UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2020

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission File Number: 001-12400

INCYTE CORPORATION
(Exact name of registrant as specified in its charter)

Delaware
(State of incorporation or organization)

1801 Augustine Cut-Off
Wilmington, DE
(Address of principal executive offices)

94-3136539
(I.R.S. Employer Identification No.)

19803
(zip code)

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

INCY
Trading Symbol(s)

The Nasdaq Stock Market LLC

Title of each class
Common Stock, $.001 par value per share

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

☑ Yes ☐ No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

☑ Yes ☐ No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

☑ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

☑ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (check one)

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐

Emerging growth company ☐

The aggregate market value of Common Stock held by non-affiliates (based on the closing sale price on The Nasdaq Global Select Market on June 30, 2020) was approximately $19.1 billion.

As of February 2, 2021 there were 219,843,497 shares of Common Stock, $.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Items 10 (as to directors and Delinquent Section 16(a) Reports), 11, 12, 13 and 14 of Part III incorporate by reference information from the registrant’s proxy statement to be filed with the Securities and Exchange Commission in connection with the solicitation of proxies for the registrant’s 2021 Annual Meeting of Stockholders to be held on May 26, 2021.
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Forward-Looking Statements

This report contains forward-looking statements that involve risks and uncertainties. These statements relate to future periods, future events or our future operating or financial plans or performance. Often, these statements include the words “believe,” “expect,” “target,” “anticipate,” “intend,” “plan,” “seek,” “estimate,” “potential,” or words of similar meaning, or future or conditional verbs such as “will,” “would,” “should,” “could,” “might,” or “may,” or the negative of these terms, and other similar expressions. These forward-looking statements include statements as to:

- the discovery, development, formulation, manufacturing and commercialization of our compounds, our drug candidates and JAKAFI®/JAKAVI® (ruxolitinib), PEMAZYRE® (pemigatinib), ICLUSIG® (ponatinib) and MONJUVI® (tafasitamab-cxix);
- our plans to further develop our operations outside of the United States;
- conducting clinical trials internally, with collaborators, or with clinical research organizations;
- our collaboration and strategic relationship strategy and anticipated benefits and disadvantages of entering into collaboration agreements;
- our licensing, investment and commercialization strategies, including our plans to commercialize JAKAFI, PEMAZYRE, ICLUSIG and MONJUVI;
- the regulatory approval process, including obtaining U.S. Food and Drug Administration and other international health authorities approval for our products in the United States and abroad;
- the safety, effectiveness and potential benefits and indications of our drug candidates and other compounds under development;
- the timing and size of our clinical trials; the compounds expected to enter clinical trials; timing of clinical trial results;
- our ability to manage expansion of our drug discovery and development operations;
- future required expertise relating to clinical trials, manufacturing, sales and marketing;
- obtaining and terminating licenses to products, drug candidates or technology, or other intellectual property rights;
- the receipt from or payments pursuant to collaboration or license agreements resulting from milestones or royalties;
- plans to develop and commercialize products on our own;
- plans to use third-party manufacturers;
- plans for our manufacturing operations;
- expected expenses and expenditure levels; expected uses of cash; expected revenues and sources of revenues, including milestone payments; expectations with respect to inventory;
- expectations with respect to reimbursement for our products;
- the expected impact of recent accounting pronouncements and changes in tax laws;
- expected losses; fluctuation of losses; currency translation impact associated with collaboration royalties;
- our profitability; the adequacy of our capital resources to continue operations;
- the need to raise additional capital;
- the costs associated with resolving matters in litigation;
- our expectations regarding competition;
• expectations relating to our new European headquarters and the anticipated completion date for our large molecule production facility;
• our investments, including anticipated expenditures, losses and expenses;
• our patent prosecution and maintenance efforts; and
• the potential effects of the COVID-19 pandemic and efforts undertaken or to be undertaken by us or applicable governmental authorities on local and global economic conditions, and on our business, results of operations and financial condition.

These forward-looking statements reflect our current views with respect to future events, are based on assumptions and are subject to risks and uncertainties. These risks and uncertainties could cause actual results to differ materially from those projected and include, but are not limited to:

• our ability to successfully commercialize JAKAFI, ICLUSIG, PEMAZYRE and MONJUVI;
• our ability to maintain at anticipated levels reimbursement for our products from government health administration authorities, private health insurers and other organizations;
• our ability to establish and maintain effective sales, marketing and distribution capabilities;
• the risk of reliance on other parties to manufacture our products, which could result in a short supply of our products, increased costs, and withdrawal of regulatory approval;
• our ability to maintain regulatory approvals to market our products;
• our ability to achieve a significant market share in order to achieve or maintain profitability;
• the risk of civil or criminal penalties if we market our products in a manner that violates health care fraud and abuse and other applicable laws, rules and regulations;
• our ability to discover, develop, formulate, manufacture and commercialize our drug candidates;
• the risk of unanticipated delays in, or discontinuations of, research and development efforts;
• the risk that previous preclinical testing or clinical trial results are not necessarily indicative of future clinical trial results;
• risks relating to the conduct of our clinical trials;
• changing regulatory requirements;
• the risk of adverse safety findings;
• the risk that results of our clinical trials do not support submission of a marketing approval application for our drug candidates;
• the risk of significant delays or costs in obtaining regulatory approvals;
• risks relating to our reliance on third-party manufacturers, collaborators, and clinical research organizations;
• risks relating to the development of new products and their use by us and our current and potential collaborators;
• risks relating to our inability to control the development of out-licensed compounds or drug candidates;
• risks relating to our collaborators’ ability to develop and commercialize JAKAVI, OLUMIANT, TABRECTA and the drug candidates licensed from us;
• costs associated with prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights;
• our ability to maintain or obtain adequate product liability and other insurance coverage;
the risk that our drug candidates may not obtain or maintain regulatory approval;
the impact of technological advances and competition, including potential generic competition;
our ability to compete against third parties with greater resources than ours;
risk of changes in pricing and reimbursement in the markets in which we may compete;
risk of governmental healthcare reform efforts, including efforts to control, set or cap pricing for our commercial drugs in the U.S. and abroad;
competition to develop and commercialize similar product candidates;
our ability to obtain and maintain patent protection and freedom to operate for our discoveries and to continue to be effective in expanding our patent coverage;
the impact of changing laws on our patent portfolio;
developments in and expenses relating to litigation;
our ability to in-license drug candidates or other technology;
unanticipated construction, other delays or changes in plans relating to our new European headquarters and large molecule production facility;
our ability to integrate successfully acquired businesses, development programs or technology;
our ability to obtain additional capital when needed;
fluctuations in net cash provided and used by operating, financing and investing activities;
our ability to analyze the effects of new accounting pronouncements and apply new accounting rules;
our history of operating losses;
risk related to public health pandemics such as the COVID-19 pandemic; and
the risks set forth under "Risk Factors."

Given these risks and uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by federal securities laws, we undertake no obligation to update any forward-looking statements for any reason, even if new information becomes available or other events occur in the future.

In this report all references to "Incyte," "we," "us," "our" or the "Company" mean Incyte Corporation and our subsidiaries, except where it is made clear that the term means only the parent company.

Incyte, JAKAFI and PEMAZYRE are our registered trademarks. We also refer to trademarks of other corporations and organizations in this Annual Report on Form 10-K.
Summary Risk Factors

Our business is subject to numerous risks and uncertainties that could affect our ability to successfully implement our business strategy and affect our financial results. You should carefully consider all of the information in this report and, in particular, the following principal risks and all of the other specific factors described in Item 1A. of this report, “Risk Factors,” before deciding whether to invest in our company.

- We depend heavily on JAKAFI/JAKAVI (ruxolitinib), and if we are not able to maintain revenues from JAKAFI/JAKAVI or those revenues decrease, our business may be materially harmed.
- If we or our collaborators are unable to obtain, or maintain at anticipated levels, reimbursement for JAKAFI/JAKAVI or our other products from government and other third-party payors, our results of operations and financial condition could be harmed.
- A limited number of specialty pharmacies and wholesalers represent a significant portion of revenues from JAKAFI, and the loss of, or significant reduction in sales to, any one of these specialty pharmacies or wholesalers could harm our operations and financial condition.
- If we are unable to establish and maintain effective sales, marketing and distribution capabilities, or to enter into agreements with third parties to do so, we will not be able to successfully commercialize our products.
- If we fail to comply with applicable laws and regulations, we could lose our approval to market our products or be subject to other governmental enforcement activity.
- If the use of our products harms or is perceived to harm patients, our regulatory approvals could be revoked or otherwise negatively impacted or we could be subject to costly product liability claims.
- If we market our products in a manner that violates various laws and regulations, we may be subject to civil or criminal penalties.
- Competition for our products, in particular JAKAFI/JAKAVI, could harm our business and result in a decrease in our revenue.
- The COVID-19 pandemic and measures to address the pandemic have adversely affected and can in the future adversely affect our business and results of operations.
- We or our collaborators may be unsuccessful in discovering and developing drug candidates, and we may spend significant time and money attempting to do so, in particular with our later stage drug candidates.
- If we or our collaborators are unable to obtain regulatory approval in and outside of the United States for drug candidates, we and our collaborators will be unable to commercialize those drug candidates.
- Health care reform measures could impact the pricing and profitability of pharmaceuticals, and adversely affect the commercial viability of our or our collaborators’ products and drug candidates.
- Conflicts between us and our collaborators or termination of our collaboration agreements could limit future development and commercialization of our drug candidates and harm our business.
- If we are unable to establish collaborations to fully exploit our drug discovery and development capabilities or if future collaborations are unsuccessful, our future revenue prospects could be diminished.
- If we fail to enter into additional in-licensing agreements or if these arrangements are unsuccessful, we may be unable to increase our number of successfully marketed products and our revenues.
- Even if one of our drug candidates receives regulatory approval, we may determine that commercialization would not be worth the investment.
- Any approved drug product that we bring to the market may not gain market acceptance by physicians, patients, healthcare payors and others in the medical community.
● We have limited capacity to conduct preclinical testing and clinical trials, and our resulting dependence on other parties could result in delays in and additional costs for our drug development efforts.

● We face significant competition for our drug discovery and development efforts, and if we do not compete effectively, our commercial opportunities will be reduced or eliminated.

● Our reliance on others to manufacture our drug products and drug candidates could result in drug supply constraints, delays in clinical trials, increased costs, and withdrawal or denial of regulatory approvals.

● If we fail to comply with the extensive legal and regulatory requirements affecting the health care industry, we could face increased costs, penalties and a loss of business.

● The illegal distribution and sale by third parties of counterfeit or unfit versions of our or our collaborators’ products or stolen products could harm our business and reputation.

● As most of our drug discovery and development operations are conducted at our headquarters in Wilmington, Delaware, the loss of access to this facility would negatively impact our business.

● If we lose any of our key employees or are unable to attract and retain additional personnel, our business and ability to achieve our objectives could be harmed.

● If we fail to manage our growth effectively, our ability to develop and commercialize products could suffer.

● We may acquire businesses or assets, form joint ventures or make investments in other companies that may be unsuccessful, divert our management’s attention and harm our operating results and prospects.

● Risks associated with our operations outside of the United States could adversely affect our business.

● If product liability lawsuits are brought against us, we could face substantial liabilities and may be required to limit commercialization of our products, and our results of operations could be harmed.

● Because our activities involve the use of hazardous materials, we may be subject to claims relating to improper handling, storage or disposal of these materials that could be time consuming and costly.

● We expect to continue to incur significant expenses to discover and develop drugs, which could result in future losses and impair our achievement of and ability to sustain profitability in the future.

● If we are unable to raise additional capital in the future when we require it, our efforts to broaden our product portfolio or commercialization efforts could be limited.

● Our marketable securities and long term investments are subject to risks that could adversely affect our overall financial position.

● If we are unable to achieve milestones, develop product candidates to license or renew or enter into new collaborations, our royalty and milestone revenues and future prospects for those revenues may decrease.

● Any arbitration or litigation involving us and regarding intellectual property infringement claims could be costly and disrupt our drug discovery and development efforts.

● Our inability to adequately protect or enforce our proprietary information may result in loss of revenues or otherwise reduce our ability to compete.

● If the effective term of our patents is decreased or if we need to refile some of our patent applications, the value of our patent portfolio and the revenues we derive from it may be decreased.

● International patent protection is particularly uncertain and costly, and our involvement in opposition proceedings may result in the expenditure of substantial sums and management resources.

● Significant disruptions of information technology systems, breaches of data security, or unauthorized disclosures of sensitive data could harm our business and subject us to liability or reputational damage.

● Increasing use of social media could give rise to liability, breaches of data security, or reputational damage, which could harm our business and results of operations.
**Item 1. Business**

**Overview**

Incyte is a biopharmaceutical company focused on the discovery, development and commercialization of proprietary therapeutics. Our global headquarters is located in Wilmington, Delaware, where we conduct global commercial and clinical development operations. We also conduct commercial and clinical development operations from our European headquarters in Morges, Switzerland and clinical development operations from our Japanese office in Tokyo.

As described in more detail below, our business is composed of three franchises that are defined by the indications of our approved medicines and the diseases for which our clinical candidates are being developed.

**Hematology and Oncology**

Our hematology and oncology franchise is comprised of four approved products, which are JAKAFI (ruxolitinib), MONJUVI (tafasitamab-cxix), PEMAZYRE (pemigatinib) and ICLUSIG (ponatinib), as well as numerous clinical development programs.

**JAKAFI (ruxolitinib)**

JAKAFI (ruxolitinib) is our first product to be approved for sale in the United States. It was approved by the U.S. Food and Drug Administration (FDA) in November 2011 for the treatment of adults with intermediate or high-risk myelofibrosis (MF), in December 2014 for the treatment of adults with polycythemia vera (PV) who have had an inadequate response to or are intolerant of hydroxyurea and in May 2019 for the treatment of steroid-refractory acute graft-versus-host disease (GVHD) in adult and pediatric patients 12 years and older. Myelofibrosis and polycythemia vera are both myeloproliferative neoplasms (MPNs), a type of rare blood cancer, and GVHD is an adverse immune response to an allogeneic hematopoietic stem cell transplant (HSCT). Under our collaboration agreement with our collaboration partner Novartis Pharmaceutical International Ltd., Novartis received exclusive development and commercialization rights to ruxolitinib outside of the United States for all hematologic and oncologic indications and sells ruxolitinib outside of the United States under the name JAKAVI.

In 2003, we initiated a research and development program to explore the inhibition of enzymes called janus associated kinases (JAK). The JAK family is composed of four tyrosine kinases—JAK1, JAK2, JAK3 and Tyk2—that are involved in the signaling of a number of cytokines and growth factors. JAKs are central to a number of biologic processes, including the formation and development of blood cells and the regulation of immune functions. Dysregulation of the JAK-STAT signaling pathway has been associated with a number of diseases, including myeloproliferative neoplasms, other hematological malignancies, rheumatoid arthritis and other chronic inflammatory diseases.

We have discovered multiple potent, selective and orally bioavailable JAK inhibitors that are selective for JAK1 or JAK1 and JAK2. JAKAFI is the most advanced compound in our JAK program. It is an oral JAK1 and JAK2 inhibitor.

JAKAFI is marketed in the United States through our own specialty sales force and commercial team. JAKAFI was the first FDA-approved JAK inhibitor for any indication and was the first FDA-approved product in all three of its current indications. JAKAFI remains the first-line standard of care in MF and remains the only FDA-approved product for PV and steroid-refractory acute GVHD. The FDA has granted JAKAFI orphan drug status for MF, PV, ET, acute lymphoblastic leukemia (ALL) and GVHD.

To help ensure that all eligible patients have access to JAKAFI, we have established a patient assistance program called IncyteCARES (CARES stands for Connecting to Access, Reimbursement, Education and Support). IncyteCARES helps ensure that any patient with intermediate or high-risk MF, uncontrolled PV or steroid-refractory acute GVHD who meets certain eligibility criteria and is prescribed JAKAFI has access to the product regardless of ability to pay and has access to ongoing support and educational resources during treatment.
JAKAFI is distributed primarily through a network of specialty pharmacy providers and wholesalers that allow for efficient delivery of the medication by mail directly to patients or direct delivery to the patient’s pharmacy. Our distribution process uses a model that is well-established and familiar to physicians who practice within the oncology field.

To further support appropriate use and future development of JAKAFI, our U.S. Medical Affairs department is responsible for providing appropriate scientific and medical education and information to physicians, preparing scientific presentations and publications, and overseeing the process for supporting investigator sponsored trials.

**Myelofibrosis.** Myelofibrosis is a rare, life-threatening condition. MF, considered the most serious of the myeloproliferative neoplasms, can occur either as primary MF, or as secondary MF that develops in some patients who previously had polycythemia vera or essential thrombocytthemia. We estimate there are between 16,000 and 18,500 patients with MF in the United States. Based on the modern prognostic scoring systems referred to as International Prognostic Scoring System and Dynamic International Prognostic Scoring System, we believe intermediate and high-risk patients represent 80% to 90% of all patients with MF in the United States and encompass patients over the age of 65, or patients who have or have ever had any of the following: anemia, constitutional symptoms, elevated white blood cell or blast counts, or platelet counts less than 100,000 per microliter of blood.

Most MF patients have enlarged spleens and many suffer from debilitating symptoms, including abdominal discomfort, pruritus (itching), night sweats and cachexia (involuntary weight loss). There were no FDA approved therapies for MF until the approval of JAKAFI.

The FDA approval was based on results from two randomized Phase III trials (COMFORT-I and COMFORT-II), which demonstrated that patients treated with JAKAFI experienced significant reductions in splenomegaly (enlarged spleen). COMFORT-I also demonstrated improvements in symptoms. The most common hematologic adverse reactions in both trials were thrombocytopenia and anemia. These events rarely led to discontinuation of JAKAFI treatment. The most common non-hematologic adverse reactions were bruising, dizziness and headache.

In August 2014, the FDA approved supplemental labeling for JAKAFI to include Kaplan-Meier overall survival curves as well as additional safety and dosing information. The overall survival information is based on three-year data from COMFORT-I and II, and shows that at three years the probability of survival for patients treated with JAKAFI in COMFORT-I was 70% and for those patients originally randomized to placebo it was 61%. In COMFORT-II, at three years the probability of survival for patients treated with JAKAFI was 79% and for patients originally randomized to best available therapy it was 59%. In December 2016, we announced an exploratory pooled analysis of data from the five-year follow-up of the COMFORT-I and COMFORT-II trials of patients treated with JAKAFI, which further supported previously published overall survival findings.

In September 2016, we announced that JAKAFI had been included as a recommended treatment in the latest National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology for myelofibrosis, underscoring the important and long-term clinical benefits seen in patients treated with JAKAFI.

In October 2017, the FDA approved updated labeling for JAKAFI to include the addition of new patient-reported outcome (PRO) data from the COMFORT-I study, as well as updating the warning related to progressive multifocal leukoencephalopathy. An exploratory analysis of PRO data of patients with myelofibrosis receiving JAKAFI showed improvement in fatigue-related symptoms at Week 24. Fatigue response (defined as a reduction of 4.5 points or more from baseline in the PROMIS® Fatigue total score) was reported in 35% of patients treated with JAKAFI versus 14% of the patients treated with placebo.

**Polycythemia Vera.** PV is a myeloproliferative neoplasm typically characterized by elevated hematocrit, the volume percentage of red blood cells in whole blood, which can lead to a thickening of the blood and an increased risk of blood clots, as well as an elevated white blood cell and platelet count. When phlebotomy can no longer control PV, chemotherapy such as hydroxyurea, or interferon, is utilized. Approximately 25,000 patients with PV in the United States are considered uncontrolled because they have an inadequate response to or are intolerant of hydroxyurea, the most commonly used chemotherapeutic agent for the treatment of PV.