# 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): **November 2, 2021**

# 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**<br>**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 November 2, 2021, Incyte Corporation issued a press release announcing financial results for its third fiscal quarter ended September 30, 2021. 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 November 2, 2021. |
| 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: November 2, 2021

INCYTE CORPORATION

By: /s/ Christianna Stamoulis
Christiana Stamoulis
Executive Vice President and
Chief Financial Officer

**FOR IMMEDIATE RELEASE**

**Incyte Reports 2021 Third Quarter Financial Results and Provides Updates on Key Clinical Programs**

- *Total product and royalty revenues of $778 million in Q3 2021 (+25% vs. Q3 2020); Jakafi® (ruxolitinib) revenues of $547 million in Q3 2021 (+12% vs. Q3 2020)*

- *Three regulatory approvals including Opzelura™ (ruxolitinib) cream in the U.S. for the treatment of atopic dermatitis, Jakafi in the U.S. for the treatment of chronic graft-versus-host disease (GVHD) and Minjuvi® (tafasitamab) in Europe for the treatment of relapsed or refractory DLBCL*

- *Pivotal TRuE-V data presentation at EADV highlighted significant improvements in facial and total body repigmentation in vitiligo patients treated with ruxolitinib cream; Company pursuing regulatory approvals in the U.S. and Europe*

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

**WILMINGTON, Del. – November 2, 2021** – Incyte (Nasdaq:INCY) today reports 2021 third quarter financial results and provides a status update on the Company's development portfolio.

"Incyte has transformed as a Company over the last two years, as we deliver on our goal of diversifying and growing our revenue," said Hervé Hoppenot, Chief Executive Officer, Incyte. "Multiple product approvals and global launches have significantly expanded our portfolio; our robust development pipeline continues to mature and progress; and we expect several additional regulatory submissions to occur over the coming months. Our strong third quarter performance is the result of an increasingly diversified portfolio, driven by double-digit growth in patient demand for Jakafi® (ruxolitinib), continued uptake of both Pemazyre® (pemigatinib) and Monjuvi®/Minjuvi® (tafasitamab) as well as a significant and rapidly-growing royalty revenue stream."

**Portfolio Update**

***MPNs and GVHD – key highlights***

**Jakafi approval in chronic graft-versus-host disease (GVHD):** In September, the U.S. Food and Drug Administration (FDA) granted approval of Jakafi for the treatment of chronic GVHD after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older. There are approximately 14,000 people in the U.S. living with chronic GVHD, with more than half requiring therapy beyond systemic

corticosteroids.

**Collaboration with Syndax Pharmaceuticals:** In September, Incyte and Syndax Pharmaceuticals announced an exclusive worldwide collaboration and license agreement to develop and commercialize axatilimab, Syndax's anti-CSF-1R monoclonal antibody, in chronic GVHD and other fibrotic diseases, pending regulatory clearance. The global pivotal Phase 2 AGAVE-201 trial of axatilimab monotherapy in patients with chronic GVHD in the third line setting is ongoing. Additional trials of axatilimab are planned, including a Phase 2 trial in combination with a JAK inhibitor in patients with steroid-refractory chronic GVHD.

**LIMBER (Leadership In MPNs BEyond Ruxolitinib) program:** Once-daily (QD) ruxolitinib is in stability testing and is on track for a new drug application (NDA) submission early next year. Multiple JAK-based combination studies are either ongoing or planned.

| | **Indication and status** |
|---|---|
| **QD ruxolitinib (JAK1/JAK2)** | Myelofibrosis, polycythemia vera and GVHD: clinical pharmacology studies |
| **ruxolitinib + parsaclisib (JAK1/JAK2 + PI3Kδ)** | Myelofibrosis: Phase 3 (first-line therapy) (LIMBER-313)<br>Myelofibrosis: Phase 3 (suboptimal responders to ruxolitinib) (LIMBER-304) |
| **ruxolitinib + INCB57643 (JAK1/JAK2 + BET)** | Myelofibrosis: Phase 2 in preparation |
| **ruxolitinib + INCB00928 (JAK1/JAK2 + ALK2)** | Myelofibrosis: Phase 2 in preparation |
| **ruxolitinib + CK0804[1] (JAK1/JAK2 + CB-Tregs)** | Myelofibrosis: PoC in preparation |
| **itacitinib (JAK1)** | Treatment-naïve chronic GVHD: Phase 3 (GRAVITAS-309) |
| **axatilimab (anti-CSF-1R)[2]** | Chronic GVHD (third-line therapy): Phase 2 (AGAVE-201) |

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

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

**Minjuvi approval in relapsed or refractory DLBCL:** In August, Incyte and MorphoSys announced that the European Commission granted conditional marketing authorization for Minjuvi in combination with lenalidomide, followed by Minjuvi monotherapy, for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are not eligible for autologous stem cell transplantation (ASCT). In Europe, each year approximately 16,000 patients are diagnosed with relapsed or refractory DLBCL, of which the majority would be eligible for Minjuvi.

**Parsaclisib in non-Hodgkin lymphomas (NHLs):** In November, we announced that the FDA accepted a NDA seeking approval of parsaclisib for the treatment of patients with relapsed or refractory follicular lymphoma, marginal zone lymphoma and mantle cell lymphoma. The submission is based on data from several Phase 2 studies (CITADEL-203, -204 and -205) evaluating parsaclisib as a treatment for relapsed or refractory NHLs (follicular, marginal zone and mantle cell). Priority Review was granted by the FDA for the treatment of adult patients with relapsed or refractory MZL who have received at least one prior anti-CD20-based regimen and for the treatment of adult patients with MCL who have received at least one prior therapy; the Prescription Drug User Fee Act (PDUFA) target action date for these indications is April 30, 2022. The NDA for use of parsaclisib in adult patients with relapsed or refractory follicular lymphoma (FL) who have received at least two prior systemic therapies will have a Standard Review and a PDUFA target action date of August 30, 2022.

**Parsaclisib in hemolytic anemia:** A Phase 3 trial evaluating the efficacy and safety of parsaclisib in adults with warm autoimmune hemolytic anemia is planned.

**Retifanlimab:** In October, Incyte withdrew the marketing authorization application (MAA) seeking approval of retifanlimab in squamous cell carcinoma of the anal canal (SCAC) in Europe. The withdrawal was based on the provisional view of the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) that the available data to date, provided in the MAA, were not sufficient to permit an approval for the proposed indication.

| | **Indication and status[1]** |
|---|---|
| **pemigatinib (FGFR1/2/3)** | CCA: Phase 3 (FIGHT-302)<br>Myeloid/lymphoid neoplasms (MLN): Phase 2 (FIGHT-203)<br>Tumor agnostic: Phase 2 (FIGHT-207)<br>Glioblastoma: Phase 2 in preparation<br>NSCLC: Phase 2 in preparation |
| **tafasitamab (CD19)[2]** | Relapsed or refractory DLBCL: Phase 2 (L-MIND); Phase 3 (B-MIND)<br>First-line DLBCL: Phase 1b (*firstMIND*); Phase 3 (*frontMIND*)<br>Relapsed or refractory FL and Relapsed or refractory MZL: Phase 3 (*inMIND*)<br>Relapsed or refractory CLL: Phase 2 (*coreMIND*) in preparation<br>Relapsed or refractory B-cell malignancies: PoC (*topMIND*) with parsaclisib (PI3Kδ)<br>Relapsed or refractory B-cell malignancies: PoC with lenalidomide and plamotamab in preparation[3] |
| **parsaclisib (PI3Kδ)** | Relapsed or refractory FL: Phase 2 (CITADEL-203)<br>Relapsed or refractory MZL: Phase 2 (CITADEL-204)<br>Relapsed or refractory MCL: Phase 2 (CITADEL-205)<br>Relapsed or refractory FL and Relapsed or refractory MZL: Phase 3 (CITADEL-302) in preparation<br>First-line MCL: Phase 3 (CITADEL-310) in preparation<br>Autoimmune hemolytic anemia: Phase 2; Phase 3 in preparation |
| **retifanlimab (PD-1)[4]** | SCAC: Phase 2 (POD1UM-202); Phase 3 (POD1UM-303)<br>MSI-high endometrial cancer: Phase 2 (POD1UM-101, POD1UM-204)<br>Merkel cell carcinoma: Phase 2 (POD1UM-201)<br>NSCLC: Phase 3 (POD1UM-304) |

[1] CCA = cholangiocarcinoma; DLBCL = diffuse large B-cell lymphoma; SCAC = squamous cell anal carcinoma; FL = follicular lymphoma; MZL = marginal zone lymphoma; MCL = mantle cell lymphoma; CLL = chronic lymphocytic leukemia
[2] Development of tafasitamab in collaboration with MorphoSys.
[3] Clinical collaboration with MorphoSys and Xencor, Inc. to investigate the combination of tafasitamab plus lenalidomide in combination with Xencor's CD20xCD3 XmAb bispecific antibody, plamotamab.
[4] Retifanlimab licensed from MacroGenics.

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

**Dermatology**

**Opzelura™ (ruxolitinib) cream approval in atopic dermatitis (AD):** In September, Incyte announced that the FDA approved Opzelura, a novel cream formulation of Incyte's selective JAK1/JAK2 inhibitor ruxolitinib, for the topical short-term and non-continuous chronic treatment of mild to moderate 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.

**Ruxolitinib cream in vitiligo:** In October, full 24-week safety and efficacy data from the two Phase 3 TRuE-V studies evaluating ruxolitinib cream in vitiligo were presented at the European Academy of Dermatology and Venereology (EADV) 30th Congress. In October, Incyte announced the validation of the European Marketing Authorization Application (MAA) for ruxolitinib cream as a potential treatment for adolescents and adults (age >12 years) with non-segmental vitiligo with facial involvement. A supplementary NDA is in progress.

**INCB54707:** In October, Incyte initiated a Phase 2 trial evaluating adults with prurigo nodularis. Phase 2 trials in vitiligo and in hidradenitis suppurativa are ongoing.

**Other IAI**

**INCB00928 in fibrodysplasia ossificans progressiva (FOP):** A Phase 2 trial evaluating adults with FOP is in preparation. The FDA has granted Fast Track designation and orphan drug designation to INCB00928 as a treatment for patients with FOP.

| | **Indication and status** |
|---|---|
| **ruxolitinib cream[1] (JAK1/JAK2)** | Atopic dermatitis: Phase 3 pediatric study (TRuE-AD3)<br>Vitiligo: Phase 3 (TRuE-V1, TRuE-V2, primary endpoint met in both studies); sNDA and MAA in progress |
| **INCB54707 (JAK1)** | Hidradenitis suppurativa: Phase 2b<br>Vitiligo: Phase 2<br>Prurigo nodularis: Phase 2 |
| **INCB00928 (ALK2)** | Fibrodysplasia ossificans progressiva: Phase 2 in preparation |

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

***Discovery and early development – key highlights***

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

| **Modality** | **Candidates** |
|---|---|
| **Small molecules** | INCB81776 (AXL/MER), epacadostat (IDO1), INCB86550 (PD-L1), INCB99280 (PD-L1), INCB99318 (PD-L1), INCB106385 (A2A/A2B) |
| **Monoclonal antibodies[1]** | INCAGN1876 (GITR), INCAGN2385 (LAG-3), INCAGN1949 (OX40), INCAGN2390 (TIM-3), INCA00186 (CD73) |
| **Bispecific antibodies** | MCLA-145 (PD-L1xCD137)[2] |

[1] Discovery collaboration with Agenus.
[2] MCLA-145 development in collaboration with Merus.

***Partnered – key highlights***

**Baricitinib in alopecia areata:** In September, Incyte and Lilly announced detailed results from BRAVE-AA1 and BRAVE-AA2 at the European Academy of Dermatology and Venereology Congress (EADV). The two studies showed statistically significant improvement in scalp hair regrowth across both baricitinib dosing groups when compared to placebo.

| | Indication and status |
|---|---|
| **baricitinib (JAK1/JAK2)[1]** | Atopic dermatitis: Phase 3 (BREEZE-AD); approved in EU and Japan; sNDA under review<br>Severe alopecia areata: Phase 3 (BRAVE-AA1, BRAVE-AA2)<br>Systemic lupus erythematosus: Phase 3 (BRAVE I, BRAVE II) |
| **capmatinib (MET)[2]** | NSCLC (with MET exon 14 skipping mutations): Approved as Tabrecta in U.S. and Japan |

[1] Worldwide rights to baricitinib licensed to Lilly: approved as Olumiant in multiple territories globally for certain patients with moderate-to-severe rheumatoid arthritis; approved as Olumiant in EU and Japan for certain patients with atopic dermatitis.
[2] Worldwide rights to capmatinib licensed to Novartis.

**2021 Third Quarter Financial Results**

The financial measures presented in this press release for the three and nine months ended September 30, 2021 and 2020 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.

**Financial Highlights**

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Total GAAP revenue | $ 812,987 | $ 620,643 | $ 2,123,414 | $ 1,877,193 |
| | | | | |
| Total GAAP operating income (loss) | 235,410 | 5,326 | 475,043 | (427,905) |
| Total Non-GAAP operating income (loss) | 293,148 | 61,619 | 659,019 | (259,347) |
| GAAP net income (loss) | 181,739 | (15,203) | 384,730 | (445,547) |
| Non-GAAP net income (loss) | 261,824 | 50,059 | 589,413 | (295,283) |
| | | | | |
| GAAP basic EPS | $ 0.82 | $ (0.07) | $ 1.75 | $ (2.05) |
| Non-GAAP basic EPS | $ 1.19 | $ 0.23 | $ 2.68 | $ (1.36) |
| GAAP diluted EPS | $ 0.82 | $ (0.07) | $ 1.73 | $ (2.05) |
| Non-GAAP diluted EPS | $ 1.18 | $ 0.23 | $ 2.65 | $ (1.36) |

**Revenue Details**

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

| | Three Months Ended September 30, | | % | Nine Months Ended September 30, | | % |
|---|---|---|---|---|---|---|
| | 2021 | 2020 | Change | 2021 | 2020 | Change |
| Revenues: | | | | | | |
| Jakafi net product revenues | $ 547,373 | $ 487,783 | 12% | $ 1,542,138 | $ 1,420,968 | 9% |
| Iclusig net product revenues | 28,522 | 26,380 | 8% | 82,356 | 76,426 | 8% |
| Pemazyre net product revenues | 17,562 | 8,089 | 117% | 48,924 | 11,875 | 312% |
| Minjuvi net product revenues | 556 | — | NM | 556 | — | NM |
| Jakavi product royalty revenues | 94,655 | 68,306 | 39% | 242,295 | 190,856 | 27% |
| Olumiant product royalty revenues | 86,572 | 28,647 | 202% | 154,875 | 79,924 | 94% |
| Tabrecta product royalty revenues | 2,747 | 1,438 | 91% | 7,270 | 2,144 | 239% |
| Product and royalty revenues | 777,987 | 620,643 | 25% | 2,078,414 | 1,782,193 | 17% |
| Milestone and contract revenues | 35,000 | — | NM | 45,000 | 95,000 | (53)% |
| Total GAAP revenues | $ 812,987 | $ 620,643 | 31% | $ 2,123,414 | $ 1,877,193 | 13% |

NM = not meaningful

**Product and Royalty Revenues** Product and royalty revenues for the quarter ended September 30, 2021 increased 25% over the prior year comparative period as a result of increases in Jakafi, Iclusig and Pemazyre net product revenues and higher product royalty revenues from Jakavi, Olumiant and Tabrecta. The 202% growth in Olumiant royalty revenues reflects an increase in net product sales as a result of the use of Olumiant for the treatment of COVID-19.

**Operating Expenses**

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

| | Three Months Ended September 30, | | % | Nine Months Ended September 30, | | % |
|---|---|---|---|---|---|---|
| | 2021 | 2020 | Change | 2021 | 2020 | Change |
| GAAP cost of product revenues | $ 39,869 | $ 34,322 | 16% | $ 107,117 | $ 95,005 | 13% |
| Non-GAAP cost of product revenues[1] | 33,965 | 28,693 | 18% | 89,863 | 78,137 | 15% |
| | | | | | | |
| GAAP research and development | 334,945 | 438,109 | (24)% | 985,352 | 1,809,997 | (46)% |
| Non-GAAP research and development[2] | 308,675 | 409,134 | (25)% | 901,170 | 1,719,816 | (48)% |
| | | | | | | |
| GAAP selling, general and administrative | 190,704 | 120,788 | 58% | 513,358 | 349,934 | 47% |
| Non-GAAP selling, general and administrative[3] | 168,050 | 106,208 | 58% | 443,886 | 308,215 | 44% |
| | | | | | | |
| GAAP change in fair value of acquisition-related contingent consideration | 2,910 | 7,109 | (59)% | 13,068 | 19,790 | (34)% |
| Non-GAAP change in fair value of acquisition-related contingent consideration[4] | — | — | | — | — | |
| | | | | | | |
| GAAP collaboration loss sharing | 9,149 | 14,989 | (39)% | 29,476 | 30,372 | (3)% |
| Non-GAAP collaboration loss sharing | 9,149 | 14,989 | (39)% | 29,476 | 30,372 | (3)% |

[1] Non-GAAP cost of product revenues excludes the amortization of licensed intellectual property for Iclusig relating to the acquisition of the European business of ARIAD Pharmaceuticals, Inc. and the cost of stock-based compensation.
[2] Non-GAAP research and development expenses exclude the cost of stock-based compensation.
[3] Non-GAAP selling, general and administrative expenses exclude the cost of stock-based compensation and legal settlements.
[4] Non-GAAP change in fair value of acquisition-related contingent consideration is null.

**Research and development expenses** GAAP and Non-GAAP research and development expense for the quarter ended September 30, 2021 decreased 24% and 25%, respectively, compared to the same period in 2020, primarily due to $120 million of expense related to the purchase of an FDA priority review voucher in the prior year period that enabled an acceleration of the review of Opzelura for atopic dermatitis.

**Selling, general and administrative expenses** GAAP and Non-GAAP selling, general and administrative expenses for the quarter ended September 30, 2021 increased 58% compared to the same period in 2020, primarily due to expenses related to the establishment of our dermatology commercial organization and activities to support the launch of Opzelura for the treatment of atopic dermatitis.

**Other Financial Information**

**Operating income (loss)** GAAP and Non-GAAP operating income for the quarter ended September 30, 2021 increased by $230 million and $232 million, respectively, compared to the same period in 2020 primarily due to higher total revenues and lower research and development expenses, partially offset by higher selling, general and administrative expenses.

**Cash, cash equivalents and marketable securities position** As of September 30, 2021 and December 31, 2020, cash, cash equivalents and marketable securities totaled $2.3 billion and $1.8 billion, respectively.

**2021 Financial Guidance**

The Company has reaffirmed its full year 2021 financial guidance, as detailed below. Guidance does not include revenue from Opzelura in the U.S., Minjuvi in Europe or the impact of any potential future strategic transactions.

| | **Current** | **Previous** |
|---|---|---|
| Jakafi net product revenues | $2,125 - $2,170 million | Unchanged |
| Other Hematology/Oncology net product revenues | $155 - $170 million | Unchanged |
| GAAP Cost of product revenues | 6 – 7% of net product revenues | Unchanged |
| Non-GAAP Cost of product revenues[1] | 5 – 6% of net product revenues | Unchanged |
| GAAP Research and development expenses | $1,350 - $1,390 million | Unchanged |
| Non-GAAP Research and development expenses[2] | $1,220 - $1,250 million | Unchanged |
| GAAP Selling, general and administrative expenses | $725 - $755 million | Unchanged |
| Non-GAAP Selling, general and administrative expenses[3] | $655 - $680 million | Unchanged |

[1] 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.
[2] Adjusted to exclude the estimated cost of stock-based compensation.
[3] Adjusted to exclude the estimated cost of stock-based compensation and legal settlements.

**Conference Call and Webcast Information**
Incyte will hold a conference call and webcast this morning at 8:00 a.m. EDT. 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, 13718346.

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, 13718346.

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

**About Incyte**
Incyte is a Wilmington, Delaware-based, global biopharmaceutical company focused on finding solutions for serious unmet medical needs through the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit Incyte.com and follow @Incyte.

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

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

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

**About Opzelura™ (ruxolitinib) Cream**
Opzelura, a novel cream formulation of Incyte's selective JAK1/JAK2 inhibitor ruxolitinib, is the first and only topical JAK inhibitor approved for use in the United States 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.

Additionally, ruxolitinib cream is in Phase 3 development for the treatment of adolescents and adults with vitiligo in the TRuE-V clinical program. Results from this Phase 3 program were recently announced.

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

Opzelura is a trademark of Incyte.

**About Monjuvi®/Minjuvi® (tafasitamab)**
Tafasitamab is a humanized Fc-modified cytolytic CD19 targeting 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).

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

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

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

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

XmAb® is a registered trademark of Xencor, Inc.

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

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. Incyte has granted Innovent Biologics, Inc. rights to develop and commercialize pemigatinib in hematology and oncology in Mainland China, Hong Kong, Macau and Taiwan. Incyte has retained all other rights to develop and commercialize pemigatinib outside of the United States.

Pemazyre is a trademark of Incyte Corporation.

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

**About Iclusig® (ponatinib) tablets**

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

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

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

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

**Forward-Looking Statements**

Except for the historical information set forth herein, the matters set forth in this release contain predictions, estimates and other forward-looking statements, including any discussion of the following: Incyte's expectations with respect to submitting additional regulatory submissions over the coming months, including the NDA submission for QD ruxolitinib and the regulatory submissions seeking approval of ruxolitinib cream in vitiligo; Incyte's plans for collaborating with Syndax; Incyte's expectations regarding ongoing clinical trials and clinical trials to be initiated, including the LIMBER program, a proof of concept trial of tafasitamab in combination with lenalidomide and plamotamab in relapsed/refractory B-cell malignancies, a Phase 2 trial of tafasitamab in chronic lymphocytic leukemia, Phase 2 trials of pemigatinib in glioblastoma and non-small cell lung cancer, Phase 3 clinical trials of parsaclisib in autoimmune hemolytic anemia and non-Hodgkin lymphomas and a Phase 2 trial of INCB00928 in fibrodysplasia ossificans progressiva; and the Company's reaffirmation of its full year 2021 financial guidance and the expectations underlying such guidance.

These forward-looking statements are based on the Company's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: further research and development and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials and the ability to enroll subjects in accordance with planned schedules; the effects of the COVID 19 pandemic and measures to address the pandemic on the Company's clinical trials, supply chain and other third-party providers, sales and marketing efforts and business, development and discovery operations; determinations made by the FDA, FTC and other regulatory agencies both inside and outside of the United States; the Company's dependence on its relationships with and changes in the plans of its collaboration partners; the efficacy or safety of the Company's products and the products of the Company's collaboration partners; the acceptance of the Company's products and the products of the Company's collaboration partners in the marketplace; market competition; unexpected variations in the demand for the Company's products and the products of the Company's collaboration partners; the effects of announced or unexpected price regulation or limitations on reimbursement or coverage for the Company's products and the products of the Company's collaboration partners; sales, marketing, manufacturing and distribution requirements, including the Company'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; and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including its quarterly report on Form 10-Q for the quarter ended June 30, 2021. The Company disclaims any intent or obligation to update these forward-looking statements.

# # #

**Contacts**


| **Media** | | **Investors** | |
|---|---|---|---|
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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, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| | GAAP | | GAAP | |
| Revenues: | | | | |
| Product revenues, net | $ 594,013 | $ 522,252 | $ 1,673,974 | $ 1,509,269 |
| Product royalty revenues | 183,974 | 98,391 | 404,440 | 272,924 |
| Milestone and contract revenues | 35,000 | — | 45,000 | 95,000 |
| Total revenues | 812,987 | 620,643 | 2,123,414 | 1,877,193 |
| Costs and expenses: | | | | |
| Cost of product revenues (including definite-lived intangible amortization) | 39,869 | 34,322 | 107,117 | 95,005 |
| Research and development | 334,945 | 438,109 | 985,352 | 1,809,997 |
| Selling, general and administrative | 190,704 | 120,788 | 513,358 | 349,934 |
| Change in fair value of acquisition-related contingent consideration | 2,910 | 7,109 | 13,068 | 19,790 |
| Collaboration loss sharing | 9,149 | 14,989 | 29,476 | 30,372 |
| Total costs and expenses | 577,577 | 615,317 | 1,648,371 | 2,305,098 |
| Income (loss) from operations | 235,410 | 5,326 | 475,043 | (427,905) |
| Other income (expense), net | 1,948 | 4,917 | 4,931 | 18,396 |
| Interest expense | (439) | (544) | (1,156) | (1,746) |
| Unrealized gain (loss) on long term investments | (27,450) | (13,207) | (28,394) | 10,935 |
| Income (loss) before provision for income taxes | 209,469 | (3,508) | 450,424 | (400,320) |
| Provision for income taxes | 27,730 | 11,695 | 65,694 | 45,227 |
| Net income (loss) | $ 181,739 | $ (15,203) | $ 384,730 | $ (445,547) |
| Net income (loss) per share: | | | | |
| Basic | $ 0.82 | $ (0.07) | $ 1.75 | $ (2.05) |
| Diluted | $ 0.82 | $ (0.07) | $ 1.73 | $ (2.05) |
| Shares used in computing net income (loss) per share: | | | | |
| Basic | 220,845 | 218,784 | 220,243 | 217,684 |
| Diluted | 222,248 | 218,784 | 222,113 | 217,684 |

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

| | September 30, 2021 | December 31, 2020 |
|---|---|---|
| **ASSETS** | | |
| Cash, cash equivalents and marketable securities | $ 2,284,075 | $ 1,801,377 |
| Accounts receivable | 516,689 | 481,994 |
| Property and equipment, net | 686,718 | 559,625 |
| Finance lease right-of-use assets, net | 27,133 | 28,451 |
| Inventory | 52,188 | 35,973 |
| Prepaid expenses and other assets | 128,200 | 103,313 |
| Long term investments | 192,096 | 222,301 |
| Other intangible assets, net | 156,139 | 172,291 |
| Goodwill | 155,593 | 155,593 |
| Total assets | $ 4,198,831 | $ 3,560,918 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Accounts payable, accrued expenses and other liabilities | $ 764,398 | $ 648,793 |
| Finance lease liabilities | 33,776 | 34,857 |
| Acquisition-related contingent consideration | 252,000 | 266,000 |
| Stockholders' equity | 3,148,657 | 2,611,268 |
| Total liabilities and stockholders' equity | $ 4,198,831 | $ 3,560,918 |

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| **GAAP Net Income (Loss)** | $ 181,739 | $ (15,203) | $ 384,730 | $ (445,547) |
| *Adjustments[1]:* | | | | |
| Non-cash stock compensation from equity awards (R&D)[2] | 26,270 | 28,975 | 84,182 | 90,181 |
| Non-cash stock compensation from equity awards (SG&A)[2] | 15,904 | 14,580 | 49,500 | 41,719 |
| Non-cash stock compensation from equity awards (COGS)[2] | 520 | 245 | 1,102 | 716 |
| Non-cash interest[3] | 72 | 168 | 72 | 617 |
| Changes in fair value of equity investments[4] | 27,450 | 13,207 | 28,394 | (10,935) |
| Amortization of acquired product rights[5] | 5,384 | 5,384 | 16,152 | 16,152 |
| Change in fair value of contingent consideration[6] | 2,910 | 7,109 | 13,068 | 19,790 |
| Legal settlements[7] | 6,750 | — | 19,972 | — |
| Tax effect of Non-GAAP adjustments[8] | (5,175) | (4,406) | (7,759) | (7,976) |
| **Non-GAAP Net Income (Loss)** | $ 261,824 | $ 50,059 | $ 589,413 | $ (295,283) |
| | | | | |
| Non-GAAP net income (loss) per share: | | | | |
| Basic | $ 1.19 | $ 0.23 | $ 2.68 | $ (1.36) |
| Diluted | $ 1.18 | $ 0.23 | $ 2.65 | $ (1.36) |
| | | | | |
| Shares used in computing Non-GAAP net income (loss) per share: | | | | |
| Basic | 220,845 | 218,784 | 220,243 | 217,684 |
| Diluted | 222,248 | 221,357 | 222,113 | 217,684 |

[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, 2021 are milestones of $35,000 and $45,000, respectively, earned from our collaborative partners as compared to $0 and $95,000, respectively, for the same periods in 2020. 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, 2021 are upfront consideration and milestones of $4,333 and $20,833, respectively, related to our collaborative partners as compared to $141,450 and $950,482, respectively, related to our collaborative partners and FDA priority review voucher for the same periods in 2020.
[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 Change in fair value of acquisition-related contingent consideration line item in the Condensed Consolidated Statements of Operations.
[7] As included within Selling, general and administrative expenses line item in the Condensed Consolidated Statements of Operations.
[8] As included within the Provision for income taxes line item in the Condensed Consolidated Statements of Operations. Income tax effects of Non-GAAP adjustments are calculated using the applicable statutory tax rate for the jurisdictions in which the charges are incurred, while taking into consideration any valuation allowances.