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

August 2, 2022

- *Total revenues increased 29% year-over-year (Y/Y) to $911 million; total product revenues of $664 million (+15% Y/Y)*
- *Jakafi® (ruxolitinib) net product revenues of $598 million in Q2'22 (+13% Y/Y) driven by volume growth; raising the bottom end of full year guidance to new range of $2.36 to $2.40 billion*
- *Opzelura ™ (ruxolitinib) cream approved as first and only treatment for repigmentation of nonsegmental vitiligo in patients aged 12 and older; launch progressing in atopic dermatitis (AD)*
- *Multiple approvals including Olumiant® (baricitinib) as the first and only systemic treatment approved for alopecia areata in the U.S., Europe and Japan and Jakavi® (ruxolitinib) approved as the first post-steroid treatment for acute and chronic graft-versus-host disease in Europe*

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

WILMINGTON, Del.--(BUSINESS WIRE)--Aug. 2, 2022-- Incyte (Nasdaq:INCY) today reports 2022 second quarter financial results, and provides a status update on the Company's clinical development portfolio.

"The second quarter was strong with total revenues up 29% year-over-year, multiple approvals and the continued advancement of our pipeline. The launch of Opzelura in atopic dermatitis continues to progress well and in recent weeks, improvements in reimbursement have translated into an increase in covered claims. Revenues in the second quarter were temporarily impacted by the shift from free drug to paid prescription. Patient demand and satisfaction remain strong," said Hervé Hoppenot, Chief Executive Officer, Incyte. "In July, Opzelura was also approved by the FDA in nonsegmental vitiligo, creating a new growth opportunity as the first therapy approved for repigmentation of vitiligo."

Portfolio Updates

MPNs and GVHD – key highlights

LIMBER (Leadership In MPNs BEyond Ruxolitinib) program: The LIMBER development program is advancing with the FDA acceptance of the NDA for once-daily (QD) ruxolitinib, and the progression of multiple ongoing and planned combination trials with ruxolitinib. The Prescription Drug User Fee Act (PDUFA) target action date for QD ruxolitinib extended release (XR) formulation is March 23, 2023. Incyte's partner, Cellenkos, announced the FDA clearance of its Investigational New Drug (IND) application to initiate a Phase 1b, open-label study of CK0804 as an add on therapy to ruxolitinib in patients with myelofibrosis who experience a suboptimal response to ruxolitinib. Combination trials of parsaclisib, INCB57643 (BET) and INCB00928 (ALK2) with ruxolitinib are also ongoing.

Itacitinib in chronic graft-versus-host disease (GVHD): Incyte no longer intends to develop itacitinib, a selective JAK1 inhibitor, in treatment-naïve chronic GVHD (cGVHD). Based on efficacy data from Part 1 of the Phase 2/3 GRAVITAS-309 trial, it was determined that a pivotal trial was unlikely to be successful.

	Indication and status
QD ruxolitinib (JAK1/JAK2)	Myelofibrosis, polycythemia vera and GVHD: clinical pharmacology studies; NDA under review
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 (LIMBER-TREG108)
axatilimab (anti-CSF-1R)[2]	Chronic GVHD: Pivotal Phase 2 (third-line plus therapy) (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

Pemigatinib (Pemazyre®): 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 ongoing.

	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) Non-small cell lung cancer (NSCLC): Phase 2 (FIGHT-210)
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[2]
parsaclisib (PI3Kδ)	Warm 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

Continued momentum with Opzelura launch in atopic dermatitis (AD) in the U.S.: Coverage for Opzelura has been established with the three largest PBM/GPOs and more plans continue to add Opzelura to formularies. The demand for Opzelura continues to be strong with nearly 48,000 units of Opzelura shipped in the second quarter and we expect strong physician and patient perceptions of Opzelura to drive increased usage in mild to moderate AD patients.

Opzelura approved for vitiligo in the U.S.; under review in Europe: Opzelura was approved as a treatment for nonsegmental vitiligo - which account for ~85% of patients with vitiligo - in adolescents and adults in the U.S., becoming the first and only medicine approved for repigmentation in vitiligo. The marketing authorization application (MAA) is under review at the European Medicines Agency (EMA) with an expected decision from the Committee for Medicinal Products for Human Use (CHMP) by the end of the year.

Povorcitinib (INCB54707): Povorcitinib is currently in Phase 2 trials for hidradenitis suppurativa (HS), vitiligo and prurigo nodularis. Based on findings from the Phase 2 trial, Incyte intends to initiate a Phase 3 study in HS later this year.

	Indication and status
ruxolitinib cream[1] (JAK1/JAK2)	AD: Phase 3 pediatric study (TRuE-AD3) Vitiligo: Phase 3 (TRuE-V1, TRuE-V2); approved by FDA; MAA under review CHE: Phase 3 (TRuE-CHE1 and TRuE-CHE2) in preparation
ruxolitinib cream + UVB (JAK1/JAK2 + phototherapy)	Vitiligo: Phase 2
povorcitinib (JAK1)	Hidradenitis suppurativa: Phase 2b; Phase 3 in preparation 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.

INCB123667 (CDK2): 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 has been initiated.

INCA32459 (LAG-3xPD-1): In collaboration with Merus, Incyte has developed INCA32459, a novel LAG3xPD-1 bispecific antibody that is planned to enter clinical studies later this year.

Modality	Candidates
Small molecules	INCB81776 (AXL/MER), 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)
Bi-specific antibodies	INCA32459 (LAG-3xPD-1)[2]

[1] Discovery collaboration with Agenus.

[2] Development in collaboration with Merus

Partnered – key highlights

Jakavi® (ruxolitinib) approved for acute and chronic GVHD in Europe: In May, Incyte and Novartis announced the European Commission (EC) approval of Jakavi as the first post-steroid treatment for acute and chronic graft-versus-host disease (GVHD).

Olumiant® (baricitinib) approved for alopecia areata (AA) in U.S., Europe and Japan: In June, Incyte and Eli Lilly announced the approval of Olumiant for the treatment of adults with severe alopecia areata in the U.S., becoming the first-in-disease systemic treatment. Olumiant was also approved in Europe and Japan in June. The approval was based on Lilly's BRAVE-AA1 and BRAVE-AA2 trials, which showed one in three adults taking Olumiant 4-mg/day achieved significant hair regrowth resulting in 80% or more scalp coverage.

Tabrecta® (capmatinib) approved in non-small cell lung cancer (NSCLC) with MET exon-14 in Europe: In June, Tabrecta was approved by the European Commission as a monotherapy for the treatment of adults with advanced NSCLC harboring alterations leading to mesenchymal-epithelial-transition factor gene (MET) exon 14 (METex14) skipping who require systemic therapy following prior treatment with immunotherapy and/or platinum-based chemotherapy.

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

[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 Second Quarter Financial Results

The financial measures presented in this press release for the three and six months ended June 30, 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 June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Total GAAP revenues	$ 911,397	$ 705,709	$ 1,644,632	$ 1,310,427
Total GAAP operating income	254,431	140,836	370,971	239,633
Total Non-GAAP operating income	309,624	195,568	481,771	365,871
GAAP net income	161,432	149,456	199,424	202,991
Non-GAAP net income	226,353	178,833	349,220	327,589
GAAP basic EPS	$ 0.73	$ 0.68	$ 0.90	$ 0.92
Non-GAAP basic EPS	$ 1.02	$ 0.81	$ 1.58	$ 1.49
GAAP diluted EPS	$ 0.72	$ 0.67	$ 0.89	$ 0.91
Non-GAAP diluted EPS	$ 1.01	$ 0.80	$ 1.56	$ 1.48

Revenue Details

Revenue Details
(unaudited, in thousands)

	Three Months Ended June 30,		%	Six Months Ended June 30,		%
	2022	2021	Change	2022	2021	Change
Net product revenues:						
Jakafi	$ 597,673	$ 529,055	13%	$ 1,142,137	$ 994,765	15%
Iclusig	26,224	28,189	(7%)	52,293	53,834	(3%)
Pemazyre	18,983	17,906	6%	37,015	31,362	18%
Minjuvi	4,411	—	NM	8,913	—	NM
Opzelura	16,560	—	NM	29,314	—	NM
Royalty revenues:						
Jakavi	83,711	82,038	2%	154,578	147,640	5%
Olumiant	30,254	36,045	(16%)	78,318	68,303	15%
Tabrecta	3,581	2,476	45%	7,064	4,523	56%
Total product and royalty revenues	781,397	695,709	12%	1,509,632	1,300,427	16%
Milestone and contract revenues	130,000	10,000	1,200%	135,000	10,000	1,250%
Total GAAP revenues	$ 911,397	$ 705,709	29%	$ 1,644,632	$ 1,310,427	26%

NM = not meaningful

Product and Royalty Revenues Product and royalty revenues for the quarter ended June 30, 2022 increased 12% over the prior year comparative period primarily as a result of increases in Jakafi and Opzelura net product revenues, and higher royalty revenues from Jakavi. Jakafi net product revenues for the quarter ended June 30, 2022 increased 13% over the prior year comparative period, primarily driven by growth in patient demand across all indications.

Operating Expenses

Operating Expense Summary
(unaudited, in thousands)

	Three Months Ended June 30,		%	Six Months Ended June 30,		%
	2022	2021	Change	2022	2021	Change
GAAP cost of product revenues	$ 50,636	$ 38,028	33%	$ 93,250	$ 67,248	39%
Non-GAAP cost of product revenues[1]	44,575	32,302	38%	81,194	55,898	45%
GAAP research and development	347,196	343,511	1%	700,569	650,407	8%
Non-GAAP research and development[2]	319,059	315,473	1%	646,104	592,495	9%
GAAP selling, general and administrative	253,277	168,859	50%	462,861	322,654	43%
Non-GAAP selling, general and administrative[3]	235,595	152,523	54%	428,277	275,836	55%
GAAP change in fair value of acquisition-related contingent consideration	3,313	4,632	(28%)	9,695	10,158	(5%)
Non-GAAP change in fair value of acquisition-related contingent consideration[4]	—	—		—	—	
GAAP collaboration loss sharing	2,544	9,843	(74%)	7,286	20,327	(64%)

[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 quarter ended June 30, 2022 increased 1%, 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 quarter ended June 30, 2022 increased 50% and 54%, 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 treatments of atopic dermatitis and pre-launch activities for vitiligo.

Other Financial Information

Operating income GAAP operating income for the quarter ended June 30, 2022 increased compared to the same period in 2021, driven by growth in product revenues.

Cash, cash equivalents and marketable securities position As of June 30, 2022 and December 31, 2021, cash, cash equivalents and marketable securities totaled $2.7 billion and $2.3 billion, respectively.

2022 Financial Guidance

Incyte is tightening its full year 2022 guidance for Jakafi net product revenues as a result of our strong second quarter performance.

	Current	Previous
Jakafi net product revenues	$2.36 - $2.40 billion	$2.33 - $2.40 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, 13731520.

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, 13731520.

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, 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, indicated for the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older and 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.

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 its NDA submission for once-daily ruxolitinib; Incyte's expectations with respect to Opzelura, including the Company's ongoing discussions with payers and regulatory review in the EU; Incyte's expectations regarding ongoing clinical trials and clinical trials to be initiated, including the LIMBER program, a phase 3 trial of povorcitinib in hidradenitis suppurativa, 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 clinical studies regarding INCA32459.

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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	GAAP		GAAP	
Revenues:				
Product revenues, net	$ 663,851	$ 575,150	$ 1,269,672	$ 1,079,961
Product royalty revenues	117,546	120,559	239,960	220,466
Milestone and contract revenues	130,000	10,000	135,000	10,000
Total revenues	911,397	705,709	1,644,632	1,310,427
Costs and expenses:				
Cost of product revenues (including definite-lived intangible amortization)	50,636	38,028	93,250	67,248
Research and development	347,196	343,511	700,569	650,407
Selling, general and administrative	253,277	168,859	462,861	322,654
Change in fair value of acquisition-related contingent consideration	3,313	4,632	9,695	10,158
Collaboration loss sharing	2,544	9,843	7,286	20,327
Total costs and expenses	656,966	564,873	1,273,661	1,070,794
Income from operations	254,431	140,836	370,971	239,633
Other income (expense), net	522	4,390	1,782	2,983
Interest expense	(678)	(358)	(1,358)	(717)
Unrealized (loss) gain on long term investments	(24,897)	26,765	(71,482)	(944)
Income before provision for income taxes	229,378	171,633	299,913	240,955
Provision for income taxes	67,946	22,177	100,489	37,964
Net income	$ 161,432	$ 149,456	$ 199,424	$ 202,991
Net income per share:				
Basic	$ 0.73	$ 0.68	$ 0.90	$ 0.92
Diluted	$ 0.72	$ 0.67	$ 0.89	$ 0.91
Shares used in computing net income per share:				
Basic	221,660	220,083	221,493	219,942
Diluted	223,661	222,250	223,277	222,061

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

	June 30, 2022	December 31, 2021
ASSETS		
Cash, cash equivalents and marketable securities	$ 2,722,425	$ 2,348,192
Accounts receivable	682,968	616,300

Property and equipment, net	721,328	723,920
Finance lease right-of-use assets, net	27,349	27,548
Inventory	94,128	56,938
Prepaid expenses and other assets	190,606	165,302
Long term investments	149,784	221,266
Other intangible assets, net	139,987	150,755
Goodwill	155,593	155,593
Deferred income tax asset	434,867	467,538
Total assets	$ 5,319,035	$ 4,933,352
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 962,781	$ 885,081
Finance lease liabilities	34,193	34,267
Acquisition-related contingent consideration	237,000	244,000
Stockholders' equity	4,085,061	3,770,004
Total liabilities and stockholders' equity	$ 5,319,035	$ 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 June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
GAAP Net Income	$ 161,432	$ 149,456	$ 199,424	$ 202,991
Adjustments[1]:				
Non-cash stock compensation from equity awards (R&D)[2]	28,137	28,038	54,465	57,912
Non-cash stock compensation from equity awards (SG&A)[2]	17,682	16,354	34,584	33,596
Non-cash stock compensation from equity awards (COGS)[2]	677	342	1,288	582
Non-cash interest[3]	108	—	216	—
Changes in fair value of equity investments[4]	24,897	(26,765)	71,482	944
Amortization of acquired product rights[5]	5,384	5,384	10,768	10,768
Change in fair value of contingent consideration[6]	3,313	4,632	9,695	10,158
Legal settlements[7]	—	(18)	—	13,222
Tax effect of Non-GAAP pre-tax adjustments[8]	(15,277)	1,410	(32,702)	(2,584)
Non-GAAP Net Income	$ 226,353	$ 178,833	$ 349,220	$ 327,589
Non-GAAP net income per share:				
Basic	$ 1.02	$ 0.81	$ 1.58	$ 1.49
Diluted	$ 1.01	$ 0.80	$ 1.56	$ 1.48
Shares used in computing Non-GAAP net income per share:				
Basic	221,660	220,083	221,493	219,942
Diluted	223,661	222,250	223,277	222,061

[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, 2022 are milestones of $130,000 and $135,000, respectively, earned from our collaborative partners, as compared to milestones of $10,000 for both the three and six months ended June 30, 2021. 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, 2022 are upfront consideration and milestones of $2,500 and $22,500, respectively, related to our collaborative partners, as compared to upfront consideration and milestones of $5,000 and $16,500, respectively, for the three and six months ended June 30, 2021.

[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.

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