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

August 4, 2020

- Total product and royalty revenues of \$593 million (+16% vs Q2 2019) for the quarter ended June 30, 2020; Jakafi® (ruxolitinib) revenues of \$474 million in Q2 2020 (+16% vs Q2 2019)
- Monjuvi® (tafasitamab-cxix; collaboration with MorphoSys) approved by U.S. FDA; launch preparations already underway
- Tabrecta™ (capmatinib; licensed to Novartis) approved by U.S. FDA and Japanese MHLW; Incyte eligible for milestones and royalties on global net sales
- Primary and both key secondary endpoints met in Phase 3 REACH3 trial of Jakafi in patients with steroid-refractory chronic graft-versus-host disease

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

WILMINGTON, Del.--(BUSINESS WIRE)--Aug. 4, 2020-- Incyte (Nasdaq: INCY) today reports 2020 second quarter financial results, and provides a status update on the Company's development portfolio.

"We continue to execute successfully across all aspects of our business," stated Hervé Hoppenot, Chief Executive Officer, Incyte. "Demand for Jakafi® (ruxolitinib) is robust and the recent approval of Pemazyre® (pemigatinib), as well as those of Monjuvi® (tafasitamab-cxix) with MorphoSys and Tabrecta™ (capmatinib) with Novartis, add to our momentum. In addition, clinical updates from the tafasitamab and LIMBER programs at the recent EHA congress, the successful outcome of REACH3, and our plan to submit an NDA seeking approval for ruxolitinib cream at the end of this year, further illustrate the opportunities within our portfolio to drive additional diversification and growth."

Portfolio Update

LIMBER – key highlights

Positive proof-of-concept data for piasclisib in combination with ruxolitinib in myelofibrosis (MF) patients with an inadequate response to ruxolitinib monotherapy were presented at the virtual 25th Congress of the European Hematology Association (EHA). Incyte plans to initiate pivotal trials of the combination of ruxolitinib and piasclisib as both first-line therapy for MF patients and in MF patients with an inadequate response to ruxolitinib monotherapy.

Monotherapy treatment cohorts in the trials of INCB57643 (BET) and INCB00928 (ALK2) in patients with myelofibrosis are being opened for recruitment, and these are expected to be followed by the initiation of ruxolitinib combination trials with both agents. Further development of the combination of INCB53914 (PIM) plus ruxolitinib has been discontinued.

Indication and status

Once-a-day ruxolitinib (JAK1/JAK2)	Myelofibrosis and polycythemia vera: clinical pharmacology studies
ruxolitinib + piasclisib (JAK1/JAK2 + PI3Kδ)	Refractory myelofibrosis: Phase 3 in preparation First-line myelofibrosis: Phase 3 in preparation
ruxolitinib + INCB57643 (JAK1/JAK2 + BET)	Refractory myelofibrosis: Phase 2 in preparation
ruxolitinib + INCB00928 (JAK1/JAK2 + ALK2)	Myelofibrosis: Phase 2 in preparation

Oncology beyond MPNs – key highlights

In July, the FDA granted approval for Monjuvi® (tafasitamab-cxix), an Fc-engineered anti-CD19 antibody, in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and who are not eligible for autologous stem cell transplant (ASCT). Monjuvi was reviewed under Priority Review and granted accelerated approval based on overall response rate data from the L-MIND trial of tafasitamab in combination with lenalidomide.

Incyte and MorphoSys will co-commercialize Monjuvi in the U.S. Medical and commercial teams from both companies were ready for the early approval and launch activities are already underway, including engagements with prescribing physicians and payors.

In May, Incyte and MorphoSys announced the validation of the European Marketing Authorization Application (MAA) for tafasitamab. Incyte has exclusive development and commercialization rights to tafasitamab outside of the U.S.

Updated results from the ongoing Phase 2 L-MIND study investigating the combination of tafasitamab and lenalidomide in patients with relapsed or refractory DLBCL (r/r DLBCL) were reported at EHA. The results were consistent with the primary analysis and those included in the U.S. prescribing information, and confirmed the durability of the response and measurements of overall survival of tafasitamab in combination with lenalidomide followed by tafasitamab monotherapy in ASCT-ineligible patients with r/r DLBCL.

In July, Incyte and Novartis announced that the REACH3 study, evaluating ruxolitinib in patients with steroid-refractory chronic graft-versus-host disease (GVHD), met its primary endpoint of overall response rate (ORR) at Month 6 and both key secondary endpoints (modified Lee symptom scale and failure-free survival). No new safety signals were observed, and the ruxolitinib safety profile in REACH3 was consistent with that seen in previously reported studies. REACH3 is the largest randomized trial ever conducted in the steroid-refractory chronic GVHD setting. Data are being prepared for presentation at an upcoming medical meeting and for regulatory submission.

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)

Cholangiocarcinoma: Phase 2 (FIGHT-202), Phase 3 (FIGHT-302); MAA under review

Bladder cancer: Phase 2 (FIGHT-201, FIGHT-205)

**pemigatinib
(FGFR1/2/3)** 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
First-line DLBCL: Phase 1b (First-MIND)

Follicular lymphoma: Phase 2 (CITADEL-203)

**parsaclisib
(PI3Kδ)** Marginal zone lymphoma: Phase 2 (CITADEL-204)
Mantle cell lymphoma: Phase 2 (CITADEL-205)

MSI-high endometrial cancer: Phase 2 (POD1UM-101)

Merkel cell carcinoma: Phase 2 (POD1UM-201)

**retifanlimab
(PD-1)³** SCAC: Phase 2 (POD1UM-202); Phase 3 (POD1UM-303) in preparation
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; SCAC = squamous cell carcinoma of the anal canal

Inflammation and Autoimmunity (IAI) – key highlights

The 44-week long-term safety and efficacy portions of both the TRuE-AD1 and TRuE-AD2 Phase 3 trials of ruxolitinib cream in patients with mild-to-moderate atopic dermatitis are proceeding as planned, and the NDA submission is expected at the end of 2020.

Data from the randomized Phase 2 trial of ruxolitinib cream in patients with vitiligo were recently published in The Lancet. The two randomized Phase

3 trials in the TRuE-V pivotal program evaluating ruxolitinib cream in patients with vitiligo are proceeding as planned, with results 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 (PI3Kδ) 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 LSD1 inhibitor program, development of INCB59872 has been discontinued. Incyte's portfolio of other earlier-stage clinical candidates is summarized below.

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 development in collaboration with Calithera

2) Discovery collaboration with Agenus

3) MCLA-145 development in collaboration with Merus

Potential therapies for patients with COVID-19

There are several ongoing studies of ruxolitinib, conducted by Incyte alone or in collaboration with Novartis, and of baricitinib, conducted by Lilly, in patients with COVID-19. Initial results from these trials are expected in the second half of 2020.

Incyte and Lilly have amended their agreement to enable Lilly to move rapidly in the development and commercialization of baricitinib as a potential therapy for patients with COVID-19, moving financial obligations post-approval.

Status

ruxolitinib (JAK1/JAK2) COVID-19 associated cytokine storm: Phase 3 (RUXCOVID¹; 369-DEVENT)

baricitinib (JAK1/JAK2)² Hospitalized patients with COVID-19: Phase 3 (ACTT-2³; 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
- 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 May, Incyte and Novartis announced the FDA approval of Tabrecta™ (capmatinib) for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to MET exon 14 skipping (METex14) as detected by an FDA-approved test. Tabrecta was reviewed under Priority Review and granted accelerated approval based on Phase 2 data in first-line and previously treated patients with METex14 mutated NSCLC.

In June, the Japanese Ministry of Health, Labour and Welfare (MHLW) approved Tabrecta™ (capmatinib) for METex14 mutation-positive advanced and/or recurrent unresectable NSCLC.

Indication and status

Atopic dermatitis: Phase 3 (BREEZE-AD)

baricitinib (JAK1/JAK2)¹ Systemic lupus erythematosus: Phase 3

Severe alopecia areata: Phase 3 (BRAVE-AA1)

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 Second Quarter Financial Results

The financial measures presented in this press release for the three and six months ended June 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		Six Months Ended	
	June 30,		June 30,	
	2020	2019	2020	2019
Total GAAP revenue	\$ 688,043	\$ 529,932	\$ 1,256,550	\$ 1,027,789

Total GAAP operating income (loss)	230,773	98,612	(433,231)	172,682
Total Non-GAAP operating income (loss)	288,514	151,219	(320,966)	277,936
GAAP net income (loss)	290,298	105,318	(430,344)	207,630
Non-GAAP net income (loss)	273,578	162,469	(345,342)	297,011
GAAP basic EPS	\$ 1.33	\$ 0.49	\$ (1.98)	\$ 0.97
Non-GAAP basic EPS	\$ 1.26	\$ 0.76	\$ (1.59)	\$ 1.39
GAAP diluted EPS	\$ 1.32	\$ 0.48	\$ (1.98)	\$ 0.96
Non-GAAP diluted EPS	\$ 1.24	\$ 0.75	\$ (1.59)	\$ 1.37

Revenue Details

Revenue Details

(unaudited, in thousands)

	Three Months Ended			Six Months Ended		
	June 30,		%	June 30,		%
	2020	2019	Change	2020	2019	Change
Revenues:						
Jakafi net product revenue	\$ 473,706	\$ 409,506	16%	\$ 933,185	\$ 785,117	19%
Iclusig net product revenue	22,798	24,391	(7%)	50,046	45,029	11%
Pemazyre net product revenue	3,786	-		3,786	-	
Jakavi product royalty revenues	66,217	56,895	16%	122,550	102,466	20%
Olumiant product royalty revenues	25,830	19,140	35%	51,277	35,177	46%
Tabrecta product royalty revenues	706	-		706	-	
Product and royalty revenues	593,043	509,932	16%	1,161,550	967,789	20%
Milestone and contract revenues	95,000	20,000	375%	95,000	60,000	58%
Total GAAP revenues	\$ 688,043	\$ 529,932	30%	\$ 1,256,550	\$ 1,027,789	22%

Product and Royalty Revenues Product and royalty revenues for the three and six months ended June 30, 2020 increased 16% and 20%, respectively, over the prior year comparative periods primarily as a result of increases in Jakafi net product revenues and higher product royalty revenues from Jakavi and Olumiant. Jakafi net product revenues for the three and six months ended June 30, 2020 increased 16% and 19%, 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			Six Months Ended		
	June 30,		%	June 30,		%
	2020	2019	Change	2020	2019	Change
GAAP cost of product revenues	\$ 33,364	\$ 29,406	13 %	\$ 60,683	\$ 51,994	17%
Non-GAAP cost of product revenues ¹	27,734	23,846	16 %	49,444	40,874	21%
GAAP research and development	286,601	289,363	(1%)	1,371,888	559,908	145%
Non-GAAP research and development ²	254,108	261,747	(3%)	1,310,682	504,870	160%
GAAP selling, general and administrative	117,998	105,943	11%	229,146	229,926	(0%)
Non-GAAP selling, general and administrative ³	104,434	93,120	12%	202,007	204,109	(1%)
GAAP change in fair value of acquisition-related contingent consideration	6,054	6,608	(8%)	12,681	13,279	(5%)
Non-GAAP change in fair value of acquisition-related contingent consideration ⁴	-	-		-	-	
GAAP collaboration loss sharing	13,253	-		15,383	-	
Non-GAAP collaboration loss sharing	13,253	-		15,383	-	

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 June 30, 2020 decreased 1% and 3%, respectively, compared to the same period in 2019. For the six months ended June 30, 2020, GAAP and Non-GAAP research and development expense increased 145% and 160%, 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 three months ended June 30, 2020 increased 11% and 12%, respectively, compared to the same period in 2019, primarily due to increased headcount and commercialization efforts of our products. For the six months ended June 30, 2020, GAAP and Non-GAAP selling, general and administrative expenses remained relatively flat compared to the same period in 2019.

Other Financial Information

Operating income (loss) GAAP and Non-GAAP operating income for the three months ended June 30, 2020 increased compared to the same period in 2019, due to growth in both product and royalty revenues and milestone and contract revenues. For the six months ended June 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 collaborative agreement with MorphoSys, partially offset by the growth in product and royalty revenues.

Cash, cash equivalents and marketable securities position As of June 30, 2020 and December 31, 2019, cash, cash equivalents and marketable securities totaled \$1.6 billion and \$2.1 billion, respectively. The decrease reflects the upfront payment and stock purchase related to our collaborative agreement with MorphoSys and was partially offset by the cash flow generated during this six-month period.

2020 Financial Guidance

The Company has reaffirmed its full year 2020 financial guidance, as detailed below. The R&D expense guidance 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 future 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 convertible 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, 13706620.

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, 13706620.

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](https://twitter.com/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 timing for submission of NDAs for ruxolitinib cream for atopic dermatitis and for the once-a-day formulation of ruxolitinib; plans to initiate pivotal trials of the combination of ruxolitinib and pascalisib; plans for ruxolitinib combination trials with INCB57643 (BET) and INCB00928 (ALK2); 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 ruxolitinib cream for vitiligo, retifanlimab and ruxolitinib for COVID-19; 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 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 March 31, 2020. The Company disclaims any intent or obligation to update these forward-looking statements.

INCYTE CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited, in thousands, except per share amounts)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2020	2019	2020	2019
	GAAP		GAAP	
Revenues:				
Product revenues, net	\$ 500,290	\$ 433,897	\$ 987,017	\$ 830,146
Product royalty revenues	92,753	76,035	174,533	137,643
Milestone and contract revenues	95,000	20,000	95,000	60,000
Total revenues	688,043	529,932	1,256,550	1,027,789
Costs and expenses:				
Cost of product revenues (including definite-lived intangible amortization)	33,364	29,406	60,683	51,994
Research and development	286,601	289,363	1,371,888	559,908
Selling, general and administrative	117,998	105,943	229,146	229,926
Change in fair value of acquisition-related contingent consideration	6,054	6,608	12,681	13,279
Collaboration loss sharing	13,253	-	15,383	-
Total costs and expenses	457,270	431,320	1,689,781	855,107
Income (loss) from operations	230,773	98,612	(433,231)	172,682
Other income (expense), net	4,817	15,000	13,479	24,373

Interest expense	(600)	(316)	(1,202)	(651)
Unrealized gain (loss) on long term investments	72,274	(4,625)	24,142	16,364
Income (loss) before provision for income taxes	307,264	108,671	(396,812)	212,768
Provision for income taxes	16,966	3,353	33,532	5,138
Net income (loss)	\$ 290,298	\$ 105,318	\$ (430,344)	\$ 207,630
Net income (loss) per share:				
Basic	\$ 1.33	\$ 0.49	\$ (1.98)	\$ 0.97
Diluted	\$ 1.32	\$ 0.48	\$ (1.98)	\$ 0.96
Shares used in computing net income (loss) per share:				
Basic	217,549	214,620	217,135	214,342
Diluted	220,434	217,483	217,135	217,274

INCYTE CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited, in thousands)

	June 30,	December 31,
	2020	2019
ASSETS		
Cash, cash equivalents and marketable securities	\$ 1,589,486	\$ 2,117,554
Accounts receivable	420,250	308,809
Property and equipment, net	453,777	377,567
Finance lease right-of-use assets, net	28,133	29,058
Inventory	25,889	16,505
Prepaid expenses and other assets	107,402	94,179
Long term investments	248,731	133,657
Other intangible assets, net	183,060	193,828

Goodwill	155,593	155,593
Total assets	\$ 3,212,321	\$ 3,426,750

LIABILITIES AND STOCKHOLDERS' EQUITY

Accounts payable, accrued expenses and other liabilities	\$ 542,023	\$ 500,462
Finance lease liabilities	33,106	32,582
Convertible senior notes	18,588	18,300
Acquisition-related contingent consideration	274,000	277,000
Stockholders' equity	2,344,604	2,598,406
Total liabilities and stockholders' equity	\$ 3,212,321	\$ 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		Six Months Ended	
	June 30,		June 30,	
	2020	2019	2020	2019
GAAP Net Income (Loss)	\$ 290,298	\$ 105,318	\$ (430,344)	\$ 207,630
<i>Adjustments¹:</i>				
Non-cash stock compensation from equity awards (R&D) ²	32,493	27,616	61,206	55,038
Non-cash stock compensation from equity awards (SG&A) ²	13,564	12,823	27,139	25,817
Non-cash stock compensation from equity awards (COGS) ²	246	176	471	352
Non-cash interest expense related to convertible notes ³	226	215	449	428
Changes in fair value of equity investments ⁴	(72,274)	4,625	(24,142)	(16,364)
Amortization of acquired product rights ⁵	5,384	5,384	10,768	10,768
Change in fair value of contingent consideration ⁶	6,054	6,608	12,681	13,279
Tax effect of Non-GAAP adjustments ⁷	(2,413)	(296)	(3,570)	63

Non-GAAP Net Income (Loss)	\$ 273,578	\$ 162,469	\$ (345,342)	\$ 297,011
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Non-GAAP net income (loss) per share:

Basic	\$ 1.26	\$ 0.76	\$ (1.59)	\$ 1.39
Diluted	\$ 1.24	\$ 0.75	\$ (1.59)	\$ 1.37

Shares used in computing Non-GAAP net income (loss) per share:

Basic	217,549	214,620	217,135	214,342
Diluted	220,434	217,483	217,135	217,274

1. Included within the Milestone and contract revenues line item in the Condensed Consolidated Statements of Operations (in thousands) for the three and six months ended June 30, 2020 are milestones of \$95,000 earned from our collaborative partners as compared to upfront consideration and milestones of \$20,000 and \$60,000, 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 six months ended June 30, 2020 are upfront consideration and milestones of \$3,500 and \$809,032, respectively, related to our collaborative partners as compared to \$25,000 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.



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Source: Incyte