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): May 5, 2020

INCYTE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware

(State or Other Jurisdiction of

Incorporation)

001-12400 (Commission File Number) **94-3136539** (I.R.S. Employer Identification No.)

1801 Augustine Cut-Off Wilmington, DE

(Address of principal executive offices)

19803 (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 \Box

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 May 5, 2020, Incyte Corporation issued a press release announcing financial results for its first fiscal quarter ended March 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 May 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: May 5, 2020

INCYTE CORPORATION

By:

/s/ Christiana Stamoulis

Christiana Stamoulis Executive Vice President and Chief Financial Officer



FOR IMMEDIATE RELEASE

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

- Total product and royalty revenues of \$569 million (+24% vs Q1 2019) for the quarter ended March 31, 2020; Jakafi[®] (ruxolitinib) revenues of \$459 million in Q1 2020 (+22% vs Q1 2019)
- PemazyreTM (pemigatinib) approved by FDA as first targeted treatment for adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma
- Data from successful Phase 3 TRuE-AD program for ruxolitinib cream presented at Revolutionizing Atopic Dermatitis (RAD) conference; NDA on track for end 2020
- Ruxolitinib and baricitinib in clinical trials to treat patients suffering from COVID-19

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

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

"Our strong first quarter results highlight continued revenue momentum, led by robust demand across all three indications for Jakafi[®] (ruxolitinib)," stated Hervé Hoppenot, Chief Executive Officer, Incyte. "As we navigate this unprecedented and uncertain time, we have implemented numerous initiatives as we seek to ensure continuity of patient care. We are continuing to execute on our goals, and we were very pleased to announce the FDA approval of PemazyreTM (pemigatinib), the first of three potential product approvals that we expect to announce in 2020. The FDA review of the capmatinib NDA and tafasitamab BLA are proceeding as expected and, following positive results from our Phase 3 TRuE-AD development program in atopic dermatitis, we are also on track to submit the NDA for ruxolitinib cream at the end of 2020, all of which positions us for what I expect to be a transformational year."

COVID-19

Commercial, Supply and Clinical & Regulatory Impact

While it is currently not possible to predict the overall long-term impact of the COVID-19 pandemic on Incyte's business, to-date, there has been no impact on the commercial side of the business, and Incyte currently has ample commercial and clinical supply of our medicines to meet the needs of patients receiving Incyte's approved medicines and those participating in global clinical trials. Incyte's manufacturing processes are proceeding as usual, with increased manufacturing efforts for ruxolitinib in place to respond to the COVID-19 pandemic and study requests. Incyte continues to move forward with its global clinical trials, and late-stage programs remain broadly on track, although short-term effects may continue to emerge. For example, while ongoing monitoring of already-enrolled patients is expected to continue, new patient recruitment in certain clinical studies may be impacted. The impact on clinical trials may also vary by disease state and by severity of disease, as well as by geography, as some regions are more adversely impacted.

Ruxolitinib and baricitinib as potential therapies for patients with COVID-19

Incyte has initiated a Phase 3 clinical trial (RUXCOVID) to evaluate the efficacy and safety of ruxolitinib plus standard-of-care (SoC), compared to SoC therapy alone, in patients with COVID-19 associated cytokine storm. The collaborative study is sponsored by Incyte in the United States and by Novartis outside of the United States.

Incyte is also opening a second Phase 3 clinical trial in the United States to evaluate the efficacy and safety of ruxolitinib plus SoC, compared to SoC therapy alone, in COVID-19 patients on mechanical ventilation and who have acute respiratory distress syndrome (ARDS), a type of respiratory failure characterized by rapid onset of widespread inflammation in the lungs.

Additionally, Incyte has launched an emergency Expanded Access Program in the United States to allow eligible patients with COVID-19 associated cytokine storm to receive ruxolitinib.

In April, Lilly announced it has entered into an agreement with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), to study baricitinib as an arm in NIAID's Adaptive COVID-19 Treatment Trial. The study will investigate the efficacy and safety of baricitinib as a potential treatment for hospitalized patients diagnosed with COVID-19 in the US, and Lilly is also planning a study expansion to include Europe and Asia.

Portfolio Update

LIMBER - key highlights

Key LIMBER development programs, including the once-a-day (QD) formulation of ruxolitinib, and the ongoing and planned ruxolitinib combinations with parsaclisib (PI3Kδ), PIM, BET and ALK2 are currently on track.

	Indication and status
Once-a-day ruxolitinib	Myelofibrosis and polycythemia vera: clinical pharmacology studies
(JAK1/JAK2)	
ruxolitinib + parsaclisib	Refractory myelofibrosis: Phase 3 in preparation
(JAK1/JAK2 + PI3Kδ)	
ruxolitinib + INCB53914	Refractory myelofibrosis: Phase 2
(JAK1/JAK2 + PIM)	
ruxolitinib + INCB57643	Refractory myelofibrosis: Phase 2 in preparation
(JAK1/JAK2 + BET)	
ruxolitinib + INCB00928	Myelofibrosis: Phase 2 in preparation
(JAK1/JAK2 + ALK2)	

Oncology beyond MPNs - key highlights

In April, the FDA approved Pemazyre, Incyte's selective fibroblast growth factor receptor (FGFR) inhibitor, for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with an FGFR2 fusion or other rearrangement as detected by an FDA-approved test. Pemazyre was reviewed under Breakthrough Therapy designation and granted accelerated approval based on overall response rate and duration of response. The marketing authorization application (MAA) seeking approval for pemigatinib in Europe is under review by the European Medicines Agency (EMA).

Delays in data collection and validation, caused by COVID-19 related disruption, mean that data from the FIGHT-201 clinical trial of pemigatinib in patients with bladder cancer are now expected to be presented at a medical conference in early 2021; all other clinical trials of pemigatinib are currently progressing as expected.

Data from the Phase 3 REACH 2 trial of ruxolitinib versus best available therapy (BAT) in patients with steroid-refractory acute graft-versus-host disease (GVHD) have been published in *The New England Journal of Medicine* and are also expected to be presented at the 46th annual meeting of the European Society for Blood and Marrow Transplantation (EBMT) in August 30-September 2, 2020 (postponed from March 22-25, 2020). The Phase 3 REACH 3 trial of ruxolitinib versus BAT in patients with steroid-refractory chronic GVHD has completed recruitment and results are expected in the second half of 2020.

The collaboration and license agreement with MorphoSys for the development and commercialization of tafasitamab became effective in March. In February, the FDA granted Priority Review for tafasitamab in combination with lenalidomide for the treatment of relapsed or refractory diffuse large B-cell lymphoma (r/r DLBCL), and set a PDUFA goal date of August 30, 2020.

Preparations are ongoing to initiate the Phase 3 POD1UM-304 trial of retifanlimab (formerly INCMGA0012) in combination with platinum-based chemotherapy as a first-line treatment for patients with non-small cell lung cancer (NSCLC). Incyte no longer plans to pursue the Phase 3 POD1UM-301 trial of retifanlimab in combination with chemoradiation therapy (CRT) in participants with unresectable, Stage III NSCLC.

	Indication and status
ruxolitinib (JAK1/JAK2)	Steroid-refractory chronic GVHD: Phase 3 (REACH3) ¹
itacitinib (JAK1)	Treatment-naïve chronic GVHD: Phase 3 (GRAVITAS-309)
pemigatinib (FGFR1/2/3)	Cholangiocarcinoma: Phase 2 (FIGHT-202), Phase 3 (FIGHT-302); MAA under review Bladder cancer: Phase 2 (FIGHT-201, FIGHT-205) 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); BLA under review 1L DLBCL: Phase 1b (First-MIND)
parsaclisib (PI3K8)	Follicular lymphoma: Phase 2 (CITADEL-203) Marginal zone lymphoma: Phase 2 (CITADEL-204) Mantle cell lymphoma: Phase 2 (CITADEL-205)
retifanlimab (PD-1) ³	MSI-high endometrial cancer: Phase 2 (POD1UM-101) Merkel cell carcinoma: Phase 2 (POD1UM-201) Anal cancer: Phase 2 (POD1UM-202) NSCLC: Phase 3 (POD1UM-304) in preparation

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

In April, safety and efficacy data from the two Phase 3 trials in the TRuE-AD program evaluating ruxolitinib cream in mild-to-moderate atopic dermatitis were presented at the Revolutionizing Atopic Dermatitis (RAD) virtual symposium. The 44-week long-term safety and efficacy portion of both the TRuE-AD1 and TRuE-AD2 trials are ongoing and the NDA submission is expected before the end of 2020.

The two Phase 3 trials in the TRuE-V pivotal program evaluating ruxolitinib cream in patients with vitiligo are currently proceeding as planned, and results are expected in 2021.

	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 2
parsaclisib (ΡΙ3Κδ)	Autoimmune hemolytic anemia: Phase 2
INCB00928 (ALK2)	Fibrodysplasia ossificans progressiva: Phase 2 in preparation

Discovery and early development - key highlights

Based on emerging data from the FGFR4 inhibitor program, development of INCB62079 has been discontinued because of insufficient efficacy in the target patient population. Incyte's portfolio of other earlier-stage clinical candidates is summarized below.

Modality	Candidates
Small molecules	INCB01158 (ARG) ¹ , INCB81776 (AXL/MER), epacadostat (IDO1), INCB59872 (LSD1), 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 development in collaboration with Calithera

2) Discovery collaboration with Agenus

3) MCLA-145 development in collaboration with Merus

Partnered – key highlights

In March, Incyte and Lilly announced the FDA has granted Breakthrough Therapy designation for baricitinib for the treatment of alopecia areata, an autoimmune disorder that can cause unpredictable hair loss on the scalp, face and other areas of the body. In January, Lilly submitted baricitinib for regulatory review in Europe and Japan as a treatment for patients with moderate-to-severe atopic dermatitis, and has announced plans to submit for approval in the U.S. in 2020.

In February, Incyte and Novartis announced that the NDA for capmatinib, seeking approval in patients with metastatic non-small cell lung cancer (NSCLC) and with a mutation leading to exon 14 skipping as detected by an FDA-approved test, was accepted for Priority Review by the FDA.

	Indication and status
baricitinib (JAK1/JAK2) ¹	Atopic dermatitis: Phase 3 (BREEZE-AD) Systemic lupus erythematosus: Phase 3 Severe alopecia areata: Phase 3 (BRAVE-AA1)
capmatinib (MET) ²	NSCLC (with MET exon 14 skipping mutations): NDA (by Novartis) under review

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 First Quarter Financial Results

The financial measures presented in this press release for the three months ended March 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 (unaudited, in thousands, except per share amounts)

	 Three Months Ended March 31,		
	2020		2019
Total GAAP revenue	\$ 568,507	\$	497,857
Total GAAP operating income (loss)	(664,004)		74,070
Total Non-GAAP operating income (loss)	(609,480)		126,717
GAAP net income (loss)	(720,642)		102,312
Non-GAAP net income (loss)	(618,920)		134,542
GAAP basic EPS	\$ (3.33)	\$	0.48
Non-GAAP basic EPS	\$ (2.86)	\$	0.63
GAAP diluted EPS	\$ (3.33)	\$	0.47
Non-GAAP diluted EPS	\$ (2.86)	\$	0.62

Revenue Details

Revenue Details (unaudited, in thousands)

	Three Months Ended March 31,			%	
	 2020 2019		20 2019 Chai		
Revenues:		-			
Jakafi net product revenue	\$ 459,479	\$	375,611	22%	
Iclusig net product revenue	27,248		20,638	32%	
Jakavi product royalty revenues	56,333		45,571	24%	
Olumiant product royalty revenues	25,447		16,037	59%	
Product and royalty revenues	 568,507		457,857	24%	
Milestone and contract revenues	-		40,000		
Total GAAP revenues	\$ 568,507	\$	497,857	14%	

Product and Royalty Revenues Product and royalty revenues for the quarter ended March 31, 2020 increased 24% over the prior year comparative period as a result of increases in Jakafi and Iclusig net product revenues and higher product royalty revenues from Jakavi and Olumiant. Jakafi net product revenues for the quarter ended March 31, 2020 increased 22% over the prior year comparative period, primarily driven by growth in patient demand across all indications.

Operating Expense Summary (unaudited, in thousands)

	Three Months Ended				
	March 31,				%
		2020		2019	Change
GAAP cost of product revenues	\$	27,319	\$	22,588	21%
Non-GAAP cost of product revenues ¹		21,710		17,028	27%
GAAP research and development		1,085,287		270,545	301%
Non-GAAP research and development ²		1,056,574		243,123	335%
GAAP selling, general and administrative		111,148		123,983	(10%)
Non-GAAP selling, general and administrative ³		97,573		110,989	(12%)
GAAP change in fair value of acquisition-related contingent consideration		6,627		6,671	(1%)
Non-GAAP change in fair value of acquisition-related contingent consideration ⁴		-		-	
GAAP collaboration loss sharing		2,130		-	
Non-GAAP collaboration loss sharing		2,130		-	

^{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 March 31, 2020 increased 301% and 335%, respectively, compared to the same period in 2019, primarily due to upfront consideration of \$805 million related to our collaborative agreement with MorphoSys.

Selling, general and administrative expenses GAAP and Non-GAAP selling, general and administrative expenses for the quarter ended March 31, 2020 decreased 10% and 12%, respectively, compared to the same period in 2019, primarily due to the timing of certain expenses.

Other Financial Information

Operating income (loss) GAAP and Non-GAAP operating income (loss) for the quarter ended March 31, 2020 decreased compared to the same period in 2019 primarily due to upfront consideration related to our collaborative agreement with MorphoSys, partially offset by the growth in product and royalty revenues.

Cash, cash equivalents and marketable securities position As of March 31, 2020 and December 31, 2019, cash, cash equivalents and marketable securities totaled \$1.3 billion and \$2.1 billion, respectively. The decrease reflects the upfront payment and stock purchase related to our collaborative agreement with MorphoSys.

2020 Financial Guidance

The Company has reaffirmed its full year 2020 financial guidance, as detailed below. The R&D expense guidance now includes the expenses related to Incyte's share of tafasitamab development costs under the MorphoSys collaboration, but excludes \$805 million of upfront consideration paid under the MorphoSys collaboration. The financial guidance also excludes the impact of any potential future strategic transactions.

All data in millions	Current	Previous
Jakafi net product revenues	\$1,880 - \$1,950	Unchanged
Iclusig net product revenues	\$100 - \$105	Unchanged
GAAP Cost of product revenues	\$130 - \$135	Unchanged
Non-GAAP Cost of product revenues ¹	\$107 - \$112	Unchanged
GAAP Research and development expenses	\$1,210 - \$1,280	Unchanged
Non-GAAP Research and development expenses ²	\$1,079 - \$1,149	Unchanged
GAAP Selling, general and administrative expenses	\$505 - \$535	Unchanged
Non-GAAP Selling, general and administrative expenses ²	\$447 - \$477	Unchanged
GAAP Change in fair value of acquisition-related contingent consideration	\$25 - \$27	Unchanged
Non-GAAP Change in fair value of acquisition-related contingent consideration ³	\$0	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 change in fair value of estimated future royalties relating to sales of Iclusig in the licensed territory relating to the acquisition of the European business of ARIAD Pharmaceuticals, Inc.

Future Non-GAAP financial measures may also exclude impairment of goodwill or other assets, changes in the fair value of equity investments in our collaboration partners, non-cash interest expense related to the amortization of the initial discount on our 2020 Senior Notes and the impact on our tax provision of discrete changes in our valuation allowance position on deferred tax assets.

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, 13702083.

If you are unable to participate, a replay of the conference call will be available for 30 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, 13702083.

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 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 PemazyreTM (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 timing for submission of an NDA for ruxolitinib cream for atopic dermatitis; the expected timing and results of decisions from the FDA on capmatinib and tafasitamab; expectations regarding the number of product approvals and whether 2020 will be a transformational year for the Company; the potential impacts of the COVID-19 pandemic and measures taken to address the pandemic on the Company's business, operations and financial results; plans with respect to clinical trials of ruxolitinib and baricitinib for patients with COVID-19; expectations with respect to the LIMBER program and the timing of the LIMBER development programs being on track; plans and expectations for the rest of the Company's development portfolio, including the timing of receipt and announcement of clinical trial results and progress of development programs for pemigatinib, ruxolitinib for GVHD, retifanlimab, and ruxolitinib cream for vitiligo; expectations of the Company's collaboration partner for the submission for approval in the U.S. of baricitinib for atopic dermatitis; and the Company's reaffirmed 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: 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; 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; 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; unexpected price regulation or limitations on reimbursement or coverage for the Company's products; sales, marketing, manufacturing and distribution requirements, including the Company's 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 annual report on Form 10-K for the year ended December 31, 2019. The Company disclaims any intent or obligation to update these forward-looking statements.

###

Investors

Incyte Contacts

Media

Catalina Loveman

+1 302 498 6171 <u>cloveman@incyte.com</u> Michael Booth, DPhil

+1 302 498 5914 mbooth@incyte.com

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

	Three Months Ended March 31,		
	 2020		2019
	 GA	AP	
Revenues:			
Product revenues, net	\$ 486,727	\$	396,249
Product royalty revenues	81,780		61,608
Milestone and contract revenues	-		40,000
Total revenues	568,507		497,857
Costs and expenses:			
Cost of product revenues (including definite-lived intangible amortization)	27,319		22,588
Research and development	1,085,287		270,545
Selling, general and administrative	111,148		123,983
Change in fair value of acquisition-related contingent consideration	6,627		6,671
Collaboration loss sharing	2,130		0,071
Total costs and expenses	 1,232,511		423,787
	 1,202,011		423,707
Income (loss) from operations	(664,004)		74,070
Other income (expense), net	8,662		9,373
Interest expense	(602)		(335)
Unrealized gain (loss) on long term investments	(48,132)		20,989
Income (loss) before provision for income taxes	 (704,076)		104,097
Provision for income taxes	16,566		1,785
Net income (loss)	\$ (720,642)	\$	102,312
Net income (loss) per share:			
Basic	\$ (3.33)		0.48
Diluted	\$ (3.33)	\$	0.47
Shares used in computing net income (loss) per share:			
Basic	216,721		214,065
Diluted	216,721		217,061

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

	Ν	March 31, 2020		cember 31, 2019
ASSETS				
Cash, cash equivalents and marketable securities	\$	1,302,592	\$	2,117,554
Accounts receivable		351,522		308,809
Property and equipment, net		410,034		377,567
Finance lease right-of-use assets, net		28,622		29,058
Inventory		22,217		16,505
Prepaid expenses and other assets		112,405		94,179
Long term investments		180,993		133,657
Other intangible assets, net		188,444		193,828
Goodwill		155,593		155,593
Total assets	\$	2,752,422	\$	3,426,750
LIABILITIES AND STOCKHOLDERS' EQUITY				
Accounts payable, accrued expenses and other liabilities	\$	488,308	\$	500,462
Finance lease liabilities		32,869		32,582
Convertible senior notes		18,524		18,300
Acquisition-related contingent consideration		275,000		277,000
Stockholders' equity		1,937,721		2,598,406
Total liabilities and stockholders' equity	\$	2,752,422	\$	3,426,750

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

	г	Three Months Ended March 31,	
	20	20	2019
GAAP Net Income (Loss)	\$	(720,642) \$	102,312
Adjustments ¹ :			
Non-cash stock compensation from equity awards (R&D) ²		28,713	27,422
Non-cash stock compensation from equity awards (SG&A) ²		13,575	12,994
Non-cash stock compensation from equity awards (COGS) ²		225	176
Non-cash interest expense related to convertible notes ³		223	213
Changes in fair value of equity investments ⁴		48,132	(20,989)
Amortization of acquired product rights ⁵		5,384	5,384
Change in fair value of contingent consideration ⁶		6,627	6,671
Tax effect of Non-GAAP adjustments ⁷		(1,157)	359
Non-GAAP Net Income (Loss)	\$	(618,920) \$	134,542
Non-GAAP net income (loss) per share:			
Basic	\$	(2.86) \$	0.63
Diluted	\$	(2.86) \$	0.62
Channell's second the New CAAD set is seen (loss) and have			
Shares used in computing Non-GAAP net income (loss) per share: Basic		216,721	214.065
Diluted		,	214,065
Diuleu		216,721	217,061

^{1.} Included within the Milestone and contract revenues line item in the Condensed Consolidated Statements of Operations (in thousands) for the three months ended March 31, 2020 and 2019 are upfront consideration and milestones of \$0 and \$40,000, respectively, earned from our collaborative partners. Included within the Research and development expenses line item in the Condensed Consolidated Statements of Operations (in thousands) for the three months ended March 31, 2020 are upfront consideration and milestones of \$805,532 related to our collaborative partners.

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

^{3.} As included within the Interest expense line item in the Condensed Consolidated Statements of Operations.

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

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

^{6.} As included within the 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.