UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 9, 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 **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:

☐ 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(s)**	**Name of each exchange on which registered**
Common Stock, $.001 par value per share	INCY	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b–2 of the Securities Exchange Act of 1934 (§240.12b–2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On February 9, 2021, Incyte Corporation issued a press release announcing financial results for its fourth fiscal quarter and year ended December 31, 2020. The full text of the press release is furnished as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) **Exhibits**

99.1	Press release issued by Incyte Corporation dated February 9, 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.

Dated: February 9, 2021

INCYTE CORPORATION

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

FOR IMMEDIATE RELEASE

Incyte Reports 2020 Fourth Quarter and Year-End Financial Results,
Provides 2021 Financial Guidance and Updates on Key Clinical Programs

- *Total FY revenues of $2.67 billion (+24% y/y); total FY product and royalty revenues increased 18% to $2.46 billion; three new FDA approvals in 2020*
- *Jakafi®(ruxolitinib) FY revenue increased to $1.94 billion (+15% y/y); Jakafi® guidance range of $2.125 to $2.20 billion for 2021*
- *Successful launches of Monjuvi®(tafasitamab-cxix) and Pemazyre® (pemigatinib) in the U.S.*
- *Opportunities for additional growth provided by broad late-stage pipeline, with the potential approval of ruxolitinib cream for atopic dermatitis in the U.S. and six other regulatory approval decisions expected across the U.S., EU and Japan during 2021*

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

WILMINGTON, Del. – February 9, 2021 – Incyte (Nasdaq: INCY) today reports 2020 fourth quarter and full year financial results, and provides a status update on the Company's development portfolio.

"Our team achieved many important accomplishments in the past year. Revenue growth was strong, driven by demand for Jakafi® (ruxolitinib), and the launches of Monjuvi® (tafasitamab-cxix) and Pemazyre® (pemigatinib) continue to gain momentum. During 2020, we also announced positive results across multiple late-stage programs, including the pivotal trials of ruxolitinib in chronic GVHD, ruxolitinib cream in atopic dermatitis, parsaclisib in NHL, and retifanlimab in SCAC," stated Hervé Hoppenot, Chief Executive Officer, Incyte. "During 2021, we expect regulatory decisions on seven applications seeking approval, including four in the U.S, two in Europe and one in Japan, and we are working towards the potential U.S. launch of ruxolitinib cream, which we expect to be approved by the FDA in the middle of the year."

Portfolio Updates

MPNs and GVHD – key highlights

Our LIMBER development program, to improve patient outcomes in MPNs and GHVD, is progressing well.

The two Phase 3 trials of ruxolitinib in combination with parsaclisib are both underway, evaluating the combination versus monotherapy ruxolitinib as a first-line therapy for patients with myelofibrosis (MF) (LIMBER-313) and as a therapy for MF patients with a suboptimal response to ruxolitinib monotherapy (LIMBER-304).

Monotherapy trials of INCB57643 (BET) and INCB00928 (ALK2) are underway, and are expected to lead to proof-of-concept combination trials of both agents with ruxolitinib in patients with myelofibrosis. A monotherapy trial of itacitinib (JAK1) in patients previously treated with ruxolitinib is ongoing.

In December 2020, Incyte and Cellenkos announced a development collaboration to investigate the combination of ruxolitinib and CK0804, Cellenkos' cryopreserved CXCR4 enriched, allogeneic, umbilical cord blood-derived T-regulatory cells, in patients with myelofibrosis. In addition, Incyte obtained an exclusive option to acquire sole rights to develop and commercialize CK0804, and genetically-modified variants of CK0804, in benign and malignant hematology indications.

The sNDA seeking approval of Jakafi in steroid-refractory chronic graft-versus-host disease (GVHD) has been submitted, based on data from the successful results of the REACH3 trial, which were presented at ASH 2020.

	Indication and status
Once-a-day ruxolitinib (JAK1/JAK2)	Myelofibrosis, polycythemia vera & GVHD: clinical pharmacology studies
ruxolitinib + parsaclisib (JAK1/JAK2 + PI3Kδ)	Myelofibrosis: Phase 3 (first-line therapy) (LIMBER-313) Myelofibrosis: Phase 3 (suboptimal responders to ruxolitinib) (LIMBER-304)
ruxolitinib + INCB57643 (JAK1/JAK2 + BET)	Myelofibrosis: Phase 2 in preparation
ruxolitinib + INCB00928 (JAK1/JAK2 + ALK2)	Myelofibrosis: Phase 2 in preparation
itacitinib (JAK1)	Myelofibrosis: Phase 2 (low platelets)
ruxolitinib + CK0804[1] (JAK1/JAK2 + CB-Tregs)	Myelofibrosis: PoC in preparation
ruxolitinib (JAK1/JAK2)	Steroid-refractory chronic GVHD[2]: sNDA submitted
itacitinib (JAK1)	Treatment-naïve chronic GVHD: Phase 3 (GRAVITAS-309)

1. Development collaboration with Cellenkos
2. Clinical development of ruxolitinib in GVHD conducted in collaboration with Novartis

Other Hematology/Oncology – key highlights

Momentum is strong behind the U.S. launch of Monjuvi (tafasitamab-cxix), with good uptake in both academic and community settings and illustrated by the market share gained in the first several months since launch.

The Phase 3 inMIND trial evaluating tafasitamab plus lenalidomide and rituximab (R-squared) versus R-squared in patients with relapsed or refractory follicular or marginal zone lymphoma is open for recruitment, and the Phase 3 frontMIND trial of tafasitamab plus lenalidomide and R-CHOP versus R-CHOP as a first-line treatment in patients with DLBCL is expected to open in the coming months.

The U.S. launch of Pemazyre (pemigatinib) has been successful and, in January, Incyte announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion recommending the conditional marketing authorization of pemigatinib for the treatment of adults with unresectable locally advanced or metastatic cholangiocarcinoma with an FGFR2 fusion or rearrangement that is relapsed or refractory, after at least one line of systemic therapy.

In December 2020, data from three ongoing Phase 2 studies evaluating parsaclisib for the treatment of patients with relapsed or refractory follicular (CITADEL-203), marginal zone (CITADEL-204) and mantle cell (CITADEL-205) lymphomas were presented at ASH 2020. Data from the CITADEL program are expected to form the basis of an NDA seeking FDA approval of parsaclisib, which is expected to be submitted in the second half of 2021.

In January 2021, Incyte announced that the FDA had accepted for Priority Review its Biologics License Application (BLA) for retifanlimab as a treatment for previously treated patients with advanced squamous cell anal carcinoma (SCAC) who have progressed following standard platinum-based chemotherapy. The BLA submission was based on data from the Phase 2 POD1UM-202 trial evaluating retifanlimab in previously treated patients with advanced SCAC who have progressed following standard platinum-based chemotherapy; the Phase 3 POD1UM-303 trial in patients with SCAC is underway.

	Indication and status
pemigatinib (FGFR1/2/3)	CCA: Phase 2 (FIGHT-202), Phase 3 (FIGHT-302); J-NDA under review 8p11 MPN: Phase 2 (FIGHT-203) Tumor agnostic: Phase 2 (FIGHT-207)
tafasitamab (CD19)[1]	r/r DLBCL: Phase 2 (L-MIND); Phase 3 (B-MIND); MAA under review 1L DLBCL: Phase 1b (firstMIND); Phase 3 (frontMIND) in preparation r/r FL and r/r MZL: Phase 3 (inMIND) open for recruitment r/r B-cell malignancies: PoC with parsaclisib (PI3Kδ) in preparation r/r B-cell malignancies: PoC with lenalidomide and plamotamab in preparation[2]
parsaclisib (PI3Kδ)	r/r follicular lymphoma: Phase 2 (CITADEL-203) r/r marginal zone lymphoma: Phase 2 (CITADEL-204) r/r mantle cell lymphoma: Phase 2 (CITADEL-205)
retifanlimab (PD-1)[3]	SCAC: Phase 2 (POD1UM-202); Phase 3 (POD1UM-303); BLA under review MSI-high endometrial cancer: Phase 2 (POD1UM-101, POD1UM-204) Merkel cell carcinoma: Phase 2 (POD1UM-201) NSCLC: Phase 3 (POD1UM-304)

CCA = cholangiocarcinoma; DLBCL = diffuse large B-cell lymphoma; SCAC = squamous cell anal carcinoma; FL = follicular lymphoma; MZL = marginal zone lymphoma

1. Development of tafasitamab in collaboration with MorphoSys
2. 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.
3. retifanlimab licensed from MacroGenics

Incyte's emerging clinical candidates in hematology/oncology include INCB86550, the first in a series of selective oral inhibitors of PD-L1; INCB81776, a dual AXL/MER inhibitor; INCB106385, an adenosine (A_{2A}/A_{2B}) inhibitor and, via a collaboration with Merus, MCLA-145, a PD-L1xCD137 bispecific antibody.

Inflammation and Autoimmunity (IAI) – key highlights

Dermatology

As planned, the NDA seeking approval of ruxolitinib cream as a treatment for patients with atopic dermatitis was submitted to the FDA late in the fourth quarter of 2020, including use of the previously acquired priority review voucher (PRV). The use of the PRV is expected to accelerate the time to an FDA decision.

Recruitment has been completed in both Phase 3 trials in the TRuE-V development program evaluating ruxolitinib cream as a treatment for patients with vitiligo, and topline results are expected to be announced in the first half of 2021. If successful, data from TRuE-V are expected to form the basis of an sNDA seeking approval of ruxolitinib cream as a treatment for patients with vitiligo, which would be submitted as soon as practicable after the FDA decision on the atopic dermatitis NDA.

	Indication and status
ruxolitinib cream (JAK1/JAK2)	Atopic dermatitis: NDA submitted Vitiligo: Phase 3 (TRuE-V1, TRuE-V2; recruitment complete in both trials)
INCB54707 (JAK1)	Hidradenitis suppurativa: Phase 2b
parsaclisib (PI3Kδ)	Autoimmune hemolytic anemia: Phase 2
INCB00928 (ALK2)	Fibrodysplasia ossificans progressiva: Phase 2 in preparation

Partnered – key highlights

In December 2020, Incyte and Lilly announced that Olumiant had been approved in Japan as a treatment of patients with atopic dermatitis who have inadequate response to conventional therapies.

	Indication and status
baricitinib (JAK1/JAK2)[1]	Atopic dermatitis: Phase 3 (BREEZE-AD); approved in EU and Japan Systemic lupus erythematosus: Phase 3 (BRAVE I, BRAVE II) Severe alopecia areata: Phase 3 (BRAVE-AA1, BRAVE-AA2)
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

Potential therapies for patients with COVID-19

In November 2020, Incyte and Lilly announced that the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the distribution and emergency use of baricitinib to be used in combination with remdesivir in hospitalized adult and pediatric patients two years of age or older with suspected or laboratory confirmed COVID-19 who require supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation.

In December 2020, the *New England Journal of Medicine* published peer-reviewed results from the Adaptive COVID-19 Treatment Trial (ACTT-2) sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the

National Institutes of Health (NIH). The Phase 3 study included 1,033 patients from 67 trial sites in eight countries. These results supported the EUA issued by the FDA.

	Status
ruxolitinib (JAK1/JAK2)	COVID-19 associated cytokine storm: Phase 3 (369-DEVENT)
baricitinib (JAK1/JAK2)[1]	Hospitalized patients with COVID-19: Phase 3 (COV-BARRIER)

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

2020 Fourth Quarter and Year-End Financial Results

The financial measures presented in this press release for the quarter and year ended December 31, 2020 and 2019 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 December 31,		Twelve Months Ended December 31,	
	2020	**2019**	**2020**	**2019**
Total GAAP revenue	$ 789,509	$ 579,389	$ 2,666,702	$ 2,158,759
Total GAAP operating income (loss)	164,229	95,008	(263,676)	402,006
Total Non-GAAP operating income (loss)	218,469	145,538	(40,878)	609,812
GAAP net income (loss)	149,850	111,005	(295,697)	446,906
Non-GAAP net income (loss)	204,773	141,936	(90,510)	615,459
GAAP basic EPS	$ 0.68	$ 0.51	$ (1.36)	$ 2.08
Non-GAAP basic EPS	$ 0.93	$ 0.66	$ (0.42)	$ 2.86
GAAP diluted EPS	$ 0.68	$ 0.51	$ (1.36)	$ 2.05
Non-GAAP diluted EPS	$ 0.93	$ 0.65	$ (0.42)	$ 2.83

Revenue Details

Revenue Details
(unaudited, in thousands)

	Three Months Ended December 31,		%	Twelve Months Ended December 31,		%
	2020	**2019**	**Change**	**2020**	**2019**	**Change**
Revenues:						
Jakafi net product revenues	$ 516,882	$ 466,464	11%	$ 1,937,850	$ 1,684,968	15%
Iclusig net product revenues	28,576	24,314	18%	105,002	89,954	17%
Pemazyre net product revenues	14,009	-	NM	25,884	-	NM
Jakavi product royalty revenues	87,046	65,007	34%	277,902	225,913	23%
Olumiant product royalty revenues	30,996	23,604	31%	110,920	80,424	38%
Tabrecta product royalty revenues	2,000	-	NM	4,144	-	NM
Product and royalty revenues	679,509	579,389	17%	2,461,702	2,081,259	18%
Milestone and contract revenues	110,000	-	NM	205,000	77,500	NM
Total GAAP revenues	$ 789,509	$ 579,389	36%	$ 2,666,702	$ 2,158,759	24%

NM = not meaningful

Product and Royalty Revenues Product and royalty revenues for the quarter and year ended December 31, 2020 increased 17% and 18%, respectively, over the prior year comparative periods primarily as a result of increases in Jakafi net product revenues, the launch of Pemazyre and higher product royalty revenues from Jakavi and Olumiant. Jakafi net product revenues for the quarter and year ended December 31, 2020 increased 11% and 15%, respectively, over the prior year comparative periods, primarily driven by growth in patient demand across all indications.

Operating Expenses

Operating Expense Summary
(unaudited, in thousands)

	Three Months Ended December 31,		%	Twelve Months Ended December 31,		%
	2020	**2019**	**Change**	**2020**	**2019**	**Change**
GAAP cost of product revenues	$ 36,323	$ 32,215	13%	$ 131,328	$ 114,249	15%
Non-GAAP cost of product revenues[1]	30,693	26,658	15%	108,830	92,015	18%
GAAP research and development	405,945	312,867	30%	2,215,942	1,154,111	92%
Non-GAAP research and development[2]	375,770	284,389	32%	2,095,586	1,040,169	101%
GAAP selling, general and administrative	166,988	136,177	23%	516,922	468,711	10%
Non-GAAP selling, general and administrative[3]	152,148	122,804	24%	460,363	416,763	10%
GAAP change in fair value of acquisition-related contingent consideration	3,595	3,122	15%	23,385	19,682	19%
Non-GAAP change in fair value of acquisition-related contingent consideration[4]	-	-		-	-	
GAAP collaboration loss sharing	12,429	-	NM	42,801	-	NM
Non-GAAP collaboration loss sharing	12,429	-	NM	42,801	-	NM

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.
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 December 31, 2020 increased 30% and 32%, respectively, compared to the same period in 2019 primarily due to our 55% share of the global and U.S. specific development costs for tafasitamab, product supply related costs to support the potential launch of ruxolitinib cream as a treatment for atopic dermatitis in 2021 and an increase in upfront and milestone payments under our collaborative agreements. Excluding the $42 million impact of product supply costs and the upfront and milestone payments, research and development expense for the quarter ended December 31, 2020 increased approximately 17% compared to the same period in 2019.

For the year ended December 31, 2020, GAAP and Non-GAAP research and development expense increased 92% and 101%, respectively, compared to the year ended December 31, 2019 primarily due to higher upfront and milestone payments under our collaborative agreements which includes upfront consideration of $805 million related to our collaborative agreement with MorphoSys, $120 million of expense related to the purchase of an FDA priority review voucher (“PRV”) utilized to accelerate the FDA review of ruxolitinib cream in atopic dermatitis, our 55% share of the global and U.S. specific development costs for tafasitamab, and product supply costs to support the potential launch of ruxolitinib cream. Excluding the $1.02 billion impact of upfront consideration and milestone payments, purchase of the PRV and product supply related costs, research and development expense for the year ended December 31, 2020 increased approximately 4% compared with the prior year period.

Selling, general and administrative expenses GAAP and Non-GAAP selling, general and administrative expenses for the quarter ended December 31, 2020 increased 23% and 24%, respectively, compared to the same period in 2019, primarily due to the timing of certain expenses. GAAP and Non-GAAP selling, general and administrative expenses for the year ended December 31, 2020 increased 10% compared to the year ended December 31, 2019 primarily due to an increase in sales and marketing spend to support the commercialization of Pemazyre in the US and to prepare for the potential launch of ruxolitinib cream in the U.S. and pemigatinib and tafasitamab in the EU.

Other Financial Information

Operating income (loss) GAAP and Non-GAAP operating income for the quarter ended December 31, 2020 increased compared to the same period in 2019, due to the growth in total revenues exceeding the growth in operating expenses. For the year ended December 31, 2020, Incyte recorded an operating loss compared to operating income for the same period in 2019, on both a GAAP and Non-GAAP basis, primarily due to upfront consideration related to our collaboration with MorphoSys and expense related to the PRV, partially offset by the growth in product and royalty revenues.

Cash, cash equivalents and marketable securities position As of December 31, 2020 and 2019, cash, cash equivalents and marketable securities totaled $1.8 billion and $2.1 billion, respectively. The decrease is primarily due to the upfront payment and stock purchase related to our collaborative agreement with MorphoSys and purchase of the PRV, partially offset by the cash flow generated in 2020.

2021 Financial Guidance

Due to the continuing growth and diversification of Incyte's commercial product portfolio, 2021 net product revenue guidance is being provided for Jakafi and in total for other Hematology/Oncology products, which currently include Iclusig in Europe and Pemazyre in the U.S. Guidance does not include revenue from any potential new product launches. However, GAAP and Non-GAAP selling, general and administrative expense guidance for 2021 includes costs to support the potential launches of ruxolitinib cream as a treatment for atopic dermatitis in the U.S., pemigatinib as a treatment for cholangiocarcinoma in the EU and Japan, and tafasitamab as a treatment for DLBCL in the EU. The 2021 financial guidance does not include the impact of any potential future strategic transactions.

Jakafi net product revenues	$2,125 - $2,200 million
Other Hematology/Oncology net product revenues	$145 - $160 million
GAAP Cost of product revenues	6 – 7% of net product revenues
Non-GAAP Cost of product revenues[1]	5 – 6% of net product revenues
GAAP Research and development expenses	$1,350 - $1,390 million
Non-GAAP Research and development expenses[2]	$1,220 - $1,250 million
GAAP Selling, general and administrative expenses	$735 - $775 million
Non-GAAP Selling, general and administrative expenses[2]	$665 - $700 million

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.

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, 13715042.

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, 13715042.

The conference call will also be webcast; the livestream and the replay 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 steroid-refractory acute GVHD 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 as well as adults with intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF.

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 Monjuvi® (tafasitamab-cxix)

Monjuvi 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).

Monjuvi is approved by the U.S. Food and Drug Administration 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). 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 January 2020, MorphoSys and Incyte entered into a collaboration and licensing agreement to further develop and commercialize tafasitamab globally. Monjuvi is being co-commercialized by Incyte and MorphoSys in the United States. Incyte has exclusive commercialization rights outside the United States.

A marketing authorization application (MAA) seeking the approval of tafasitamab in combination with lenalidomide in the EU has been validated by the European Medicines Agency (EMA) and is currently under review for the treatment of adult patients with relapsed or refractory DLBCL, including DLBCL arising from low grade lymphoma, who are not candidates for ASCT.

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

Monjuvi is a registered trademark of MorphoSys AG. XmAb® is a registered trademark of Xencor, Inc.

About Pemazyre® (pemigatinib)

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

Pemazyre is 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. 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.

Additionally, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending the conditional marketing authorization of pemigatinib for the treatment of adults with unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that is relapsed or refractory, after at least one line of systemic therapy.

Pemazyre is a trademark of Incyte Corporation.

About Iclusig® (ponatinib) tablets

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.

Incyte has an exclusive license from ARIAD Pharmaceuticals, Inc., since acquired by Takeda Pharmaceutical Company Limited, to develop and commercialize Iclusig in the European Union and 22 other countries, including Switzerland, Norway, Turkey, Israel and Russia.

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 without limitation statements regarding expectations for up to seven drug application approvals in 2021 in the U.S, Europe and Japan; the Company's ongoing clinical development program for ruxolitinib cream as well as its dermatology program generally; whether and when ruxolitinib cream will be approved in the U.S. or elsewhere for atopic dermatitis and the extent of our launch readiness; the expected timing of receipt and announcement of results for ruxolitinib cream for vitiligo; continued development of our LIMBER program, including expectations for, and timing and results of, ruxolitinib combination trials with parsaclisib; expectations for our monotherapy trials for INCB57643 (BET), and INCB00928 (ALK2); our collaboration with Cellenkos investigating the combination of ruxolitinib and CK0804; whether and when Jakafi will be approved in the U.S. or elsewhere for steroid-refractory chronic graft-versus-host disease (GVHD); whether and when the BLA for retifanlimab for SCAC will be approved; expectations for tafasitamab development, including the inMIND and frontMIND trials and plans to further broaden the development program of tafasitamab in other B-cell malignancies and clinical trial plans for such program; whether or when the European Commission will grant marketing authorization for pemigatinib in Europe; plans for ongoing and further development of parsaclisib in the CITADEL program and the planned timing of an NDA submission based on that program; and the expected timing of receipt and announcement of clinical trial results for INCB86550; and our financial guidance for 2021 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:; the actual time required by the FDA to review the Company's NDA for approval for ruxolitinib cream in atopic dermatitis, the Company's sNDA for Jakafi in steroid-refractory chronic graft-versus-host disease (GVHD) and the Company's BLA for retifanlimab in SCAC, and the results of such reviews; 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 and regulatory agencies 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 September 30, 2020. The Company disclaims any intent or obligation to update these forward-looking statements.

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2020	2019	2020	2019
	GAAP		GAAP	
Revenues:				
Product revenues, net	$ 559,467	$ 490,778	$ 2,068,736	$ 1,774,922
Product royalty revenues	120,042	88,611	392,966	306,337
Milestone and contract revenues	110,000	-	205,000	77,500
Total revenues	789,509	579,389	2,666,702	2,158,759
Costs and expenses:				
Cost of product revenues (including definite-lived intangible amortization)	36,323	32,215	131,328	114,249
Research and development	405,945	312,867	2,215,942	1,154,111
Selling, general and administrative	166,988	136,177	516,922	468,711
Change in fair value of acquisition-related contingent consideration	3,595	3,122	23,385	19,682
Collaboration loss sharing	12,429	-	42,801	-
Total costs and expenses	625,280	484,381	2,930,378	1,756,753
Income (loss) from operations	164,229	95,008	(263,676)	402,006
Other income (expense), net	4,810	15,848	23,206	52,182
Interest expense	(428)	(607)	(2,174)	(1,855)
Unrealized gain (loss) on long term investments	(509)	15,755	10,426	34,458
Income (loss) before provision for income taxes	168,102	126,004	(232,218)	486,791
Provision for income taxes	18,252	14,999	63,479	39,885
Net income (loss)	$ 149,850	$ 111,005	$ (295,697)	$ 446,906
Net income (loss) per share:				
Basic	$ 0.68	$ 0.51	$ (1.36)	$ 2.08
Diluted	$ 0.68	$ 0.51	$ (1.36)	$ 2.05
Shares used in computing net income (loss) per share:				
Basic	219,239	215,770	218,073	214,913
Diluted	221,228	218,542	218,073	217,657

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

	December 31, 2020	December 31, 2019
ASSETS		
Cash, cash equivalents and marketable securities	$ 1,801,377	$ 2,117,554
Accounts receivable	481,994	308,809
Property and equipment, net	559,625	377,567
Finance lease right-of-use assets, net	28,451	29,058
Inventory	35,973	16,505
Prepaid expenses and other assets	103,313	94,179
Long term investments	222,301	133,657
Other intangible assets, net	172,291	193,828
Goodwill	155,593	155,593
Total assets	$ 3,560,918	$ 3,426,750
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 648,793	$ 500,462
Finance lease liabilities	34,857	32,582
Convertible senior notes	-	18,300
Acquisition-related contingent consideration	266,000	277,000
Stockholders' equity	2,611,268	2,598,406
Total liabilities and stockholders' equity	$ 3,560,918	$ 3,426,750

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2020	**2019**	**2020**	**2019**
GAAP Net Income (Loss)	$ 149,850	$ 111,005	$ (295,697)	$ 446,906
Adjustments[1]*:*				
Non-cash stock compensation from equity awards (R&D)[2]	30,175	28,478	120,356	113,942
Non-cash stock compensation from equity awards (SG&A)[2]	14,840	13,373	56,559	51,948
Non-cash stock compensation from equity awards (COGS)[2]	246	173	962	698
Non-cash interest expense related to convertible notes[3]	66	221	683	867
Changes in fair value of equity investments[4]	509	(15,755)	(10,426)	(34,458)
Amortization of acquired product rights[5]	5,384	5,384	21,536	21,536
Change in fair value of contingent consideration[6]	3,595	3,122	23,385	19,682
Tax effect of Non-GAAP adjustments[7]	108	(4,065)	(7,868)	(5,662)
Non-GAAP Net Income (Loss)	$ 204,773	$ 141,936	$ (90,510)	$ 615,459
Non-GAAP net income (loss) per share:				
Basic	$ 0.93	$ 0.66	$ (0.42)	$ 2.86
Diluted	$ 0.93	$ 0.65	$ (0.42)	$ 2.83
Shares used in computing Non-GAAP net income (loss) per share:				
Basic	219,239	215,770	218,073	214,913
Diluted	221,228	218,542	218,073	217,657

1. Included within the Milestone and contract revenues line item in the Condensed Consolidated Statements of Operations (in thousands) for the three and twelve months ended December 31, 2020 are milestones of $110,000 and $205,000, respectively, earned from our collaborative partners as compared to upfront consideration and milestones of $0 and $77,500, respectively, for the same periods in 2019. Included within the Research and development expenses line item in the Condensed Consolidated Statements of Operations (in thousands) for the three and twelve months ended December 31, 2020 are upfront consideration and milestones of $25,600 and $976,082, respectively, related to our collaborative partners and FDA priority review voucher as compared to $2,500 and $27,500, respectively, for the same periods in 2019.
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 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.