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, 2019

☐ 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 other jurisdiction of incorporation or organization)

1801 Augustine Cut-Off
(Wilmington, DE)

94-3136539
(IRS Employer Identification No.)

19803
(zip code)

(Registrant’s telephone number, including area code)

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

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

Trading Symbol(s)
INCY

Name of exchange on which registered
The Nasdaq Stock Market LLC

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

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 ☐

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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

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, 2019) was approximately $15.4 billion.

As of February 6, 2020 there were 216,775,534 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 2020 Annual Meeting of Stockholders to be held on May 26, 2020.
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Item 1. Business

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) and ICLUSIG® (ponatinib);
- 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 and ICLUSIG;
- 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, including construction activities, and the anticipated completion date for our large molecule production facility;

● our investments, including anticipated expenditures, losses and expenses; and

● our patent prosecution and maintenance efforts.

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 and ICLUSIG;

● 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, OLMIANT 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;

● risks relating to changes in pricing and reimbursement in the markets in which we may compete;

● risks relating to 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 drug products;

● 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; 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 and JAKAFI are our registered trademarks. We also refer to trademarks of other corporations and organizations in this Annual Report on Form 10-K.

Overview

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

Marketed Indications - 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, in December 2014 for the treatment of adults with polycythemia vera 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 Novartis International Pharmaceutical 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 hematologic 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 thrombocythemia. 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.

In December 2014, the FDA approved JAKAFI for the treatment of patients with PV who have had an inadequate response to or are intolerant of hydroxyurea. The approval of JAKAFI for PV was based on data from the pivotal Phase III
RESPONSE trial. In this trial, patients treated with JAKAFI demonstrated superior hematocrit control and reductions in spleen volume compared to best available therapy. In addition, a greater proportion of patients treated with JAKAFI achieved complete hematologic remission—which was defined as achieving hematocrit control, and lowering platelet and white blood cell counts. In the RESPONSE trial, the most common hematologic adverse reactions (incidence > 20%) were thrombocytopenia and anemia. The most common non-hematologic adverse events (incidence >10%) were headache, abdominal pain, diarrhea, dizziness, fatigue, pruritus, dyspnea and muscle spasms.

In March 2016, the FDA approved supplemental labeling for JAKAFI to include additional safety data as well as efficacy analyses from the RESPONSE trial to assess the durability of response in JAKAFI treated patients after 80 weeks. At this time, 83% patients were still on treatment, and 76% of the responders at 32 weeks maintained their response through 80 weeks.

In June 2016, we announced data from the Phase III RESPONSE-2 study of JAKAFI in patients with inadequately controlled PV that was resistant to or intolerant of hydroxyurea who did not have an enlarged spleen. These data showed that JAKAFI was superior to best available therapy in maintaining hematocrit control (62.2% vs. 18.7%, respectively; P<0.0001) without the need for phlebotomy.

In August 2017, we announced that JAKAFI had been included as a recommended treatment in the latest NCCN Guidelines for patients with polycythemia vera who have had an inadequate response to first-line therapies, such as hydroxyurea.

Graft-versus-host disease. GVHD is a condition that can occur after an allogeneic HSCT (the transfer of genetically dissimilar stem cells or tissue). In GVHD, the donated bone marrow or peripheral blood stem cells view the recipient’s body as foreign and attack various tissues. 12-month survival rates in patients with Grade III or IV steroid-refractory acute GVHD are 50% or less, and the incidence of steroid-refractory acute and chronic GVHD is approximately 3,000 per year in the United States.

In June 2016, we announced that the FDA granted Breakthrough Therapy designation for ruxolitinib in patients with acute GVHD. In May 2019, the FDA approved JAKAFI for the treatment of steroid-refractory acute GVHD in adult and pediatric patients 12 years and older. The approval was based on data from REACH1, an open-label, single-arm, multicenter study of JAKAFI in combination with corticosteroids in patients with steroid-refractory grade II-IV acute GVHD. The overall response rate (ORR) in patients refractory to steroids alone was 57% with a complete response (CR) rate of 31%. The most frequently reported adverse reactions among all study participants were infections (55%) and edema (51%), and the most common laboratory abnormalities were anemia (75%), thrombocytopenia (75%) and neutropenia (58%).

We have retained all development and commercialization rights to JAKAFI in the United States and are eligible to receive development and commercial milestones as well as royalties from product sales outside the United States. We hold patents that cover the composition of matter and use of ruxolitinib which patients, including applicable extensions, expire in late 2027.

Marketed Indications - ICLUSIG (ponatinib)

In June 2016, we acquired the European operations of ARIAD Pharmaceuticals, Inc. (ARIAD) and obtained an exclusive license to develop and commercialize ICLUSIG (ponatinib) in Europe and other select countries. ICLUSIG is a kinase inhibitor. The primary target for ICLUSIG is BCR-ABL, an abnormal tyrosine kinase that is expressed in chronic myeloid leukemia (CML) and Philadelphia-chromosome positive acute lymphoblastic leukemia (Ph+ ALL).

In the European Union, ICLUSIG is approved for the treatment of adult patients with chronic phase, accelerated phase or blast phase 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 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.
Clinical Programs in Oncology

We believe that the future of cancer treatment lies in the use of targeted therapies, which aim to block the effects of cancer-causing mutations, and immune therapies, which seek to recruit the patient’s own immune system to tackle cancer. Our most advanced programs are detailed below.

**JAK Inhibition**

As part of our ongoing LIMBER (Leadership in MPNs BEyond Ruxolitinib) clinical development initiative, which is designed to improve and expand therapeutic options for patients with myeloproliferative neoplasms, we are evaluating combinations of ruxolitinib with other therapeutic modalities, as well as developing a once-a-day formulation of ruxolitinib for potential use as monotherapy and combination therapy. Based on positive Phase II data, we are preparing a pivotal trial program of ruxolitinib in combination with parsaclisib (PI3Kδ). Additional Phase II trials combining ruxolitinib with investigational agents from our portfolio such as INCB53914 (PIM), INCB57643 (BET) and INCB00928 (ALK2) in patients with MF are either ongoing or in preparation.

Following positive proof-of-concept data, we initiated the pivotal RESET trial investigating ruxolitinib for the treatment of patients with essential thrombocythemia (ET). In February 2020, it was decided to end recruitment into the RESET trial.

The REACH clinical program evaluates ruxolitinib in patients with steroid-refractory GVHD and includes REACH2, a Novartis-sponsored Phase III trial in steroid-refractory acute GVHD, and REACH3, a Phase III trial in steroid-refractory chronic GVHD that is co-sponsored by Incyte and Novartis.

In October 2019, we and Novartis announced that REACH2 met its primary endpoint of superior ORR at Day 28 with ruxolitinib treatment compared to best available therapy. No new safety signals were observed, and the ruxolitinib safety profile in REACH2 was consistent with that seen in previously reported studies in steroid-refractory acute GVHD. The result of REACH3 is expected to be available in 2020.

A second JAK inhibitor in development is itacitinib, which is a selective JAK1 inhibitor. In January 2020, we announced that in the pivotal Phase III GRAVITAS-301 trial in patients with steroid-naïve acute GVHD, itacitinib plus corticosteroids did not meet the primary endpoint of improving ORR at Day 28 compared to placebo plus corticosteroids. Itacitinib is also being evaluated in GRAVITAS-309, a pivotal Phase III trial of itacitinib in patients with steroid-naïve chronic GVHD. The FDA has granted itacitinib orphan drug status for GVHD.

**FGFR1/2/3 Inhibition**

Pemigatinib is a potent and selective inhibitor of the fibroblast growth factor receptor (FGFR) isoforms 1, 2 and 3 with demonstrated activity in preclinical studies. The FGFR family of receptor tyrosine kinases can act as oncogenic drivers in a number of liquid and solid tumor types.

We initiated the FIGHT clinical program to evaluate pemigatinib across a spectrum of cancers that are driven by FGF/FGFR alterations. The program initially included three Phase II trials – FIGHT-201 in patients with bladder cancer, FIGHT-202 in patients with cholangiocarcinoma, and FIGHT-203 in patients with 8p11 myeloproliferative syndrome (8p11 MPN). Based on data generated from these ongoing trials, we have initiated additional trials, including FIGHT-205, which is evaluating pemigatinib plus pembrolizumab versus pemigatinib alone versus standard of care for metastatic or unresectable urothelial carcinoma in cisplatin-ineligible patients whose tumors express FGFR3 mutation or rearrangement, and FIGHT-207 which is a solid tumor-agnostic trial evaluating pemigatinib in patients with driver alterations of FGF/FGFR.

In September 2019, we announced positive updated data from the FIGHT-202 trial evaluating pemigatinib in patients with advanced/metastatic or surgically unresectable cholangiocarcinoma who failed at least one previous treatment. FIGHT-302, a Phase III trial of pemigatinib for the first-line treatment of patients with cholangiocarcinoma and FGFR2 fusions or rearrangements was initiated in June 2019.