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 5, 2020

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 November 5, 2020, Incyte Corporation issued a press release announcing financial results for its third fiscal quarter ended September 30, 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 November 5, 2020.
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: November 5, 2020

INCYTE CORPORATION

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

FOR IMMEDIATE RELEASE

Incyte Reports 2020 Third Quarter Financial Results
and Provides Updates on Key Clinical Programs

- *Total product and royalty revenues of $621 million (+16% vs Q3 2019) for the quarter ended September 30, 2020; Jakafi® (ruxolitinib) revenues of $488 million in Q3 2020 (+13% vs Q3 2019); Incyte tightens full year 2020 Jakafi revenue guidance to a range of $1.910 to $1.940 billion*
- *Strong momentum behind commercial launches of both Monjuvi® (tafasitamab-cxix) and Pemazyre® (pemigatinib) in the U.S.*
- *Incyte Dermatology established as a new franchise in the U.S.; priority review voucher acquired and expected to be used in NDA seeking approval for ruxolitinib cream in atopic dermatitis*
- *Late-stage clinical development pipeline continues to progress with multiple pivotal trials in oncology and dermatology*

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

WILMINGTON, Del. – November 5, 2020 – Incyte (Nasdaq: INCY) today reports 2020 third quarter financial results, and provides a status update on the Company's development portfolio.

"We are pleased to report another strong quarter for Incyte, with continued strength across all Jakafi® (ruxolitinib) indications, good momentum behind the U.S. launches of both Monjuvi® (tafasitamab-cxix) and Pemazyre® (pemigatinib), as well as increasing royalty contributions from our partnered medicines globally," stated Hervé Hoppenot, Chief Executive Officer, Incyte. "In addition, we have now established Incyte Dermatology as a new franchise for Incyte in the U.S., and we are on track to submit the NDA for ruxolitinib cream at the end of this year which, by using our priority review voucher, could lead to an FDA decision in the middle of next year."

Portfolio Update

LIMBER – key highlights

Two pivotal trials are being initiated to evaluate the combination of ruxolitinib and parsaclisib as both first-line therapy for myelofibrosis (MF) patients and in MF patients with an inadequate response to ruxolitinib monotherapy.

The Phase 2 monotherapy trial of INCB57643 (BET) in patients with refractory myelofibrosis are now recruiting and the Phase 2 monotherapy trial of INCB00928 (ALK2) in patients with myelofibrosis is being opened. Both programs are expected to proceed to ruxolitinib combination trials upon completion of monotherapy cohorts.

	Indication and status
Once-a-day ruxolitinib (JAK1/JAK2)	Myelofibrosis and polycythemia vera: clinical pharmacology studies
ruxolitinib + parsaclisib (JAK1/JAK2 + PI3Kδ)	Myelofibrosis: Phase 3 in preparation Myelofibrosis: Phase 3 in preparation (inadequate responders to ruxolitinib)
ruxolitinib + INCB57643 (JAK1/JAK2 + BET)	Myelofibrosis: Phase 2 in preparation
ruxolitinib + INCB00928 (JAK1/JAK2 + ALK2)	Myelofibrosis: Phase 2 in preparation

Oncology beyond MPNs – key highlights

In August, Monjuvi® (tafasitamab-cxix) in combination with lenalidomide was included in the latest National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology for B-cell Lymphomas with a Category 2A designation as an option for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (r/r DLBCL) and who are not eligible for autologous stem cell transplant (ASCT).

The European Marketing Authorization Application (MAA) for tafasitamab as a treatment for patients with r/r DLBCL is under review. Incyte has exclusive development and commercialization rights to tafasitamab outside of the U.S.

Incyte and MorphoSys plan to further broaden the development program of tafasitamab in other B-cell malignancies. Multiple trials are in preparation, including Phase 3 trials in both first line DLBCL and relapsed/refractory follicular lymphoma, as well as a proof-of-concept trial of tafasitamab plus parsaclisib (PI3Kδ).

In September, initial results from the Phase 2 POD1UM-202 trial of retifanlimab in previously treated patients with advanced squamous cell anal carcinoma (SCAC) who have progressed following standard platinum-based chemotherapy were presented at the European Society for Medical Oncology (ESMO) annual meeting. The Phase 3 POD1UM-303 trial of retifanlimab in combination with platinum-based chemotherapy as a first-line treatment for patients with SCAC is open for recruitment.

Given the rapidly evolving treatment landscape for bladder cancer and recent regulatory feedback, Incyte is reevaluating its development strategy for pemigatinib in bladder cancer. As part of that reevaluation, new patient recruitment into FIGHT-205, which is assessing pemigatinib in cisplatin-ineligible bladder cancer patients whose tumors express FGFR3 mutation or rearrangement, has been stopped, and Incyte no longer intends to use data from FIGHT-201 to seek accelerated approval for pemigatinib in patients with previously treated bladder cancer whose tumors express FGFR3 mutation or rearrangement.

	Indication and status
ruxolitinib (JAK1/JAK2)	Steroid-refractory chronic GVHD: Phase 3 (REACH3)[1] primary endpoint met
itacitinib (JAK1)	Treatment-naïve chronic GVHD: Phase 3 (GRAVITAS-309)
pemigatinib (FGFR1/2/3)	CCA: Phase 2 (FIGHT-202), Phase 3 (FIGHT-302); MAA, NDS and J-NDA under review 8p11 MPN: Phase 2 (FIGHT-203) Tumor agnostic: Phase 2 (FIGHT-207)
tafasitamab (CD19)[2]	r/r DLBCL: Phase 2 (L-MIND); Phase 3 (B-MIND); MAA under review 1L DLBCL: Phase 1b (First-MIND); Phase 3 (Front-MIND) in preparation r/r follicular lymphoma: Phase 3 in preparation r/r B-cell malignancies: PoC with parsaclisib (PI3Kδ) in preparation
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]	MSI-high endometrial cancer: Phase 2 (POD1UM-101); Phase 2 (POD1UM-204) in preparation Merkel cell carcinoma: Phase 2 (POD1UM-201) SCAC: Phase 2 (POD1UM-202); Phase 3 (POD1UM-303) open for recruitment NSCLC: Phase 3 (POD1UM-304)

CCA = cholangiocarcinoma; DLBCL = diffuse large B-cell lymphoma; SCAC = squamous cell anal carcinoma
1) Clinical development of ruxolitinib in GVHD conducted in collaboration with Novartis
2) Development of tafasitamab in collaboration with MorphoSys
3) retifanlimab licensed from MacroGenics

Inflammation and Autoimmunity (IAI) – key highlights

Dermatology

Incyte Dermatology has been established as a new franchise for Incyte in the U.S., which will include dedicated teams for the development and commercialization of Incyte's dermatology portfolio.

The NDA for ruxolitinib cream in atopic dermatitis is on track for submission at the end of 2020. Incyte has acquired a priority review voucher, which it intends to use to accelerate the timeline to FDA decision.

Pooled results from the TRuE-AD studies were presented at the European Academy of Dermatology and Venereology (EADV) Congress. Ruxolitinib cream demonstrated clinically meaningful improvements in patient-reported quality of life assessments, such as the PROMIS (patient-reported outcomes measurement information system) sleep disturbance (8b) score, as well as substantial and sustained itch reduction, reinforcing its potential as an important treatment option for atopic dermatitis patients.

The two randomized Phase 3 trials in the TRuE-V pivotal program evaluating ruxolitinib cream in patients with vitiligo are fully recruited, with results expected in 2021.

Other IAI

Initial clinical results from INCB54707, a JAK1 selective inhibitor, were presented in October. INCB54707 demonstrated preliminary efficacy, improved quality of life (QoL) including a reduction in skin pain and a tolerable safety profile in patients with moderate-to-severe hidradenitis suppurativa (HS). A Phase 2b, randomized, double-blind, placebo-controlled trial evaluating INCB54707 in HS is ongoing.

	Indication and status
ruxolitinib cream (JAK1/JAK2)	Atopic dermatitis: Phase 3 (TRuE-AD1, TRuE-AD2; primary endpoints met) Vitiligo: Phase 3 (TRuE-V1, TRuE-V2)
INCB54707 (JAK1)	Hidradenitis suppurativa: Phase 2b
parsaclisib (PI3Kδ)	Autoimmune hemolytic anemia: Phase 2
INCB00928 (ALK2)	Fibrodysplasia ossificans progressiva: Phase 2 in preparation

Discovery and early development – key highlights

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

Clinical translational data from the ongoing proof-of-concept trial of INCB86550, Incyte's first-in-class oral small molecule inhibitor of PD-L1, have been accepted for presentation at the 2020 Society for Immunotherapy for Cancer (SITC) meeting. As previously disclosed, initial clinical efficacy and safety data from this trial are expected to be presented in 2021, once these data mature.

Modality	**Candidates**
Small molecules	INCB01158 (ARG)[1], INCB81776 (AXL/MER), epacadostat (IDO1), INCB86550 (PD-L1)
Monoclonal antibodies[2]	INCAGN1876 (GITR), INCAGN2385 (LAG-3), INCAGN1949 (OX40), INCAGN2390 (TIM-3)
Bispecific antibodies	MCLA-145 (PD-L1xCD137)[3]

1) INCB01158 licensed from Calithera
2) Discovery collaboration with Agenus
3) MCLA-145 development in collaboration with Merus

Potential therapies for patients with COVID-19

Patient recruitment into the Phase 3 RUXCOVID study evaluating ruxolitinib versus standard-of-care in hospitalized patients with COVID-19 associated cytokine storm has been completed, and topline results are expected to be available before the end of 2020.

In September, Incyte and Eli Lilly announced initial results from the baricitinib arm of the National Institute of Allergy and Infectious Diseases (NIAID) Adaptive COVID-19 Treatment Trial (ACTT-2), where baricitinib in combination with remdesivir reduced the time to recovery (primary endpoint) in comparison with remdesivir alone.

Additional data announced in October showed that baricitinib plus remdesivir resulted in a numerical decrease in mortality through Day 29 compared to remdesivir alone, with a more pronounced reduction seen in more severely ill patients.

	Status
ruxolitinib (JAK1/JAK2)	COVID-19 associated cytokine storm: Phase 3 (RUXCOVID[1]; DEVENT)
baricitinib (JAK1/JAK2)[2]	Hospitalized patients with COVID-19: Phase 3 (ACTT-2[3]; COV-BARRIER)

1) Sponsored by Incyte in the United States and by Novartis outside of the United States
2) 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 for moderate to severe atopic dermatitis.
3) ACTT-2 agreement with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health

Partnered – key highlights

In October, Lilly announced that the European Commission granted marketing authorization for Olumiant® (baricitinib) 4mg and 2mg tablets in Europe for the treatment of adults with moderate to severe atopic dermatitis (AD) who are candidates for systemic therapy, becoming the first JAK-inhibitor indicated to help treat patients with AD.

In September, Incyte and Novartis announced that GEOMETRY mono-1 results of Tabrecta™ (capmatinib) in patients with METex14 metastatic non-small cell lung cancer (NSCLC) were published in The New England Journal of Medicine.

	Indication and status
baricitinib (JAK1/JAK2)[1]	Atopic dermatitis: Phase 3 (BREEZE-AD); approved in EU Systemic lupus erythematosus: Phase 3 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
2) Worldwide rights to capmatinib licensed to Novartis

2020 Third Quarter Financial Results

The financial measures presented in this press release for the three and nine months ended September 30, 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 September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Total GAAP revenue	$ 620,643	$ 551,581	$ 1,877,193	$ 1,579,370
Total GAAP operating income (loss)	5,326	134,316	(427,905)	306,998
Total Non-GAAP operating income (loss)	61,619	186,338	(259,347)	464,274
GAAP net income (loss)	(15,203)	128,271	(445,547)	335,901
Non-GAAP net income (loss)	50,059	179,019	(295,283)	476,030
GAAP basic EPS	$ (0.07)	$ 0.60	$ (2.05)	$ 1.57
Non-GAAP basic EPS	$ 0.23	$ 0.83	$ (1.36)	$ 2.22
GAAP diluted EPS	$ (0.07)	$ 0.59	$ (2.05)	$ 1.55
Non-GAAP diluted EPS	$ 0.23	$ 0.82	$ (1.36)	$ 2.19

Revenue Details

Revenue Details
(unaudited, in thousands)

	Three Months Ended September 30,		%	Nine Months Ended September 30,		%
	2020	2019	Change	2020	2019	Change
Revenues:						
Jakafi net product revenue	$ 487,783	$ 433,387	13%	$ 1,420,968	$ 1,218,504	17%
Iclusig net product revenue	26,380	20,611	28%	76,426	65,640	16%
Pemazyre net product revenue	8,089	-		11,875	-	
Jakavi product royalty revenues	68,306	58,440	17%	190,856	160,906	19%
Olumiant product royalty revenues	28,647	21,643	32%	79,924	56,820	41%
Tabrecta product royalty revenues	1,438	-		2,144	-	
Product and royalty revenues	620,643	534,081	16%	1,782,193	1,501,870	19%
Milestone and contract revenues	-	17,500	(100)%	95,000	77,500	23%
Total GAAP revenues	$ 620,643	$ 551,581	13%	$ 1,877,193	$ 1,579,370	19%

Product and Royalty Revenues Product and royalty revenues for the three and nine months ended September 30, 2020 increased 16% and 19%, 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 three and nine months ended September 30, 2020 increased 13% and 17%, 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 September 30,		%	Nine Months Ended September 30,		%
	2020	2019	Change	2020	2019	Change
GAAP cost of product revenues	$ 34,322	$ 30,040	14%	$ 95,005	$ 82,034	16%
Non-GAAP cost of product revenues[1]	28,693	24,483	17%	78,137	65,357	20%
GAAP research and development	438,109	281,336	56%	1,809,997	841,244	115%
Non-GAAP research and development[2]	409,134	250,910	63%	1,719,816	755,780	128%
GAAP selling, general and administrative	120,788	102,608	18%	349,934	332,534	5%
Non-GAAP selling, general and administrative[3]	106,208	89,850	18%	308,215	293,959	5%
GAAP change in fair value of acquisition-related contingent consideration	7,109	3,281	117%	19,790	16,560	20%
Non-GAAP change in fair value of acquisition-related contingent consideration[4]	-	-		-	-	
GAAP collaboration loss sharing	14,989	-		30,372	-	
Non-GAAP collaboration loss sharing	14,989	-		30,372	-	

[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 three months ended September 30, 2020 increased 56% and 63%, respectively, compared to the same period in 2019, primarily due to $120 million of expense related to the purchase of an FDA priority review voucher from a third party, which we intend to use to accelerate the FDA review of ruxolitinib cream for the treatment of atopic dermatitis and an increase in milestone expenses related to our collaborative agreements. For the nine months ended September 30, 2020, GAAP and Non-GAAP research and development expense increased 115% and 128%, respectively, compared to the same period in 2019, primarily due to upfront consideration of $805 million related to our collaborative agreement with MorphoSys and expense related to the purchase of the FDA priority review voucher.

Selling, general and administrative expenses GAAP and Non-GAAP selling, general and administrative expenses for the three months and nine months ended September 30, 2020 increased 18% and 5%, respectively, compared to the same periods in 2019, primarily due to increased headcount and activities supporting the commercialization of our products and the timing of certain expenses.

Other Financial Information

Operating income (loss) GAAP and Non-GAAP operating income for the three months ended September 30, 2020 decreased compared to the same period in 2019, primarily due to $120 million of expense related to the purchase of the FDA priority review voucher and milestone expenses related to our collaborative agreements. For the nine months ended September 30, 2020 we 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 FDA priority review voucher, partially offset by the growth in product and royalty revenues.

Cash, cash equivalents and marketable securities position As of September 30, 2020 and December 31, 2019, cash, cash equivalents and marketable securities totaled $1.7 billion and $2.1 billion, respectively. The decrease is primarily driven by the upfront payment and stock purchase related to our collaborative agreement with MorphoSys and purchase of the FDA priority review voucher and is partially offset by the cash flow generated during this nine-month period.

2020 Financial Guidance

Incyte has tightened its full year 2020 guidance for Jakafi net product revenues, as detailed below. The company’s full year 2020 financial guidance is summarized in the following table. The R&D expense guidance excludes $805 million of upfront consideration paid under the MorphoSys collaboration and $120 million of expense related to the purchase of the FDA priority review voucher (PRV). The financial guidance also excludes the impact of any potential future strategic transactions.

All data in millions[1]	Current	Previous
Jakafi net product revenues	$1,910 - $1,940	$1,880 - $1,950
Iclusig net product revenues	$100 - $105	Unchanged
Cost of product revenues	$130 - $135	Unchanged
Research and development expenses (Excl. MOR upfront cons. & PRV)	$1,210 - $1,280	Unchanged
Selling, general and administrative expenses	$505 - $535	Unchanged
Change in fair value of acquisition-related contingent consideration	$25 - $27	Unchanged

[1.] Amounts exclude Non-GAAP adjustments (e.g., stock based comp, amortization of acquired product rights for Iclusig and change in fair value of estimated future royalties for Iclusig). Research and development expenses also excludes $805 million of upfront consideration paid under the MorphoSys collaboration and $120 million of expense related to the purchase of the FDA priority review voucher.

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, 13711777.

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, 13711777.

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).

In January 2020, MorphoSys and Incyte entered into a collaboration and licensing agreement to further develop and commercialize Monjuvi globally. Monjuvi will be 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 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.

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, Incyte's marketing authorization application (MAA) seeking the approval of pemigatinib for patients with cholangiocarcinoma in the EU has been validated by the European Medicines Agency (EMA) and is currently under review for the treatment of adults with 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: the expected use of the priority review voucher and its effect on the timing of the FDA review process, the expected timing for the submission of the an NDA for ruxolitinib cream for atopic dermatitis and the expected timing of any FDA decision with respect to such NDA; plans for ruxolitinib combination trials with INCB57643 (BET) and INCB00928 (ALK2); plans to further broaden the development program of tafasitamab in other B-cell malignancies and clinical trial plans for such program; the expected timing of receipt of clinical trial results for ruxolitinib cream for vitiligo and ruxolitinib for COVID-19; the expected timing of receipt and announcement of clinical trial results for INCB86550; and the Company's reaffirmed and updated financial guidance for 2020 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: unanticipated delays in the submission of the Company’s NDA for ruxolitinib cream for atopic dermatitis; the actual time required by the FDA to review the Company’s NDA for approval for ruxolitinib cream in atopic dermatitis, should such NDA be submitted, and the results of such review; 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 June 30, 2020. The Company disclaims any intent or obligation to update these forward-looking statements.

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Incyte Contacts

Media

Catalina Loveman
+1 302 498 6171
cloveman@incyte.com

Investors

Michael Booth, DPhil
+1 302 498 5914
mbooth@incyte.com

Christine Chiou
+1 302 274 4773
cchiou@incyte.com

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	GAAP		GAAP	
Revenues:				
Product revenues, net	$ 522,252	$ 453,998	$ 1,509,269	$ 1,284,144
Product royalty revenues	98,391	80,083	272,924	217,726
Milestone and contract revenues	-	17,500	95,000	77,500
Total revenues	620,643	551,581	1,877,193	1,579,370
Costs and expenses:				
Cost of product revenues (including definite-lived intangible amortization)	34,322	30,040	95,005	82,034
Research and development	438,109	281,336	1,809,997	841,244
Selling, general and administrative	120,788	102,608	349,934	332,534
Change in fair value of acquisition-related contingent consideration	7,109	3,281	19,790	16,560
Collaboration loss sharing	14,989	-	30,372	-
Total costs and expenses	615,317	417,265	2,305,098	1,272,372
Income (loss) from operations	5,326	134,316	(427,905)	306,998
Other income (expense), net	4,917	11,961	18,396	36,334
Interest expense	(544)	(597)	(1,746)	(1,248)
Unrealized gain (loss) on long term investments	(13,207)	2,339	10,935	18,703
Income (loss) before provision for income taxes	(3,508)	148,019	(400,320)	360,787
Provision for income taxes	11,695	19,748	45,227	24,886
Net income (loss)	$ (15,203)	$ 128,271	$ (445,547)	$ 335,901
Net income (loss) per share:				
Basic	$ (0.07)	$ 0.60	$ (2.05)	$ 1.57
Diluted	$ (0.07)	$ 0.59	$ (2.05)	$ 1.55
Shares used in computing net income (loss) per share:				
Basic	218,784	215,199	217,684	214,628
Diluted	218,784	217,791	217,684	217,393

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

	September 30, 2020	December 31, 2019
ASSETS		
Cash, cash equivalents and marketable securities	$ 1,734,800	$ 2,117,554
Accounts receivable	356,182	308,809
Property and equipment, net	498,335	377,567
Finance lease right-of-use assets, net	29,123	29,058
Inventory	25,709	16,505
Prepaid expenses and other assets	107,203	94,179
Long term investments	222,810	133,657
Other intangible assets, net	177,675	193,828
Goodwill	155,593	155,593
Total assets	$ 3,307,430	$ 3,426,750
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 597,871	$ 500,462
Finance lease liabilities	34,826	32,582
Convertible senior notes	11,900	18,300
Acquisition-related contingent consideration	272,000	277,000
Stockholders' equity	2,390,833	2,598,406
Total liabilities and stockholders' equity	$ 3,307,430	$ 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
GAAP Net Income (Loss)	$ (15,203)	$ 128,271	$ (445,547)	$ 335,901
Adjustments[1]*:*				
Non-cash stock compensation from equity awards (R&D)[2]	28,975	30,426	90,181	85,464
Non-cash stock compensation from equity awards (SG&A)[2]	14,580	12,758	41,719	38,575
Non-cash stock compensation from equity awards (COGS)[2]	245	173	716	525
Non-cash interest expense related to convertible notes[3]	168	218	617	646
Changes in fair value of equity investments[4]	13,207	(2,339)	(10,935)	(18,703)
Amortization of acquired product rights[5]	5,384	5,384	16,152	16,152
Change in fair value of contingent consideration[6]	7,109	3,281	19,790	16,560
Tax effect of Non-GAAP adjustments[7]	(4,406)	847	(7,976)	910
Non-GAAP Net Income (Loss)	$ 50,059	$ 179,019	$ (295,283)	$ 476,030
Non-GAAP net income (loss) per share:				
Basic	$ 0.23	$ 0.83	$ (1.36)	$ 2.22
Diluted	$ 0.23	$ 0.82	$ (1.36)	$ 2.19
Shares used in computing Non-GAAP net income (loss) per share:				
Basic	218,784	215,199	217,684	214,628
Diluted	221,357	217,791	217,684	217,393

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, 2020 are milestones of $0 and $95,000, respectively, earned from our collaborative partners as compared to upfront consideration and milestones of $17,500 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 nine months ended September 30, 2020 are upfront consideration and milestones of $141,450 and $950,482, respectively, related to our collaborative partners and FDA priority review voucher as compared to $0 and $25,000, 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.