31, 2024 | December 31, 2023 |
|---|---|---|
| **ASSETS** | | |
| Cash, cash equivalents and marketable securities | $ 3,850,688 | $ 3,656,043 |
| Accounts receivable | 745,526 | 743,557 |
| Property and equipment, net | 719,999 | 751,513 |
| Finance lease right-of-use assets, net | 25,533 | 25,535 |
| Inventory | 327,934 | 269,937 |
| Prepaid expenses and other assets | 238,262 | 236,782 |
| Long term investments | 287,663 | 187,716 |
| Other intangible assets, net | 117,841 | 123,545 |
| Goodwill | 155,593 | 155,593 |
| Deferred income tax asset | 666,566 | 631,886 |
| Total assets | $ 7,135,605 | $ 6,782,107 |
| | | |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Accounts payable, accrued expenses and other liabilities | $ 1,506,722 | $ 1,347,669 |
| Finance lease liabilities | 32,612 | 32,601 |
| Acquisition-related contingent consideration | 202,000 | 212,000 |
| Stockholders' equity | 5,394,271 | 5,189,837 |
| Total liabilities and stockholders' equity | $ 7,135,605 | $ 6,782,107 |

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

| | Three Months Ended March 31, | |
|---|---|---|
| | 2024 | 2023 |
| **GAAP Net Income** | $ 169,548 | $ 21,703 |
| *Adjustments[1]:* | | |
| Non-cash stock compensation from equity awards (R&D)[2] | 36,792 | 31,021 |
| Non-cash stock compensation from equity awards (SG&A)[2] | 22,373 | 21,589 |
| Non-cash stock compensation from equity awards (COGS)[2] | 613 | 769 |
| Non-cash interest[3] | 108 | 108 |
| Changes in fair value of equity investments[4] | (99,947) | 5,318 |
| Amortization of acquired product rights[5] | 5,384 | 5,384 |
| (Gain) loss on change in fair value of contingent consideration[6] | (456) | 6,196 |
| MorphoSys transition costs[7] | 4,579 | — |
| Tax effect of Non-GAAP pre-tax adjustments[8] | 6,275 | (7,511) |
| **Non-GAAP Net Income** | $ 145,269 | $ 84,577 |
| | | |
| Non-GAAP net income per share: | | |

| | | |
|---|---|---|
| Basic | $ 0.65 | $ 0.38 |
| Diluted | $ 0.64 | $ 0.37 |
| | | |
| Shares used in computing Non-GAAP net income per share: | | |
| Basic | 224,484 | 222,960 |
| Diluted | 227,219 | 225,589 |

[1] Included within the Milestone and contract revenues line item in the Condensed Consolidated Statements of Operations (in thousands) for the three months ended March 31, 2024 are milestones of $25,000 earned from our collaborative partners, as compared to no milestones earned for the three months ended March 31, 2023. Included within the Research and development expenses line item in the Condensed Consolidated Statements of Operations (in thousands) for the three months ended March 31, 2024 and 2023 are upfront consideration and milestones of $1,000 and $2,700, respectively, related to our collaborative partners.

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

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

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

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

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

[7] Included within the Research and development line item in the Condensed Consolidated Statements of Operations is $4,031 for the three months ended March 31, 2024, and $548 is included within the Selling, general and administrative expenses line item in the Condensed Consolidated Statements of Operations for the three months ended March 31, 2024. 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.

[8] 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.

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