Incyte Reports 2022 First Quarter Financial Results and Provides Updates on Key Clinical Programs

May 3, 2022

- *Total product and royalty revenues of $728 million in Q1'22 (+20% Y/Y)*
- *Jakafi® (ruxolitinib) net product revenues of $544 million in Q1'22 (+17% Y/Y); raising the bottom end of full year guidance to new range of $2.33 to $2.40 billion*
- *Robust uptake of Opzelura™ (ruxolitinib) cream with over 38,000 new patients treated in the first quarter; meaningful progress with payers resulting in 146 million total lives now covered*
- *Positive 52-week data from the Phase 3 TRuE-V program evaluating ruxolitinib cream in patients with vitiligo presented at AAD 2022; ruxolitinib cream is currently under review in the U.S. and Europe*

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

WILMINGTON, Del.--(BUSINESS WIRE)--May 3, 2022-- Incyte (Nasdaq:INCY) today reports 2022 first quarter financial results, and provides a status update on the Company's clinical development portfolio.

"Our double-digit growth in the first quarter reflects the strong performance of Jakafi ® (ruxolitinib) – supported by the successful launch in chronic graft-versus-host disease (GVHD) in the United States – as well as continued growth for Pemazyre® (pemigatinib) in Europe and Japan and, importantly, the fast uptake of Opzelura™ (ruxolitinib) cream in atopic dermatitis in the United States," saidHervé Hoppenot, Chief Executive Officer, Incyte. "Opzelura is an important growth driver for Incyte and the U.S. launch is off to an excellent start with over 38,000 patients treated during the first quarter and significant progress with payers on securing access for patients. Later this year we have the potential to launch Opzelura in a second indication in the U.S. and we expect a regulatory decision in Europe for the treatment of patients with vitiligo who currently have no approved therapies for repigmentation. Our strong product growth and robust pipeline position us well for long-term growth and diversification."

Portfolio Updates

MPNs and GVHD – key highlights

LIMBER (Leadership In MPNs BEyond Ruxolitinib) program: The new drug application (NDA) for once-daily ruxolitinib (QD) is on track for submission in the first half of this year. Initial data from the ongoing combination trials of ruxolitinib with INCB57643 (BET) and INCB00928 (ALK2) are expected later this year.

	Indication and status
QD ruxolitinib (JAK1/JAK2)	Myelofibrosis, polycythemia vera and 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
ruxolitinib + INCB00928 (JAK1/JAK2 + ALK2)	Myelofibrosis: Phase 2
ruxolitinib + CK0804[1] (JAK1/JAK2 + CB-Tregs)	Myelofibrosis: PoC in preparation
itacitinib (JAK1)	Treatment-naïve chronic GVHD: Phase 2/3 (GRAVITAS-309)
axatilimab (anti-CSF-1R)[2]	Chronic GVHD (third-line plus therapy): Pivotal Phase 2 (AGAVE-201)

[1] Development collaboration with Cellenkos, Inc.

[2] Clinical development of axatilimab in GVHD conducted in collaboration with Syndax Pharmaceuticals.

Other Hematology/Oncology – key highlights

Pemazyre: The ongoing launches in the U.S., Europe and Japan continue to go well. In March, Pemazyre was approved in China by the National Medical Products Administration (NMPA) for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth receptor 2 (FGFR2) fusion or rearrangement as confirmed by a validated diagnostic test that have progressed after at least one prior line of systemic therapy.

A Phase 2 open-label study evaluating the efficacy and safety of pemigatinib in adults with previously treated glioblastoma or other primary central nervous system tumors harboring activating FGFR1-3 alterations (FIGHT-209) and a Phase 2 open-label study evaluating the efficacy and safety of

pemigatinib in adults with relapsed or refractory advanced non-small cell lung cancer with an FGFR alteration (FIGHT-210) are being initiated.

	Indication and status
pemigatinib (FGFR1/2/3)	Cholangiocarcinoma (CCA): Phase 3 (FIGHT-302) Myeloid/lymphoid neoplasms (MLN): Phase 2 (FIGHT-203) Glioblastoma: Phase 2 (FIGHT-209) being initiated Non-small cell lung cancer (NSCLC): Phase 2 (FIGHT-210) being initiated
tafasitamab (CD19)[1]	Relapsed or refractory diffuse large B-cell lymphoma (DLBCL): Phase 2 (L-MIND); Phase 3 (B-MIND) First-line DLBCL: Phase 3 (*frontMIND*) Relapsed or refractory follicular lymphoma (FL) and relapsed or refractory marginal zone lymphoma (MZL): Phase 3 (*inMIND*) Relapsed or refractory B-cell malignancies: PoC (*topMIND*) with parsaclisib (PI3Kδ) Relapsed or refractory B-cell malignancies: PoC with lenalidomide and plamotamab being initiated[2]
parsaclisib (PI3Kδ)	Autoimmune hemolytic anemia: Phase 3 (PATHWAY)
retifanlimab (PD-1)[3]	Squamous cell anal cancer (SCAC): Phase 3 (POD1UM-303) MSI-high endometrial cancer: Phase 2 (POD1UM-101, POD1UM-204) Merkel cell carcinoma: Phase 2 (POD1UM-201) NSCLC: Phase 3 (POD1UM-304)

[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

Strong U.S. launch of Opzelura in atopic dermatitis (AD): Over 38,000 new patients were prescribed Opzelura in the first quarter with positive physician and patient feedback driving the robust uptake. Refill rates continue to increase with refills comprising 23% of total prescriptions in the last week of Q1. Substantial progress has been made in securing access to Opzelura for patients, and we now have agreements in place with payers which account for 146 million total lives covered including 82 million commercial lives.

We have established a broad clinical development program within dermatology that includes multiple new indications for ruxolitinib cream, as well as new products.

Ruxolitinib cream in vitiligo in the U.S. and Europe: In March, 52-week safety and efficacy data from the two Phase 3 TRuE-V studies evaluating ruxolitinib cream in vitiligo, presented at the American Academy of Dermatology (AAD) annual meeting, demonstrated that a longer duration of therapy with ruxolitinib cream was associated with greater repigmentation in patients with vitiligo. A supplemental new drug application (sNDA) and a marketing authorization application (MAA) for ruxolitinib cream as a treatment for vitiligo are under review at the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), respectively. The Prescription Drug User Fee Act (PDUFA) target action date was extended to July 18, 2022. Ruxolitinib cream has the potential to become the first product approved for repigmentation in vitiligo and would be a new therapeutic option for the millions of patients living with the disease today, pending regulatory decision.

A Phase 2 open-label study is being initiated to assess whether repigmentation response in some patients with vitiligo may be enhanced by adding phototherapy to treatment with ruxolitinb cream.

Ruxolitinib cream in chronic hand eczema (CHE): Incyte continues to expand the development of ruxolitinib cream into new indications as part of its life cycle management strategy. Two Phase 3 trials evaluating ruxolitinib cream in chronic hand eczema are being initiated (TRuE-CHE1 and TRuE-CHE2).

INCB54707 (JAK1) development across three indications: We are also assessing INCB54707, our JAK1 specific inhibitor, in Phase 2 studies for hidradenitis suppurativa, prurigo nodularis and vitiligo. There is significant potential with each of these indications where there are limited, and in some cases, no FDA-approved therapies.

	Indication and status
ruxolitinib cream[1] (JAK1/JAK2)	AD: Phase 3 pediatric study (TRuE-AD3) Vitiligo: Phase 3 (TRuE-V1, TRuE-V2, primary endpoint met in both studies); sNDA and MAA under review CHE: Phase 3 (TRuE-CHE1 and TRuE-CHE2) being initiated
ruxolitinib cream + UVB (JAK1/JAK2 + phototherapy)	Vitiligo: Phase 2 being initiated
INCB54707 (JAK1)	Hidradenitis suppurativa: Phase 2b Vitiligo: Phase 2 Prurigo nodularis: Phase 2

[1] Novartis' rights for ruxolitinib outside of the United States under our Collaboration and License Agreement with Novartis do not include topical administration.

Discovery and early development – key highlights

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

Oral PD-L1 Program: At SITC last year, Incyte highlighted clinical safety and efficacy data for the oral PD-L1 program which included three compounds, INCB86550, INCB99280 and INCB99318. Tumor shrinkage was observed for all three oral PD-L1 inhibitors. With regards to safety, both INCB99280 and INCB99318 did not show peripheral neuropathy seen with INCB86550. In May, the decision was made to prioritize the development of INCB99280 and INCB99318 based on positive therapeutic ratios.

INCB123667 (CDK2): In the cell cycle, the serine threonine kinase, CDK2, regulates the transition from the G1 phase (cell growth) to the S-phase (DNA replication). INCB123667 is a novel, potent and selective oral small molecule inhibitor of CDK2 which has been shown to suppress tumor growth as monotherapy and in combination with standard of care, in Cyclin E amplified tumor models, in vivo. A Phase 1 dose-escalation and dose-expansion study of INCB123667 in adults with selected advanced or metastatic solid tumors is being initiated.

Modality	Candidates
Small molecules	INCB81776 (AXL/MER), epacadostat (IDO1), INCB99280 (PD-L1), INCB99318 (PD-L1), INCB106385 (A2A/A2B), INCB123667 (CDK2)
Monoclonal antibodies[1]	INCAGN1876 (GITR), INCAGN2385 (LAG-3), INCAGN1949 (OX40), INCAGN2390 (TIM-3), INCA00186 (CD73)

[1] Discovery collaboration with Agenus.

Partnered – key highlights

Ruxolitinib in acute and chronic GVHD: In March, Incyte and Novartis announced a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) for ruxolitinib in acute and chronic GVHD, based on data from the Phase 3 REACH2 and REACH3 trials. GVHD is a life-threatening complication of stem cell transplants, with no established standard of care in Europe for patients who do not adequately respond to first-line steroid treatment.

Baricitinib in alopecia areata (AA): In March, Incyte and Eli Lilly presented 52-week data at the American Academy of Dermatology (AAD) annual meeting demonstrating that nearly 40% of adults with alopecia areata and who were taking baricitinib 4mg saw at least 80% scalp hair coverage. There are no approved treatments for AA.

Capmatinib in NSCLC: In April, Incyte and Novartis announced a positive opinion from the CHMP based on data from the Phase 2 GEOMETRY mono-1 study showing an overall response rate (ORR) of 51.6% in a cohort evaluating second-line patients only and 44% in all previously-treated patients with advanced non-small cell lung cancer (NSCLC) harboring alterations leading to MET exon 14 skipping.

	Indication and status
ruxolitinib (JAK1/JAK2)[1]	Acute and chronic GVHD: MAA and J-NDA under review; positive CHMP opinion received
baricitinib (JAK1/JAK2)[2]	AD: Phase 3 (BREEZE-AD); approved in EU and Japan Severe AA: Phase 3 (BRAVE-AA1, BRAVE-AA2); Submissions in U.S., EU, and Japan
capmatinib (MET)[3]	NSCLC (with MET exon 14 skipping mutations): Approved as Tabrecta in U.S. and Japan; MAA under review; positive CHMP opinion received

[1] Jakavi (ruxolitinib) licensed to Novartis ex-US.

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

[3] Worldwide rights to capmatinib licensed to Novartis.

2022 First Quarter Financial Results

The financial measures presented in this press release for the three months ended March 31, 2022 and 2021 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,	
	2022	2021
Total GAAP revenue	$ 733,235	$ 604,718
Total GAAP operating income	116,540	98,797
Total Non-GAAP operating income	172,147	170,303
GAAP net income	37,992	53,535
Non-GAAP net income	122,867	148,756
GAAP basic EPS	$ 0.17	$ 0.24
Non-GAAP basic EPS	$ 0.56	$ 0.68
GAAP diluted EPS	$ 0.17	$ 0.24
Non-GAAP diluted EPS	$ 0.55	$ 0.67

Revenue Details

Revenue Details
(unaudited, in thousands)

	Three Months Ended March 31,		%
	2022	2021	Change
Net product revenues:			
Jakafi	$ 544,464	$ 465,710	17%
Iclusig	26,069	25,645	2%
Pemazyre	18,032	13,456	34%
Minjuvi	4,502	—	NM
Opzelura	12,754	—	NM
Royalty revenues:			
Jakavi	70,867	65,602	8%
Olumiant	48,064	32,258	49%
Tabrecta	3,483	2,047	70%
Total product and royalty revenues	728,235	604,718	20%
Milestone and contract revenues	5,000	—	NM
Total GAAP revenues	$ 733,235	$ 604,718	21%

NM = not meaningful

Product and Royalty Revenues Product and royalty revenues for the three months ended March 31, 2022 increased 20% over the prior year comparative period primarily as a result of increases in Jakafi, Pemazyre and Opzelura net product revenues, and higher royalty revenues from Jakavi and Olumiant. Jakafi net product revenues for the three months ended March 31, 2022 increased 17% over the prior year comparative period, primarily driven by growth in patient demand. The 49% growth in Olumiant royalty revenues for the quarter ended March 31, 2022 reflects an increase in net product sales as a result of the use of Olumiant for the treatment of COVID-19.

Operating Expenses

Operating Expense Summary
(unaudited, in thousands)

	Three Months Ended March 31,		%
	2022	2021	Change
GAAP cost of product revenues	$ 42,614	$ 29,220	46%
Non-GAAP cost of product revenues[1]	36,619	23,596	55%
GAAP research and development	353,373	306,896	15%
Non-GAAP research and development[2]	327,045	277,022	18%
GAAP selling, general and administrative	209,584	153,795	36%
Non-GAAP selling, general and administrative[3]	192,682	123,313	56%
GAAP change in fair value of acquisition-related contingent consideration	6,382	5,526	15%
Non-GAAP change in fair value of acquisition-related contingent consideration[4]	—	—	

GAAP collaboration loss sharing	4,742	10,484	(55%)

[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 legal settlements.

[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 March 31, 2022 increased 15% and 18%, respectively, compared to the same period in 2021 primarily due to continued investment in our late stage development assets.

Selling, general and administrative expenses GAAP and Non-GAAP selling, general and administrative expenses for the three months ended March 31, 2022 increased 36% and 56%, respectively, compared to the same period in 2021, primarily due to expenses related to our dermatology commercial organization and activities to support the launch of Opzelura for the treatment of atopic dermatitis.

Other Financial Information

Operating income GAAP operating income for the three months ended March 31, 2022 increased compared to the same period in 2021, driven by growth in product and royalty revenues.

Cash, cash equivalents and marketable securities position As of March 31, 2022 and 2021, cash, cash equivalents and marketable securities totaled $2.5 billion and $2.3 billion, respectively.

2022 Financial Guidance

The Company has reaffirmed its full year 2022 financial guidance, as detailed below. Guidance does not include revenue from Opzelura or the impact of any potential future strategic transactions.

	Current	Previous
Jakafi net product revenues	$2.33 - $2.40 billion	$2.3 - $2.4 billion
Other Hematology/Oncology net product revenues[1]	$210 - $240 million	Unchanged
GAAP Cost of product revenues	6 – 7% of net product revenues	Unchanged
Non-GAAP Cost of product revenues[2]	5 – 6% of net product revenues	Unchanged
GAAP Research and development expenses	$1,550 - $1,590 million	Unchanged
Non-GAAP Research and development expenses[3]	$1,420 - $1,455 million	Unchanged
GAAP Selling, general and administrative expenses	$950 - $1,000 million	Unchanged
Non-GAAP Selling, general and administrative expenses[3]	$880 - $925 million	Unchanged

[1] Pemazyre in the U.S., EU and Japan and Iclusig and Minjuvi in the EU.

[2] 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.

[3] Adjusted to exclude the estimated cost of stock-based compensation.

Conference Call and Webcast Information
Incyte will hold a conference call and webcast this morning at 8:00 a.m. 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, 13728884.

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, 13728884.

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 chronic GVHD after failure of one or two lines of systemic therapy 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, in adults with intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF and for treatment of steroid-refractory acute GVHD in adult and pediatric patients 12 years and older.

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 Opzelura™ (ruxolitinib) Cream
Opzelura (ruxolitinib) cream is a novel cream formulation of Incyte's selective JAK1/JAK2 inhibitor ruxolitinib, is the first and only topical JAK inhibitor approved for use in the United States for the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis (AD) in non-immunocompromised patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies, or when those therapies are not advisable. Use of Opzelura in combination with therapeutic biologics, other JAK inhibitors, or potent immunosuppressants, such as azathioprine or cyclosporine, is not recommended.

In October 2021, Incyte announced the validation of the European Marketing Authorization Application (MAA) for ruxolitinib cream as a potential treatment for adolescents and adults (age >12 years) with non-segmental vitiligo with facial involvement. Additionally, in December 2021, Incyte announced the acceptance and priority review of the supplemental New Drug Application (sNDA) for ruxolitinib cream as a potential treatment for adolescents and adults (age ≥12 years) with vitiligo.

Incyte has worldwide rights for the development and commercialization of ruxolitinib cream, marketed in the United States as Opzelura.

Opzelura is a trademark of Incyte.

About Monjuvi®/Minjuvi® (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).

In the United States, 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 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 Europe, Minjuvi® (tafasitamab) received conditional approval, in combination with lenalidomide, followed by Minjuvi monotherapy, for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are not eligible for autologous stem cell transplant (ASCT).

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

Minjuvi® and Monjuvi® are registered trademarks of MorphoSys AG. Tafasitamab is co-marketed by Incyte and MorphoSys under the brand name Monjuvi® in the U.S., and marketed by Incyte under the brand name Minjuvi® in the EU.

XmAb® is a registered trademark of Xencor, Inc.

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

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.

Pemazyre is a trademark of Incyte Corporation.

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

About Iclusig® (ponatinib) tablets
Ponatinib (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.

Click here to view the Iclusig EU Summary of Medicinal Product Characteristics.

Incyte has an exclusive license from Takeda Pharmaceuticals International AG to commercialize ponatinib in the European Union and 29 other countries, including Switzerland, UK, Norway, Turkey, Israel and Russia. Iclusig is marketed in the U.S. by Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceutical Company Limited.

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 any discussion of the following: Incyte's potential for long-term growth and diversification; Incyte's financial guidance for 2022, including its expectations regarding sales of Jakafi; Incyte's expectations with regard to the regulatory submissions seeking approval of ruxolitinib cream in vitiligo; Incyte's expectations with regard to filing an NDA for once-daily ruxolitinib; Incyte's expectations with respect to Opzelura, including the Company's ongoing discussions with payers; Incyte's expectations regarding ongoing clinical trials and clinical trials to be initiated, including the LIMBER program, phase 2 trials of pemigatinib in glioblastoma and non-small cell lung cancer, a phase 2 trial of ruxolitinib cream in vitiligo to determine whether phototherapy might enhance repigmentation response, phase 3 trials for ruxolitinib cream in chronic hand eczema and a phase 1 dose-escalation and dose-expansion study of INCB123667 in adults with selected advanced or metastatic solid tumors; and the potential for INCB54707 in hidradenitis suppurativa, prurigo nodularis and vitiligo.

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, EMA, and other regulatory agencies; 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 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, 2021. 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,	
	2022	2021
	GAAP	
Revenues:		
Product revenues, net	$ 605,821	$ 504,811
Product royalty revenues	122,414	99,907
Milestone and contract revenues	5,000	—
Total revenues	733,235	604,718
Costs and expenses:		
Cost of product revenues (including definite-lived intangible amortization)	42,614	29,220
Research and development	353,373	306,896
Selling, general and administrative	209,584	153,795
Change in fair value of acquisition-related contingent consideration	6,382	5,526
Collaboration loss sharing	4,742	10,484
Total costs and expenses	616,695	505,921
Income from operations	116,540	98,797
Other income (expense), net	1,260	(1,407)
Interest expense	(680)	(359)
Unrealized loss on long term investments	(46,585)	(27,709)
Income before provision for income taxes	70,535	69,322
Provision for income taxes	32,543	15,787
Net income	$ 37,992	$ 53,535
Net income per share:		
Basic	$ 0.17	$ 0.24
Diluted	$ 0.17	$ 0.24
Shares used in computing net income per share:		
Basic	221,326	219,801
Diluted	222,950	221,867

INCYTE CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited, in thousands)

	March 31, 2022	December 31, 2021
ASSETS		
Cash, cash equivalents and marketable securities	$2,544,160	$ 2,348,192
Accounts receivable	562,344	616,300
Property and equipment, net	729,217	723,920
Finance lease right-of-use assets, net	27,392	27,548
Inventory	70,841	56,938
Prepaid expenses and other assets	179,253	165,302
Long term investments	174,681	221,266
Other intangible assets, net	145,371	150,755
Goodwill	155,593	155,593
Deferred income tax asset	465,369	467,538
Total assets	$5,054,221	$ 4,933,352
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 914,968	$ 885,081
Finance lease liabilities	34,181	34,267
Acquisition-related contingent consideration	242,000	244,000
Stockholders' equity	3,863,072	3,770,004
Total liabilities and stockholders' equity	$5,054,221	$ 4,933,352

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

	Three Months Ended March 31,	
	2022	2021
GAAP Net Income	$ 37,992	$ 53,535
Adjustments[1]:		
Non-cash stock compensation from equity awards (R&D)[2]	26,328	29,874
Non-cash stock compensation from equity awards (SG&A)[2]	16,902	17,242
Non-cash stock compensation from equity awards (COGS)[2]	611	240
Non-cash interest[3]	108	—
Changes in fair value of equity investments[4]	46,585	27,709
Amortization of acquired product rights[5]	5,384	5,384
Change in fair value of contingent consideration[6]	6,382	5,526
Legal settlements[7]	—	13,240
Tax effect of Non-GAAP pre-tax adjustments[8]	(17,425)	(3,994)
Non-GAAP Net Income	$ 122,867	$ 148,756
Non-GAAP net income per share:		
Basic	$ 0.56	$ 0.68
Diluted	$ 0.55	$ 0.67
Shares used in computing Non-GAAP net income per share:		
Basic	221,326	219,801
Diluted	222,950	221,867

[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, 2022 and 2021 are milestones of $5,000 and $0, 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, 2022 and 2021 are upfront consideration and milestones of $20,000 and $11,500, 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] Income tax effects of Non-GAAP pre-tax 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 against related deferred tax assets.

View source version on businesswire.com: https://www.businesswire.com/news/home/20220503005331/en/

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

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

Source: Incyte