UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **August 3, 2021**

INCYTE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**001-12400**	**94-3136539**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

1801 Augustine Cut-Off **Wilmington, DE**	**19803**
(Address of principal executive offices)	(Zip Code)

(302) 498-6700
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240-13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol**	**Name of exchange on which registered**
Common Stock, $.001 par value per share	INCY	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b—2 of the Securities Exchange Act of 1934 (§ 240.12b—2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On August 3, 2021, Incyte Corporation issued a press release announcing financial results for its second fiscal quarter ended June 30, 2021. The full text of the press release is furnished as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) **Exhibits.**

Exhibits	Description
99.1	Press release of issued by Incyte Corporation dated August 3, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 3, 2021

INCYTE CORPORATION

By: /s/ Christianna Stamoulis
Christiana Stamoulis
Executive Vice President and
Chief Financial Officer

FOR IMMEDIATE RELEASE

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

- *Total product and royalty revenues of $696 million in Q2 2021 (+17% vs Q2 2020)*
- *Jakafi® (ruxolitinib) revenues of $529 million in Q2 2021 (+12% vs Q2 2020)*
- *Positive CHMP opinion for tafasitamab in combination with lenalidomide for the treatment of adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL)*
- *Phase 3 TRuE-V1 and TRuE-V2 studies evaluating ruxolitinib cream in vitiligo met primary and key secondary endpoints*

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

WILMINGTON, Del. – August 3, 2021 – Incyte (Nasdaq:INCY) today reports 2021 second quarter financial results and provides a status update on the Company's development portfolio.

"In the second quarter, we saw an acceleration of growth of Jakafi® (ruxolitinib) and encouraging uptake in Europe for Pemazyre® (pemigatinib). In addition, the recent positive CHMP opinion for tafasitamab and the potential subsequent launch of tafasitamab (Minjuvi®) in Europe represents another significant growth opportunity for Incyte," stated Hervé Hoppenot, Chief Executive Officer, Incyte. "We continue to achieve clinical development success across our portfolio with positive outcomes from multiple programs, including topline results from ruxolitinib cream's pivotal trials in vitiligo (TRuE-V), 52-week safety and efficacy data of ruxolitinib cream in atopic dermatitis (TRuE-AD), Phase 2 data of parsaclisib in autoimmune hemolytic anemia (AIHA) and the achievement of bioequivalence with once-daily (QD) ruxolitinib."

Portfolio Update

MPNs and GVHD – key highlights

Ruxolitinib in GVHD: Data from the REACH3 trial of ruxolitinib versus best available therapy (BAT) in patients with steroid-refractory chronic graft-versus-host disease (GVHD) have been published in *The New England Journal of Medicine*. The supplemental New Drug Application (sNDA) seeking approval of ruxolitinib for the treatment of steroid-refractory chronic GVHD is under review; the Prescription Drug User Fee Act (PDUFA) date was extended to September 22, 2021.

LIMBER (**L**eadership **I**n **M**PNs **BE**yond **R**uxolitinib): Bioavailability and bioequivalence data were published for ruxolitinib's QD extended release (XR) formulation at the European Hematology Association (EHA) 2021 Virtual Congress. QD ruxolitinib is in stability testing with an NDA submission planned for early 2022. Clinical studies evaluating ruxolitinib in combination with parsaclisib, INCB57643 (BET) and INCB00928 (ALK2), are progressing as expected.

Updated interim data from the proof-of-concept trial evaluating parsaclisib in combination with ruxolitinib in myelofibrosis (MF) patients with an inadequate response to ruxolitinib monotherapy were also presented at EHA.

	Indication and status
Once-a-day 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 in preparation
ruxolitinib + INCB00928 (JAK1/JAK2 + ALK2)	Myelofibrosis: Phase 2 in preparation
itacitinib (JAK1)	Myelofibrosis: Phase 2 (second-line therapy)
ruxolitinib + CK0804[1] (JAK1/JAK2 + CB-Tregs)	Myelofibrosis: PoC in preparation
ruxolitinib (JAK1/JAK2)	Steroid-refractory chronic GVHD[2]: sNDA under 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: In June, Incyte and MorphoSys announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion recommending the conditional marketing authorization of tafasitamab in combination with lenalidomide, followed by tafasitamab 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 transplantation (ASCT).

Updated three-year data from the Phase 2 L-MIND study evaluating tafasitamab in combination with lenalidomide as a treatment for adult patients with relapsed or refractory DLBCL were presented at EHA. Multiple studies evaluating tafasitamab as a backbone therapy in various combinations for the treatment of patients with DLBCL, follicular lymphoma, marginal zone lymphoma and other B-cell malignancies are underway, including two Phase 3 trials (*inMIND* and *frontMIND*) currently ongoing. An additional proof of concept trial (*coreMIND*) of tafasitamab in combination with parsaclisib for the treatment of patients with relapsed or refractory chronic lymphocytic leukemia (CLL) is expected to start in the next six months.

Pemigatinib: The ongoing launch in the United States continues to go well and the recent launches in Europe and Japan are on track. FIGHT-207, evaluating pemigatinib in tumor agnostic FGFR malignancies, is now closed to recruitment. Based on findings from this study, Incyte has identified populations that may potentially benefit from treatment with pemigatinib and intends to initiate Phase 2 studies in glioblastoma and non-small cell lung cancer by early next year.

Retifanlimab: In July, Incyte announced that the FDA issued a complete response letter for the Biologics License Application (BLA) for retifanlimab as a treatment for squamous cell carcinoma of the anal canal (SCAC). Registration-directed trials of retifanlimab in MSI-high endometrial and Merkel cell carcinoma are ongoing. The Marketing Authorization Application (MAA) seeking approval of retifanlimab in SCAC remains under review with the European Medicines Agency (EMA).

	Indication and status
pemigatinib (FGFR1/2/3)	CCA: Phase 2 (FIGHT-202), Phase 3 (FIGHT-302) Myeloid/lymphoid neoplasms (MLN): Phase 2 (FIGHT-203) Tumor agnostic: Phase 2 (FIGHT-207) Glioblastoma: Phase 2 in preparation NSCLC: Phase 2 in preparation
tafasitamab (CD19)[1]	r/r DLBCL: Phase 2 (L-MIND); Phase 3 (B-MIND); CHMP+ opinion 1L DLBCL: Phase 1b (*firstMIND*); Phase 3 (*frontMIND*) r/r FL and r/r MZL: Phase 3 (*inMIND*) r/r CLL: Phase 2 (*coreMIND*) in preparation 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); CRL from FDA; 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; CLL = chronic lymphocytic leukemia

[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: In June, 52-week safety and efficacy data from the two Phase 3 TRuE-AD studies evaluating ruxolitinib cream in mild-to-moderate atopic dermatitis were presented at the Revolutionizing

Atopic Dermatitis (RAD) virtual symposium. These data were the basis for an NDA seeking approval of ruxolitinib cream for the treatment of atopic dermatitis (AD); the PDUFA date has been extended to September 21, 2021.

A Phase 3 trial (TRuE-AD3) evaluating ruxolitinib cream in children (ages 2 to <12 years) with atopic dermatitis is ongoing.

In May, Incyte announced positive topline results from its pivotal Phase 3 TRuE-V program of ruxolitinib cream in adolescent and adult patients with vitiligo. Both TRuE-V1 and TRuE-V2 studies met the primary and key secondary endpoints, including patient reported outcomes. The overall efficacy and safety profile of ruxolitinib cream is consistent with previously reported Phase 2 data, and no new safety signals were observed. The long-term efficacy and safety portions of both studies will continue as planned. The regulatory submission seeking approval of ruxolitinib cream in vitiligo is expected later this year.

Other IAI

Parsaclisib: At EHA, Incyte presented Phase 2 data evaluating parsaclisib in autoimmune hemolytic anemia. The majority of patients achieved a response with parsaclisib over the initial 12-week treatment period. Treatment with parsaclisib was generally well tolerated. Based on these results, Incyte plans to initiate a Phase 3 trial by end of year.

	Indication and status
ruxolitinib cream (JAK1/JAK2)	Atopic dermatitis: NDA under review; Phase 3 pediatric study ongoing (TRuE-AD3) Vitiligo: Phase 3 (TRuE-V1, TRuE-V2, primary endpoint met in both studies); sNDA in preparation
INCB54707 (JAK1)	Hidradenitis suppurativa: Phase 2b Vitiligo: Phase 2
parsaclisib (PI3Kδ)	Autoimmune hemolytic anemia: Phase 2; Phase 3 in preparation
INCB00928 (ALK2)	Fibrodysplasia ossificans progressiva: Phase 2 in preparation

Discovery and early development – key highlights

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

Modality	**Candidates**
Small molecules	INCB01158 (ARG)[1], INCB81776 (AXL/MER), epacadostat (IDO1), INCB86550 (PD-L1), 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 July, Incyte and Lilly announced that the FDA would not meet the PDUFA action date for the sNDA for baricitinib for the treatment of adults with moderate to severe atopic dermatitis. Baricitinib is also being studied in alopecia areata with an expected submission in H2 2021.

	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

Corporate Update

After almost 20 years at Incyte, Wenqing Yao, Ph.D. has announced his retirement as Executive Vice President and Head of Medicinal Chemistry. Dr. Yao will be succeeded by a member of his senior leadership team.

2021 Second Quarter Financial Results

The financial measures presented in this press release for the three and six months ended June 30, 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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Total GAAP revenue	$ 705,709	$ 688,043	$ 1,310,427	$ 1,256,550
Total GAAP operating income (loss)	140,836	230,773	239,633	(433,231)
Total Non-GAAP operating income (loss)	195,568	288,514	365,871	(320,966)
GAAP net income (loss)	149,456	290,298	202,991	(430,344)
Non-GAAP net income (loss)	178,833	273,578	327,589	(345,342)
GAAP basic EPS	$ 0.68	$ 1.33	$ 0.92	$ (1.98)
Non-GAAP basic EPS	$ 0.81	$ 1.26	$ 1.49	$ (1.59)
GAAP diluted EPS	$ 0.67	$ 1.32	$ 0.91	$ (1.98)
Non-GAAP diluted EPS	$ 0.80	$ 1.24	$ 1.48	$ (1.59)

Revenue Details

Revenue Details
(unaudited, in thousands)

	Three Months Ended June 30,		%	Six Months Ended June 30,		%
	2021	2020	Change	2021	2020	Change
Revenues:						
Jakafi net product revenues	$ 529,055	$ 473,706	12%	$ 994,765	$ 933,185	7%
Iclusig net product revenues	28,189	22,798	24%	53,834	50,046	8%
Pemazyre net product revenues	17,906	3,786	373%	31,362	3,786	728%
Jakavi product royalty revenues	82,038	66,217	24%	147,640	122,550	20%
Olumiant product royalty revenues	36,045	25,830	40%	68,303	51,277	33%
Tabrecta product royalty revenues	2,476	706	251%	4,523	706	541%
Product and royalty revenues	695,709	593,043	17%	1,300,427	1,161,550	12%
Milestone and contract revenues	10,000	95,000	(89)%	10,000	95,000	(89)%
Total GAAP revenues	$ 705,709	$ 688,043	3%	$ 1,310,427	$ 1,256,550	4%

Product and Royalty Revenues Product and royalty revenues for the quarter ended June 30, 2021 increased 17% over the prior year comparative period as a result of increases in Jakafi, Iclusig and Pemazyre net product revenues and higher product royalty revenues from Jakavi, Olumiant and Tabrecta.

Operating Expenses

Operating Expense Summary
(unaudited, in thousands)

	Three Months Ended June 30,		%	Six Months Ended June 30,		%
	2021	2020	Change	2021	2020	Change
GAAP cost of product revenues	$ 38,028	$ 33,364	14%	$ 67,248	$ 60,683	11%
Non-GAAP cost of product revenues[1]	32,302	27,734	16%	55,898	49,444	13%
GAAP research and development	343,511	286,601	20%	650,407	1,371,888	(53)%
Non-GAAP research and development[2]	315,473	254,108	24%	592,495	1,310,682	(55)%
GAAP selling, general and administrative	168,859	117,998	43%	322,654	229,146	41%
Non-GAAP selling, general and administrative[3]	152,523	104,434	46%	275,836	202,007	37%
GAAP change in fair value of acquisition-related contingent consideration	4,632	6,054	(23)%	10,158	12,681	(20)%
Non-GAAP change in fair value of acquisition-related contingent consideration[4]	—	—		—	—	
GAAP collaboration loss sharing	9,843	13,253	(26)%	20,327	15,383	32%
Non-GAAP collaboration loss sharing	9,843	13,253	(26)%	20,327	15,383	32%

[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 June 30, 2021 increased 20% and 24%, respectively, compared to the same period in 2020, primarily due to the progression of our pipeline including parsaclisib and our 55% share of the global and U.S. specific development costs for tafasitamab as well as product supply related costs to support the potential launch of ruxolitinib cream as a treatment for atopic dermatitis. Excluding the $12 million impact of incremental product supply costs and upfront and milestone payments, GAAP and Non-GAAP research and development expense for the quarter ended June 30, 2021 increased approximately 16% and 20%, respectively, compared to the same period in 2020.

Selling, general and administrative expenses GAAP and Non-GAAP selling, general and administrative expenses for the quarter ended June 30, 2021 increased 43% and 46%, 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.

Other Financial Information

Operating income (loss) GAAP and Non-GAAP operating income for the quarter ended June 30, 2021 decreased by $90 million and $93 million, respectively, compared to the same period in 2020 primarily due to an $85 million decrease in milestone and contract revenues.

Cash, cash equivalents and marketable securities position As of June 30, 2021 and December 31, 2020, cash, cash equivalents and marketable securities totaled $2.1 billion and $1.8 billion, respectively.

2021 Financial Guidance

Incyte is tightening its full year 2021 guidance for Jakafi net product revenues to reflect the impact of higher than anticipated government rebates and chargebacks and the new PDUFA date for ruxolitinib for the treatment of steroid-refractory chronic GVHD and is revising upward the range for other Hematology/Oncology net product revenues based on the performance of Pemazyre in the first half of 2021. In addition, the Company is reducing the range for selling, general and administrative expense to reflect lower expenses for ruxolitinib cream as a treatment for atopic dermatitis in the U.S. based on the PDUFA date extension to September 21, 2021. Guidance does not include revenue from any potential new product launches or the impact of any potential future strategic transactions. Incyte's updated guidance is summarized below.

	Current	Previous
Jakafi net product revenues	$2,125 - $2,170 million	$2,125 - $2,200 million
Other Hematology/Oncology net product revenues	$155 - $170 million	$145 - $160 million
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	$725 - $755 million	$735 - $775 million
Non-GAAP Selling, general and administrative expenses[3]	$655 - $680 million	$665 - $700 million

[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 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 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 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).

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 marketed under the brand name Monjuvi® in the US. If approved in the EU, tafasitamab will be marketed under the brand name Minjuvi®.

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. 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.

* 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 without limitation statements regarding the potential launch of tafasitamab (Minjuvi®) in Europe and the potential significant growth opportunity represented by such potential launch and the recent positive CHMP opinion for tafasitamib; expectations regarding the NDA submission for QD ruxolitinib and the regulatory submission seeking approval of ruxolitinib cream in vitiligo; expectations regarding the launches of pemigatinib in Europe and Japan; expectations

regarding the initiation of clinical trials, including a proof of concept trial of tafasitamab in combination with parsaclisib, Phase 2 trials of pemigatinib in glioblastoma and non-small cell lung cancer, and Phase 3 clinical trial for parsaclisib in autoimmune hemolytic anemia; the expected sNDA submission date for baricitinib for alopecia areata; and the Company's revised 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 approval of tafasitamab in Europe and the timing of any such approval, the actual time required by the FDA to review the Company's NDA for approval for ruxolitinib cream in atopic dermatitis and the results of such review; further research and development and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials and the ability to enroll subjects in accordance with planned schedules; the effects of the COVID 19 pandemic and measures to address the pandemic on the Company's clinical trials, supply chain and other third-party providers, sales and marketing efforts, and business, development and discovery operations; determinations made by the FDA and regulatory agencies outside of the United States; the Company's dependence on its relationships with and changes in the plans of its collaboration partners; the efficacy or safety of the Company's products and the products of the Company's collaboration partners; the acceptance of the Company's products and the products of the Company's collaboration partners in the marketplace; market competition; unexpected variations in the demand for the Company's products and the products of the Company's collaboration partners; the effects of announced or unexpected price regulation or limitations on reimbursement or coverage for the Company's products and the products of the Company's collaboration partners; sales, marketing, manufacturing and distribution requirements, including the Company's and its collaboration partners' ability to successfully commercialize and build commercial infrastructure for newly approved products and any additional products that become approved; greater than expected expenses, including expenses relating to litigation or strategic activities; and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including its quarterly report on Form 10 Q for the quarter ended March 31, 2021. The Company disclaims any intent or obligation to update these forward-looking statements.

# # #

Contacts

Media		**Investors**	
Catalina Loveman	+1 302 498 6171 cloveman@incyte.com	Christine Chiou	+1 302 274 4773 cchiou@incyte.com

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	GAAP		GAAP	
Revenues:				
Product revenues, net	$ 575,150	$ 500,290	$ 1,079,961	$ 987,017
Product royalty revenues	120,559	92,753	220,466	174,533
Milestone and contract revenues	10,000	95,000	10,000	95,000
Total revenues	705,709	688,043	1,310,427	1,256,550
Costs and expenses:				
Cost of product revenues (including definite-lived intangible amortization)	38,028	33,364	67,248	60,683
Research and development	343,511	286,601	650,407	1,371,888
Selling, general and administrative	168,859	117,998	322,654	229,146
Change in fair value of acquisition-related contingent consideration	4,632	6,054	10,158	12,681
Collaboration loss sharing	9,843	13,253	20,327	15,383
Total costs and expenses	564,873	457,270	1,070,794	1,689,781
Income (loss) from operations	140,836	230,773	239,633	(433,231)
Other income (expense), net	4,390	4,817	2,983	13,479
Interest expense	(358)	(600)	(717)	(1,202)
Unrealized gain (loss) on long term investments	26,765	72,274	(944)	24,142
Income (loss) before provision for income taxes	171,633	307,264	240,955	(396,812)
Provision for income taxes	22,177	16,966	37,964	33,532
Net income (loss)	$ 149,456	$ 290,298	$ 202,991	$ (430,344)
Net income (loss) per share:				
Basic	$ 0.68	$ 1.33	$ 0.92	$ (1.98)
Diluted	$ 0.67	$ 1.32	$ 0.91	$ (1.98)
Shares used in computing net income (loss) per share:				
Basic	220,083	217,549	219,942	217,135
Diluted	222,250	220,434	222,061	217,135

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

	June 30, 2021	December 31, 2020
ASSETS		
Cash, cash equivalents and marketable securities	$ 2,080,967	$ 1,801,377
Accounts receivable	438,170	481,994
Property and equipment, net	661,360	559,625
Finance lease right-of-use assets, net	27,683	28,451
Inventory	52,260	35,973
Prepaid expenses and other assets	106,376	103,313
Long term investments	220,691	222,301
Other intangible assets, net	161,523	172,291
Goodwill	155,593	155,593
Total assets	$ 3,904,623	$ 3,560,918
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 675,516	$ 648,793
Finance lease liabilities	34,246	34,857
Acquisition-related contingent consideration	259,000	266,000
Stockholders' equity	2,935,861	2,611,268
Total liabilities and stockholders' equity	$ 3,904,623	$ 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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
GAAP Net Income (Loss)	$ 149,456	$ 290,298	$ 202,991	$ (430,344)
Adjustments[1]:				
Non-cash stock compensation from equity awards (R&D)[2]	28,038	32,493	57,912	61,206
Non-cash stock compensation from equity awards (SG&A)[2]	16,354	13,564	33,596	27,139
Non-cash stock compensation from equity awards (COGS)[2]	342	246	582	471
Non-cash interest expense related to convertible notes[3]	—	226	—	449
Changes in fair value of equity investments[4]	(26,765)	(72,274)	944	(24,142)
Amortization of acquired product rights[5]	5,384	5,384	10,768	10,768
Change in fair value of contingent consideration[6]	4,632	6,054	10,158	12,681
Legal contingency[7]	(18)	—	13,222	—
Tax effect of Non-GAAP adjustments[8]	1,410	(2,413)	(2,584)	(3,570)
Non-GAAP Net Income (Loss)	$ 178,833	$ 273,578	$ 327,589	$ (345,342)
Non-GAAP net income (loss) per share:				
Basic	$ 0.81	$ 1.26	$ 1.49	$ (1.59)
Diluted	$ 0.80	$ 1.24	$ 1.48	$ (1.59)
Shares used in computing Non-GAAP net income (loss) per share:				
Basic	220,083	217,549	219,942	217,135
Diluted	222,250	220,434	222,061	217,135

[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, 2021 and 2020 are milestones of $10,000 and $95,000, respectively, earned from our collaborative partners. Included within the Research and development expenses line item in the Condensed Consolidated Statements of Operations (in thousands) for the three and six months ended June 30, 2021 are upfront consideration and milestones of $5,000 and $16,500, respectively, related to our collaborative partners as compard to $3,500 and $809,032, respectively, for the same periods.
[2] As included within the Cost of product revenues (including definite-lived intangible amortization) line item; the Research and development expenses line item; and the Selling, general and administrative expenses line item in the Condensed Consolidated Statements of Operations.
[3] As included within the Interest expense line item in the Condensed Consolidated Statements of Operations.
[4] As included within the Unrealized gain (loss) on long term investments line item in the Condensed Consolidated Statements of Operations.
[5] As included within the Cost of product revenues (including definite-lived intangible amortization) line item in the Condensed Consolidated Statements of Operations. Acquired product rights of licensed intellectual property for Iclusig is amortized utilizing a straight-line method over the estimated useful life of 12.5 years.
[6] As included within the Change in fair value of acquisition-related contingent consideration line item in the Condensed Consolidated Statements of Operations.
[7] As included within 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.