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

May 4, 2021

- *Total product and royalty revenues of $605 million in Q1 2021 (+6% vs Q1 2020)*
- *Jakafi® (ruxolitinib) revenues of $466 million in Q1 2021 (+1% vs Q1 2020); reaffirming full year guidance of $2.125-$2.20 billion*
- *Pemazyre® (pemigatinib) now also approved in Europe and Japan, becoming the first internally discovered product to be globally commercialized by Incyte*
- *Three regulatory submissions accepted by the FDA for Priority Review, including potential approval of ruxolitinib cream in the U.S. for atopic dermatitis in June*

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

WILMINGTON, Del.--(BUSINESS WIRE)-- Incyte (Nasdaq: INCY) today reports 2021 first quarter financial results, and provides a status update on the Company's development portfolio.

"In the first quarter, we continued to make significant progress in our strategy to drive growth and diversification. While Jakafi ® (ruxolitinib) net sales were affected by typical seasonal effects and softer patient demand growth due to the ongoing pandemic, we remain confident in our full-year outlook. We are already seeing a return of new patient starts to pre-COVID levels and are excited for the potential launch in steroid-refractory chronic graft-versus-host disease (GVHD) later this year. The launches of Monjuvi® (tafasitamab) and Pemazyre® (pemigatinib) continue to progress with good uptake by both academic and community physicians," stated Hervé Hoppenot, Chief Executive Officer, Incyte. "We expect an exciting year ahead for Incyte with the potential for multiple approvals, including ruxolitinib cream in atopic dermatitis, and several regulatory filings, notably parsaclisib in NHL and ruxolitinib cream in vitiligo. We are also initiating pivotal trials across key development programs for both tafasitamab and LIMBER this year."

Portfolio Update

MPNs and GVHD – key highlights

Ruxolitinib in GVHD: The supplemental New Drug Application (sNDA) seeking approval of ruxolitinib for the treatment of steroid-refractory chronic GVHD has been accepted for Priority Review by the U.S. Food and Drug Administration (FDA); the Prescription Drug User Fee Act (PDUFA) date is June 22, 2021. The application for approval was based on the successful randomized REACH3 trial comparing ruxolitinib with best available therapy (BAT).

LIMBER: Our **L**eadership **I**n **M**PNs **BE**yond **R**uxolitinib (LIMBER) development program continues to progress with once daily (QD) ruxolitinib in stability testing, and multiple ongoing and planned combination trials with ruxolitinib on track. Both monotherapy trials of INCB57643 (BET) and INCB00928 (ALK2) are ongoing, and combination trials of both agents with ruxolitinib in patients with myelofibrosis (MF) are expected to initiate later this year. Two Phase 3 trials of ruxolitinib in combination with parsaclisib as a first-line therapy for patients with MF (LIMBER-313) and as a therapy for MF patients with a suboptimal response to ruxolitinib monotherapy (LIMBER-304) are ongoing.

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

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

Other Hematology/Oncology – key highlights

Tafasitamab: Incyte and MorphoSys strategy to evaluate tafasitamab as a backbone therapy in multiple combinations for the treatment of various B-cell malignancies is underway. The Phase 3 *inMIND* trial, evaluating tafasitamab in combination with lenalidomide plus rituximab (R^2) versus R^2 in patients with follicular lymphoma and marginal zone lymphoma is ongoing. Preparations are underway for the Phase 3 *frontMIND* trial evaluating tafasitamab plus lenalidomide in addition to rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone (R-CHOP) compared to R-CHOP alone as a first-line treatment for patients with newly diagnosed diffuse-large B-cell lymphoma (DLBCL). A proof of concept trial evaluating tafasitamab plus parsaclisib (topMIND) is expected to start later this year and a second proof of concept trial with tafasitamab plus lenalidomide in addition to plamotamab is expected to start later this year or early next.

Pemigatinib: In March, Pemazyre® (pemigatinib) was approved by the Japanese Ministry of Health, Labour and Welfare (MHLW) for the treatment of patients with unresectable biliary tract cancer (BTC) with a fibroblast growth factor receptor 2 (FGFR2) fusion gene, worsening after cancer chemotherapy. Additionally, the European Commission (EC) approved Pemazyre for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy. The upcoming launches in Europe and Japan along with the continued launch in the U.S., signifies the first internally discovered product to be globally commercialized by Incyte. The Phase 2 tumor agnostic study of pemigatinib is ongoing and continues to enroll well.

Retifanlimab: In March, the Marketing Authorization Application (MAA) seeking approval of retifanlimab in squamous cell carcinoma of the anal canal (SCAC) was validated by the European Medicines Agency (EMA). This follows the Biologics License Application (BLA) acceptance by the FDA for the same indication earlier this year.

	Indication and status
pemigatinib (FGFR1/2/3)	CCA: Phase 2 (FIGHT-202), Phase 3 (FIGHT-302) 8p11 MPN: Phase 2 (FIGHT-203) Tumor agnostic: Phase 2 (FIGHT-207)
tafasitamab (CD19)[1]	r/r DLBCL: Phase 2 (L-MIND); Phase 3 (B-MIND); MAA under review 1L DLBCL: Phase 1b (*firstMIND*); Phase 3 (*frontMIND*) in preparation r/r FL and r/r MZL: Phase 3 (*inMIND*) r/r B-cell malignancies: PoC (*topMIND*) with parsaclisib (PI3Kδ) in preparation r/r B-cell malignancies: PoC with lenalidomide and plamotamab in preparation[2]
parsaclisib (PI3Kδ)	r/r FL: Phase 2 (CITADEL-203) r/r MZL: Phase 2 (CITADEL-204) r/r MCL: Phase 2 (CITADEL-205) r/r FL and r/r MZL: Phase 3 (CITADEL-302) in preparation 1L MCL: Phase 3 (CITADEL-310) in preparation
retifanlimab (PD-1)[3]	SCAC: Phase 2 (POD1UM-202); Phase 3 (POD1UM-303); BLA and MAA under review MSI-high endometrial cancer: Phase 2 (POD1UM-101, POD1UM-204) Merkel cell carcinoma: Phase 2 (POD1UM-201) NSCLC: Phase 3 (POD1UM-304)

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

1. Development of tafasitamab in collaboration with MorphoSys
2. Clinical collaboration with MorphoSys and Xencor, Inc. to investigate the combination of tafasitamab plus lenalidomide in combination with Xencor's CD20xCD3 XmAb bispecific antibody, plamotamab.
3. retifanlimab licensed from MacroGenics

Inflammation and Autoimmunity (IAI) – key highlights

Dermatology

Ruxolitinib cream: The NDA seeking approval of ruxolitinib cream for the treatment of atopic dermatitis (AD) has been accepted for Priority Review by the FDA and the PDUFA date has been set for June 21, 2021. The application is supported by data from the Phase 3 TRuE-AD clinical trial program - pooled results presented last month at the American Academy of Dermatology (AAD) virtual conference provided additional context regarding the impact of ruxolitinib cream on itch relief as well as sleep disturbance and sleep impairment.

Also at AAD, Incyte presented 104-week data from the Phase 2 program evaluating ruxolitinib cream in patients with vitiligo. Results showed patients on ruxolitinib cream achieved continued efficacy through 104 weeks, with a longer duration of treatment being associated with greater levels of repigmentation. Incyte also presented additional follow-up data which demonstrated a potential for maintenance of repigmentation after discontinuation of therapy (following two years of treatment with ruxolitinib cream). The two Phase 3 trials in the TRuE-V program are ongoing with results expected in Q2'21.

INCB54707: In March, Incyte initiated a Phase 2 trial evaluating INCB54707 in vitiligo. A Phase 2 trial in hidradenitis suppurativa remains ongoing.

	Indication and status

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

Discovery and early development – key highlights

INCB106385/INCA00186: At AACR, Incyte shared clinical and pre-clinical data from INCB106385, our novel A2A/A2B adenosine receptor antagonist, and INCA00186, our novel CD73 monoclonal antibody—both of which highlight our ongoing efforts targeting the adenosine pathway. Incyte also presented preclinical data for our triplet combination with retifanlimab, highlighting one of our strategies to overcome adenosine mediated PD-1 suppression.

Modality	Candidates
Small molecules	INCB01158 (ARG)[1], INCB81776 (AXL/MER), epacadostat (IDO1), INCB86550 (PD-L1), INCB106385 (A2A/A2B)
Monoclonal antibodies[2]	INCAGN1876 (GITR), INCAGN2385 (LAG-3), INCAGN1949 (OX40), INCAGN2390 (TIM-3), INCA00186 (CD73)
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

Baricitinib: In April, Incyte and Lilly announced the FDA extended the review period for the sNDA for baricitinib for the treatment of moderate to severe atopic dermatitis by three months to allow time for additional data analyses. The PDUFA action date is now expected in early Q3.

In March, Incyte and Lilly announced positive results from BRAVE-AA2 evaluating the efficacy and safety of once-daily baricitinib 2-mg and 4-mg in adults with severe alopecia areata (AA), an autoimmune disorder that can cause unpredictable hair loss on the scalp, face and other areas of the body. In April, positive results from a second Phase 3 study, BRAVE-AA1, were announced, with data consistent with the findings from BRAVE-AA2. Lilly plans to submit an sNDA to the FDA for baricitinib in AA in the second half of 2021. There are currently no FDA-approved therapies for AA, highlighting the potential for baricitinib to address a significant unmet medical need.

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

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

Potential therapies for patients with COVID-19

Ruxolitinib: In March, Incyte announced results from the Phase 3 DEVENT study assessing ruxolitinib plus standard of care (SoC) versus SoC in patients on mechanical ventilation with COVID-19 associated Acute Respiratory Disease Syndrome (ARDS). While results indicate a trend towards improvement in mortality in the overall study population, statistical significance was not reached in the primary endpoint (mortality due to any cause through Day 29). In the U.S. study population (91% of total study participants), however, there was a clinically and statistically significant improvement in mortality in each of the 5mg and 15mg ruxolitinib arms versus placebo.

Baricitinib: In April, Incyte and Lilly announced the primary endpoint in the Phase 3 COV-BARRIER study evaluating baricitinib in hospitalized COVID-19 patients - difference in the proportion of participants progressing to the first occurrence of non-invasive ventilation including high flow oxygen or invasive mechanical ventilation including extracorporeal membrane oxygenation (ECMO) or death by Day 28) - was not met. There was, however, a 38% reduction in mortality by Day 28 in patients treated with baricitinib in addition to SoC. Lilly will share these data with regulatory authorities in the U.S., European Union and other geographies to evaluate next steps.

2021 First Quarter Financial Results

The financial measures presented in this press release for the three months ended March 31, 2021 and 2020 have been prepared by the Company in accordance with U.S. Generally Accepted Accounting Principles (“GAAP”), unless otherwise identified as a Non-GAAP financial measure. Management believes that Non-GAAP information is useful for investors, when considered in conjunction with Incyte’s GAAP disclosures. Management uses such information internally and externally for establishing budgets, operating goals and financial planning purposes. These metrics

are also used to manage the Company's business and monitor performance. The Company adjusts, where appropriate, for expenses in order to reflect the Company's core operations. The Company believes these adjustments are useful to investors by providing an enhanced understanding of the financial performance of the Company's core operations. The metrics have been adopted to align the Company with disclosures provided by industry peers.

Non-GAAP information is not prepared under a comprehensive set of accounting rules and should only be used in conjunction with and to supplement Incyte's operating results as reported under GAAP. Non-GAAP measures may be defined and calculated differently by other companies in our industry.

Financial Highlights

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

	Three Months Ended March 31,	
	2021	**2020**
Total GAAP revenue	$ 604,718	$ 568,507
Total GAAP operating income (loss)	98,797	(664,004)
Total Non-GAAP operating income (loss)	170,303	(609,480)
GAAP net income (loss)	53,535	(720,642)
Non-GAAP net income (loss)	148,756	(618,920)
GAAP basic EPS	$ 0.24	$ (3.33)
Non-GAAP basic EPS	$ 0.68	$ (2.86)
GAAP diluted EPS	$ 0.24	$ (3.33)
Non-GAAP diluted EPS	$ 0.67	$ (2.86)

Revenue Details

Revenue Details
(unaudited, in thousands)

	Three Months Ended March 31,		%
	2021	**2020**	**Change**
Revenues:			
Jakafi net product revenues	$ 465,710	$ 459,479	1%
Iclusig net product revenues	25,645	27,248	(6%)
Pemazyre net product revenues	13,456	-	NM
Jakavi product royalty revenues	65,602	56,333	16%
Olumiant product royalty revenues	32,258	25,447	27%
Tabrecta product royalty revenues	2,047	-	NM
Product and royalty revenues	604,718	568,507	6%
Total GAAP revenues	$ 604,718	$ 568,507	6%

NM = not meaningful

Product and Royalty Revenues Product and royalty revenues for the quarter ended March 31, 2021 increased 6% over the prior year comparative period as a result of increases in Jakafi net product revenues, the launch of Pemazyre and higher product royalty revenues from Jakavi and Olumiant. The year-over-year growth rate in Jakafi net product revenues was impacted by a decline in new patient starts due to the COVID-19 pandemic, and higher patient demand and channel inventory stocking in the prior year comparative period, due to concerns over potential COVID-19 related supply disruptions.

Operating Expenses

Operating Expense Summary
(unaudited, in thousands)

	Three Months Ended March 31,		%
	2021	**2020**	**Change**
GAAP cost of product revenues	$ 29,220	$ 27,319	7%
Non-GAAP cost of product revenues[1]	23,596	21,710	9%
GAAP research and development	306,896	1,085,287	(72%)

Non-GAAP research and development[2]	277,022	1,056,574	(74%)
GAAP selling, general and administrative	153,795	111,148	38%
Non-GAAP selling, general and administrative[3]	123,313	97,573	26%
GAAP change in fair value of acquisition-related contingent consideration	5,526	6,627	(17%)
Non-GAAP change in fair value of acquisition-related contingent consideration[4]	-	-	
GAAP collaboration loss sharing	10,484	2,130	NM
Non-GAAP collaboration loss sharing	10,484	2,130	NM

1. Non-GAAP cost of product revenues excludes the amortization of licensed intellectual property for Iclusig relating to the acquisition of the European business of ARIAD Pharmaceuticals, Inc. and the cost of stock-based compensation.
2. Non-GAAP research and development expenses exclude the cost of stock-based compensation.
3. Non-GAAP selling, general and administrative expenses exclude the cost of stock-based compensation and a legal reserve.
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, 2021 decreased 72% and 74%, respectively, compared to the same period in 2020, primarily due to upfront consideration of $805 million related to our collaborative agreement with MorphoSys incurred during the quarter ended March 31, 2020. Excluding the impact of upfront consideration and milestones, research and development expense for the quarter ended March 31, 2021 increased approximately 5% compared to the same period in 2020 reflecting costs to support the continued progression of our pipeline of programs.

Selling, general and administrative expenses GAAP and Non-GAAP selling, general and administrative expenses for the quarter ended March 31, 2021 increased 38% and 26%, respectively, compared to the same period in 2020, primarily due to expenses related to the establishment of our dermatology commercial organization and activities to support the potential launch of ruxolitinib cream for the treatment of atopic dermatitis, a $13 million reserve related to a settlement in principle in connection with the 2018 civil investigative demand from the U.S. Department of Justice, and the timing of certain expenses. Excluding the impact of the legal reserve, GAAP selling, general and administrative expenses for the quarter ended March 31, 2021 increased approximately 26% compared to the same period in 2020.

Other Financial Information

Operating income (loss) GAAP and Non-GAAP operating income (loss) for the quarter ended March 31, 2021 increased compared to the same period in 2020 primarily due to the decrease in upfront consideration and milestones related to our collaborative agreements and the growth in product and royalty revenues.

Cash, cash equivalents and marketable securities position As of March 31, 2021 and December 31, 2020, cash, cash equivalents and marketable securities totaled $2.0 billion and $1.8 billion, respectively.

2021 Financial Guidance

The Company has reaffirmed its full year 2021 financial guidance, as detailed below. Guidance does not include revenue from any potential new product launches. However, GAAP and Non-GAAP selling, general and administrative expense guidance for 2021 includes costs to support the potential launches of ruxolitinib cream as a treatment for atopic dermatitis in the U.S., pemigatinib as a treatment for cholangiocarcinoma in the EU and Japan, and tafasitamab as a treatment for DLBCL in the EU. The 2021 financial guidance does not include the impact of any potential future strategic transactions.

	Current	Previous
Jakafi net product revenues	$2,125 - $2,200 million	Unchanged
Other Hematology/Oncology net product revenues	$145 - $160 million	Unchanged
GAAP Cost of product revenues	6 – 7% of net product revenues	Unchanged
Non-GAAP Cost of product revenues[1]	5 – 6% of net product revenues	Unchanged
GAAP Research and development expenses	$1,350 - $1,390 million	Unchanged
Non-GAAP Research and development expenses[2]	$1,220 - $1,250 million	Unchanged
GAAP Selling, general and administrative expenses	$735 - $775 million	Unchanged
Non-GAAP Selling, general and administrative expenses[3]	$665 - $700 million	Unchanged

1. Adjusted to exclude the amortization of licensed intellectual property for Iclusig relating to the acquisition of the European business of ARIAD Pharmaceuticals, Inc. and the estimated cost of stock-based compensation.
2. Adjusted to exclude the estimated cost of stock-based compensation.
3. Adjusted to exclude the estimated cost of stock-based compensation and a legal reserve.

Conference Call and Webcast Information

Incyte will hold a conference call and webcast this morning at 8:00 a.m. ET. To access the conference call, please dial 877-407-3042 for domestic callers or 201-389-0864 for international callers. When prompted, provide the conference identification number, 13718346.

If you are unable to participate, a replay of the conference call will be available for 90 days. The replay dial-in number for the United States is 877-660-6853 and the dial-in number for international callers is 201-612-7415. To access the replay you will need the conference identification

number, 13718346.

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

About Incyte

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

About Jakafi® (ruxolitinib)

Jakafi is a first-in-class JAK1/JAK2 inhibitor approved by the U.S. FDA for treatment of 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 Tafasitamab

Tafasitamab is a humanized Fc-modified cytolytic CD19 targeting monoclonal antibody. In 2010, MorphoSys licensed exclusive worldwide rights to develop and commercialize tafasitamab from Xencor, Inc. Tafasitamab incorporates an XmAb® engineered Fc domain, which mediates B-cell lysis through apoptosis and immune effector mechanism including antibody-dependent cell-mediated cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP).

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

In January 2020, MorphoSys and Incyte entered into a collaboration and licensing agreement to further develop and commercialize tafasitamab globally. Monjuvi® is being co-commercialized by Incyte and MorphoSys in the United States. Incyte has exclusive commercialization rights outside the United States.

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

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

Monjuvi® is a registered trademark of MorphoSys AG.

XmAb® is a registered trademark of Xencor, Inc.

About Pemazyre® (pemigatinib)

Pemazyre is a kinase inhibitor indicated in the United States for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test[1]. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

In Japan, Pemazyre is approved for the treatment of patients with unresectable biliary tract cancer (BTC) with a fibroblast growth factor receptor 2 (FGFR2) fusion gene, worsening after cancer chemotherapy.

In Europe, Pemazyre is approved for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy.

Pemazyre is a potent, selective, oral inhibitor of FGFR isoforms 1, 2 and 3 which, in preclinical studies, has demonstrated selective pharmacologic activity against cancer cells with FGFR alterations.

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

Pemazyre is a trademark of Incyte Corporation.

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 potential launch of Jakafi in steroid-refractory chronic GVHD; the potential for multiple approvals, including ruxolitinib cream in atopic dermatitis, and several regulatory filings, including parsaclisib in NHL and ruxolitinib cream in vitiligo; expectations regarding the initiation of multiple pivotal trials across key development programs for both tafasitamab and LIMBER; expectations for the timing of the receipt and presentation of clinical trial results for the Company's and its collaboration partners' product candidates, including ruxolitinib cream for vitiligo; the expected PDUFA action date for baricitinib for atopic dermatitis; the expected sNDA submission date for baricitinib for alopecia areata; and the Company's reaffirmed financial guidance for 2021 and the expectations underlying such guidance.

These forward-looking statements are based on the Company's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: the actual time required by the FDA to review the Company's NDA for approval for ruxolitinib cream in atopic dermatitis and the Company's sNDA for ruxolitinib in steroid-refractory chronic GVHD and the results of such reviews; further research and development and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials and the ability to enroll subjects in accordance with planned schedules; the effects of the COVID-19 pandemic and measures to address the pandemic on the Company's clinical trials, supply chain and other third-party providers, sales and marketing efforts, and business, development and discovery operations; determinations made by the FDA and regulatory agencies outside of the United States; the Company's dependence on its relationships with and changes in the plans of its collaboration partners; the efficacy or safety of the Company's products and the products of the Company's collaboration partners; the acceptance of the Company's products and the products of the Company's collaboration partners in the marketplace; market competition; unexpected variations in the demand for the Company's products and the products of the Company's collaboration partners; the effects of announced or unexpected price regulation or limitations on reimbursement or coverage for the Company's products and the products of the Company's collaboration partners; sales, marketing, manufacturing and distribution requirements, including the Company's and its collaboration partners' ability to successfully commercialize and build commercial infrastructure for newly approved products and any additional products that become approved; greater than expected expenses, including expenses relating to litigation or strategic activities; and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including its annual report on Form 10-K for the year ended December 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 March 31,	
	2021	2020
	GAAP	
Revenues:		
Product revenues, net	$ 504,811	$ 486,727
Product royalty revenues	99,907	81,780
Total revenues	604,718	568,507
Costs and expenses:		
Cost of product revenues (including definite-lived intangible amortization)	29,220	27,319
Research and development	306,896	1,085,287
Selling, general and administrative	153,795	111,148
Change in fair value of acquisition-related contingent consideration	5,526	6,627
Collaboration loss sharing	10,484	2,130
Total costs and expenses	505,921	1,232,511
Income (loss) from operations	98,797	(664,004)
Other income (expense), net	(1,407)	8,662
Interest expense	(359)	(602)
Unrealized loss on long term investments	(27,709)	(48,132)
Income (loss) before provision for income taxes	69,322	(704,076)
Provision for income taxes	15,787	16,566
Net income (loss)	$ 53,535	$ (720,642)
Net income (loss) per share:		
Basic	$ 0.24	$ (3.33)

Diluted	$ 0.24	$ (3.33)
Shares used in computing net income (loss) per share:		
Basic	219,801	216,721
Diluted	221,876	216,721

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

	March 31, 2021	December 31, 2020
ASSETS		
Cash, cash equivalents and marketable securities	$ 1,962,393	$ 1,801,377
Accounts receivable	397,357	481,994
Property and equipment, net	594,670	559,625
Finance lease right-of-use assets, net	27,987	28,451
Inventory	40,379	35,973
Prepaid expenses and other assets	113,976	103,313
Long term investments	202,174	222,301
Other intangible assets, net	166,907	172,291
Goodwill	155,593	155,593
Total assets	$ 3,661,436	$ 3,560,918
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 636,121	$ 648,793
Finance lease liabilities	34,471	34,857
Acquisition-related contingent consideration	263,000	266,000
Stockholders' equity	2,727,844	2,611,268
Total liabilities and stockholders' equity	$ 3,661,436	$ 3,560,918

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

	Three Months Ended March 31,	
	2021	2020
GAAP Net Income (Loss)	$ 53,535	$(720,642)
Adjustments[1]*:*		
Non-cash stock compensation from equity awards (R&D)[2]	29,874	28,713
Non-cash stock compensation from equity awards (SG&A)[2]	17,242	13,575
Non-cash stock compensation from equity awards (COGS)[2]	240	225
Non-cash interest expense related to convertible notes[3]	-	223
Changes in fair value of equity investments[4]	27,709	48,132
Amortization of acquired product rights[5]	5,384	5,384
Change in fair value of contingent consideration[6]	5,526	6,627
Legal reserve[7]	13,240	-
Tax effect of Non-GAAP adjustments[8]	(3,994)	(1,157)
Non-GAAP Net Income (Loss)	$ 148,756	$(618,920)
Non-GAAP net income (loss) per share:		
Basic	$ 0.68	$ (2.86)
Diluted	$ 0.67	$ (2.86)
Shares used in computing Non-GAAP net income (loss) per share:		
Basic	219,801	216,721
Diluted	221,876	216,721

1. 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, 2021 and 2020 are upfront consideration and milestones of $11,500 and $805,532, respectively, 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 loss on long term investments line item in the Condensed Consolidated Statements of Operations.

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

6. As included within the Change in fair value of acquisition-related contingent consideration line item in the Condensed Consolidated Statements of Operations.

7. As included within Selling, general and administrative expenses line item in the Condensed Consolidated Statements of Operations.

8. As included within the Provision for income taxes line item in the Condensed Consolidated Statements of Operations. Income tax effects of Non-GAAP adjustments are calculated using the applicable statutory tax rate for the jurisdictions in which the charges are incurred, while taking into consideration any valuation allowances.

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

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