

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

(mark one)

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

For the fiscal year ended December 31, 2017

or

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**  
(Address of principal executives offices)

**94-3136539**  
(IRS Employer  
Identification No.)

**19803**  
(zip code)

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

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

Title of each class	Name of exchange on which registered
Common Stock, \$.001 par value per share	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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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   
(Do not check if a 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, 2017) was approximately \$21.4 billion.

As of February 8, 2018 there were 211,663,861 shares of Common Stock, \$.001 par value per share, outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Items 10 (as to directors and Section 16(a) Beneficial Ownership Reporting Compliance), 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 2018 Annual Meeting of Stockholders to be held on May 1, 2018 .

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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);*
- *the expected benefits from our acquisition of ARIAD Pharmaceuticals (Luxembourg) S.à.r.l. and our plans to further develop our European operations;*
- *conducting clinical trials internally, with collaborators, or with clinical research organizations;*
- *our collaboration and strategic relationship strategy; 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;*
- *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 U.S. 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;*
- *our investments, including anticipated expenditures, losses and expenses;*
- *our patent prosecution and maintenance efforts; and*
- *our indebtedness, and debt service obligations.*

*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 drug candidates;*
- *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;*
- *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;*
- *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 operations from our offices in Geneva, Switzerland, and Lausanne, Switzerland, and have recently opened our Japanese 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 patients with intermediate or high-risk myelofibrosis and in December 2014 for the treatment of patients with polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea. Myelofibrosis and polycythemia vera are both rare blood cancers. 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 hematological malignancies, rheumatoid arthritis and other chronic inflammatory diseases. Myeloproliferative neoplasms are a closely related group of blood diseases in which blood cells, specifically platelets, white blood cells, and red blood cells, grow or act abnormally. These diseases include myelofibrosis (MF), polycythemia vera (PV) and essential thrombocythemia (ET).

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 and remains the only product approved by the FDA for use in MF and PV. The FDA has granted JAKAFI orphan drug status for MF, PV, ET, acute lymphoblastic leukemia (ALL) and graft-versus-host-disease (GVHD).

To help ensure that all eligible MF and PV 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 or uncontrolled PV 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. In addition, IncyteCARES works closely with payers to help facilitate insurance coverage of JAKAFI.

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 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.

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.

*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 3 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.

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 patents, 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 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.

### **Clinical Programs in Oncology**

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

#### ***JAK Inhibition***

Building upon positive, independently published third-party data of ruxolitinib in GVHD, we have initiated the REACH clinical program to evaluate ruxolitinib in patients with steroid-refractory GVHD. REACH1, a pivotal Phase II trial in steroid-refractory acute GVHD was initiated in December 2016 and is now fully-recruited. REACH2, the Novartis-sponsored Phase III trial in steroid-refractory acute GVHD, and REACH3, the Phase III trial in steroid-refractory chronic GVHD that is co-sponsored by Incyte and Novartis, are both now underway. In June 2016, we announced that the FDA granted Breakthrough Therapy Designation for ruxolitinib in patients with acute GVHD. In April 2016, we announced an agreement with Eli Lilly and Company enabling us to develop and commercialize ruxolitinib in the United States for the treatment of GVHD. We also announced an agreement with Novartis granting Novartis exclusive research, development and commercialization rights for ruxolitinib in GVHD outside the United States.

A proof-of-concept trial of itacitinib, a selective JAK1 inhibitor, is ongoing for the treatment of patients with acute GVHD. Based on preliminary data from this trial, a pivotal program investigating itacitinib for the treatment of patients with treatment-naïve acute GVHD was initiated in July 2017. The FDA has granted itacitinib orphan drug status for GVHD.

GVHD is a condition that can occur after an allogeneic transplant (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 the body. We estimate that the long-term survival in patients with corticosteroid-refractory GVHD is approximately 5% to 30% and that the diagnosed incidence of acute and chronic GVHD is approximately 17,000 per year across the United States and Europe.

Following positive proof-of-concept data, we initiated a pivotal program investigating ruxolitinib for the treatment of patients with essential thrombocythemia. ET is a Philadelphia chromosome negative myeloproliferative neoplasm, characterized by the overproduction of platelets in the bone marrow. The pivotal RESET trial is enrolling ET

patients that are refractory to or intolerant of hydroxyurea, the current standard of care for first-line treatment of these patients.

The clinical program to evaluate itacitinib in solid tumors includes a clinical trial in combination with AstraZeneca/MedImmune's EGFR inhibitor osimertinib.

### ***IDO1 Inhibition***

Epacadostat is a novel, potent and selective inhibitor of the enzyme indoleamine 2, 3-dioxygenase-1 (IDO1), which is a key regulator of the mechanisms that are responsible for allowing tumors to escape from a patient's immune surveillance. IDO1 expression by tumor cells, or by antigen presenting cells such as macrophages and dendritic cells in tumors, creates an environment in which tumor specific cytotoxic T lymphocytes are rendered functionally inactive or are no longer able to attack a patient's cancer cells. By inhibiting IDO1, it is proposed that this "brake" on the anti-tumor immune response is removed, allowing anti-tumor specific cytotoxic T cells, generated in a patient spontaneously in response to the tumor, or through a therapy designed to stimulate the immune response, to have greater anti-tumor efficacy.

The ECHO clinical development program will investigate the development of epacadostat in combination with other therapeutic agents, including checkpoint inhibitors, vaccines, epigenetic therapies, and chemotherapies. During 2014, we signed clinical trial collaboration agreements with Merck, Bristol-Myers Squibb, AstraZeneca/MedImmune and Roche/Genentech to evaluate epacadostat with their respective anti-PD-1 and anti-PD-L1 agents, pembrolizumab, nivolumab, durvalumab and atezolizumab, respectively, in Phase I/II trials. We have global development and commercialization rights to epacadostat for all indications.

In October 2015, we and Merck announced an expansion of the companies' ongoing clinical trial collaboration to include ECHO-301, a Phase III study evaluating the combination of epacadostat with pembrolizumab as a first-line treatment for patients with advanced or metastatic melanoma. In July 2017, the FDA granted Fast Track designation to the ECHO-301 trial to demonstrate a statistically robust and clinically meaningful improvement in progression free survival and/or overall survival compared to patients treated with pembrolizumab alone.

In March 2017, we and Merck announced details of the companies' planned expansion of the ongoing clinical trial collaboration to include Phase III trials in four additional tumor types, evaluating epacadostat plus pembrolizumab in patients with non-small cell lung (NSCLC), renal, bladder, and head & neck cancers. These trials have all been initiated.

In April 2017, we and Bristol-Myers Squibb announced an expansion of our clinical trial collaboration to include two Phase III programs of epacadostat in combination with nivolumab in NSCLC and head & neck cancer. Both of these trials are now open for recruitment.

In October 2017, we and AstraZeneca announced an expansion of our clinical trial collaboration to include a Phase III trial of epacadostat in combination with AstraZeneca's PD-L1 inhibitor durvalumab in patients with Stage III NSCLC.

### ***PD-1 Antagonism***

In October 2017, we and MacroGenics announced an exclusive global collaboration and license agreement for MacroGenics' MGA012, an investigational monoclonal antibody that inhibits PD-1. Under this collaboration, we obtained exclusive worldwide rights for the development and commercialization of MGA012 in all indications. Enrollment in the dose escalation portion of the Phase 1 study of MGA012 has been completed and the molecule is currently being evaluated as monotherapy across four solid tumor types in the dose expansion portion of the study.

### ***PI3K-delta Inhibition***

The PI3K-delta pathway mediates oncogenic signaling in B cell malignancies. INCB50465 is a PI3K-delta inhibitor that has demonstrated potency and selectivity in preclinical studies and has potential therapeutic utility in the treatment of patients with lymphoma. We have initiated the CITADEL clinical program to evaluate INCB50465 in non-Hodgkin lymphomas, including patients with diffuse large b-cell lymphoma (DLBCL), follicular lymphoma, marginal zone lymphoma and mantle cell lymphoma.

**FGFR 1/2/3 Inhibition**

INCB54828 is an inhibitor of the FGFR isoforms 1, 2 and 3 that has demonstrated potency and selectivity 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 INCB54828 across a spectrum of cancers that are driven by FGF/FGFR mutations. The program now has three Phase II trials enrolling – FIGHT-201 in patients with bladder cancer, FIGHT-202 in patients with cholangiocarcinoma, and FIGHT-203 in patients with 8p11 myeloproliferative syndrome (8p11 MPN).

	<b>Indication</b>	<b>Status Update</b>
<b>Ruxolitinib (JAK1/JAK2)</b>	Steroid-refractory acute GVHD	Pivotal Phase II (REACH1); Phase III (REACH2)
<b>Ruxolitinib (JAK1/JAK2)</b>	Steroid-refractory chronic GVHD	Phase III (REACH3)
<b>Ruxolitinib (JAK1/JAK2)</b>	Essential thrombocythemia	Phase II (RESET)
<b>Itacitinib (JAK1)</b>	Treatment-naïve acute GVHD	Phase III (GRAVITAS-301)
<b>Itacitinib (JAK1)</b>	NSCLC	Phase I/II in combination with osimertinib (EGFR)
<b>Epacadostat (IDO1)</b>	Melanoma	Phase III (ECHO-301) in combination with pembrolizumab (PD-1)
<b>Epacadostat (IDO1)</b>	Renal cancer	Phase III (ECHO-302) in combination with pembrolizumab (PD-1)
<b>Epacadostat (IDO1)</b>	Bladder cancer	Phase III (ECHO-303 and ECHO-307) in combination with pembrolizumab (PD-1)
<b>Epacadostat (IDO1)</b>	Head & neck cancer	Phase III (ECHO-304) in combination with pembrolizumab (PD-1)
<b>Epacadostat (IDO1)</b>	NSCLC	Phase III (ECHO-305 and ECHO-306) in combination with pembrolizumab (PD-1)
<b>Epacadostat (IDO1)</b>	NSCLC	Phase III (ECHO-309) in combination with nivolumab (PD-1)
<b>Epacadostat (IDO1)</b>	Head & neck cancer	Phase III (ECHO-310) in combination with nivolumab (PD-1)
<b>Epacadostat (IDO1)</b>	NSCLC	Phase III in combination with durvalumab (PD-L1) expected to begin in H1 2018
<b>MGA012 (PD-1)</b> <sup>1</sup>	Solid tumors	Phase I dose-escalation completed, monotherapy expansion cohorts ongoing
<b>INCB50465 (PI3Kδ)</b>	DLBCL	Phase II (CITADEL-202)
<b>INCB50465 (PI3Kδ)</b>	Follicular lymphoma	Phase II (CITADEL-203)
<b>INCB50465 (PI3Kδ)</b>	Marginal zone lymphoma	Phase II (CITADEL-204)
<b>INCB50465 (PI3Kδ)</b>	Mantel cell lymphoma	Phase II (CITADEL-205)
<b>INCB54828 (FGFR1/2/3)</b>	Bladder cancer	Phase II (FIGHT-201)
<b>INCB54828 (FGFR1/2/3)</b>	Cholangiocarcinoma	Phase II (FIGHT-202)
<b>INCB54828 (FGFR1/2/3)</b>	8p11 MPN	Phase II (FIGHT-203)

<sup>1</sup> MGA012 licensed from MacroGenics.

We also have a number of other earlier-stage clinical programs. We intend to describe these programs more fully once we have obtained clinical proof-of-concept and established that the program warrants further development in a specific indication or group of indications.

INCB57643 is a BRD inhibitor. BRDs are a family of proteins which play important roles in mediating gene transcription, most notably by facilitating the expression of oncogenes such as MYC, one of the most frequently dysregulated oncogenes in all human cancer.

INCB53914 is a pan-PIM kinase inhibitor that has demonstrated potency and selectivity in preclinical studies. PIM kinases integrate signals from multiple pathways important for the survival and proliferation of malignant cells. Over expression of PIM kinases has been reported in human hematological cancers with each isoform showing a distinct expression pattern among the various malignancy subtypes.

INCB52793 is a selective JAK1 inhibitor that has exhibited 150 times greater selectivity for JAK1 over JAK2 in preclinical studies. Dysregulation of the JAK-STAT pathway has been implicated in the pathogenesis of leukemia.

INCB59872 is an LSD1 inhibitor. LSD1 is a key enzyme that is involved in epigenetic regulation of gene transcription. Dysregulated LSD1 activity can perturb normal gene expression, leading to cellular transformation. In particular, the function of LSD1 has been reported to maintain stem cell-like gene expression patterns in various cancers, including acute myeloid leukemia and small cell lung cancer.

INCB62079 is a selective, irreversible inhibitor of FGFR4 that has exhibited 250 times greater selectivity for FGFR4 than other FGFR isoforms in preclinical studies. Preclinical data has also demonstrated the compound's selective activity against cancer cell lines with FGF19-FGFR4 pathway activation, and dose-dependent activity in murine models of FGF19-driven hepatocellular carcinoma.

INCB01158 is a first-in-class, small molecule arginase inhibitor in hematology and oncology licensed from Calithera Biosciences, Inc. In preclinical models, arginase inhibition has been shown to enhance anti-tumor immunity both as a single agent and in combination with other immuno-modulatory therapeutics.

INCAGN1876 is an anti-GITR agonist antibody and INCAGN1949 is an anti-OX40 agonist antibody. Both are programs within our antibody discovery alliance with Agenus Inc. GITR and OX40 are costimulatory receptors that are expressed on effector T cells and are important for T cell survival and enhanced cytokine production. Both are also expressed on regulatory T cells and can abrogate their suppressive function. Preclinical data demonstrate that anti-GITR and anti-OX40 agonist antibodies inhibit tumor growth by enhancing the levels and function of effector T cells and by decreasing regulatory T cells.

### Clinical Programs outside Oncology

In January 2017, we initiated a Phase II trial of ruxolitinib cream for the topical treatment of atopic dermatitis. Atopic dermatitis is a skin disorder that causes the skin to become red, scaly, and itchy. Onset can occur at any age, but is much more common in infants and children. United States and European prevalence are estimated at 10.3 million patients and 6.5 million patients, respectively.

A Phase II trial of topical ruxolitinib in patients with vitiligo, a long term skin condition characterized by patches of the skin losing their pigment, was initiated in June 2017.

	<b>Indication</b>	<b>Status Update</b>
<b>Topical ruxolitinib (JAK1/JAK2)</b>	Atopic dermatitis	Phase II (topical formulation <sup>1</sup> )
<b>Topical ruxolitinib (JAK1/JAK2)</b>	Vitiligo	Phase II (topical formulation <sup>1</sup> )

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

## Partnered Programs

### *Baricitinib*

We have a second JAK1 and JAK2 inhibitor, baricitinib, which is subject to our collaboration agreement with Eli Lilly and Company, in which Lilly received exclusive worldwide development and commercialization rights to the compound for inflammatory and autoimmune diseases. The Phase III program of baricitinib in patients with rheumatoid arthritis incorporated all three rheumatoid arthritis populations (methotrexate naïve, biologic naïve, and tumor necrosis factor (TNF) inhibitor inadequate responders); used event rates to fully power the baricitinib program for structural comparison and non-inferiority vs. adalimumab; and evaluated patient-reported outcomes. All four Phase III trials met their respective primary endpoints.

In January 2016, Lilly submitted a New Drug Application (NDA) to the FDA and a Marketing Authorization Application (MAA) to the European Medicines Agency for baricitinib as treatment for rheumatoid arthritis. In February 2017, we and Lilly announced that the European Commission approved baricitinib as OLUMIANT for the treatment of moderate-to-severe rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to, one or more disease-modifying antirheumatic drugs (DMARDs). In July 2017, Japan's Ministry of Health, Labor and Welfare (MHLW) granted marketing approval for OLUMIANT for the treatment of rheumatoid arthritis (including the prevention of structural injury of joints) in patients with inadequate response to standard-of-care therapies.

In April 2017, we and Lilly announced that the FDA had issued a complete response letter for the New Drug Application of baricitinib as a once-daily oral medication for the treatment of moderate-to-severe rheumatoid arthritis. The letter indicated that the FDA was unable to approve the application in its current form. Specifically, the FDA indicated that additional clinical data are needed to determine the most appropriate doses. The FDA also stated that additional data are necessary to further characterize safety concerns across treatment arms. In December 2017, Lilly announced that the NDA for baricitinib had been resubmitted and included new safety and efficacy data. The FDA classified the application as a Class II resubmission, which started a new six-month review cycle.

*Rheumatoid Arthritis.* Rheumatoid arthritis is an autoimmune disease characterized by aberrant or abnormal immune mechanisms that lead to joint inflammation and swelling and, in some patients, the progressive destruction of joints. Rheumatoid arthritis can also affect connective tissue in the skin and organs of the body.

Current rheumatoid arthritis treatments include the use of non-steroidal anti-inflammatory drugs, disease-modifying anti-rheumatic drugs, such as methotrexate, and the newer biological response modifiers that target pro-inflammatory cytokines, such as tumor necrosis factor, implicated in the pathogenesis of rheumatoid arthritis. None of these approaches to treatment is curative; therefore, there remains an unmet need for new safe and effective treatment options for these patients. Rheumatoid arthritis is estimated to affect about 1% of the world's population.

*Psoriatic Arthritis.* Psoriatic arthritis (PsA) is an inflammatory arthritis that is seen in association with skin psoriasis. It causes joint pain and swelling that can lead to damage of the joint if the inflammation is not controlled. Baricitinib has been shown to inhibit the JAK-STAT pathway in related conditions such as psoriasis in Phase II trials, and based on its activity profile, baricitinib also has the potential to demonstrate positive clinical outcomes in PsA. Lilly expects to initiate a Phase III program to evaluate the safety and efficacy of baricitinib in patients with PsA during 2018.

*Atopic Dermatitis.* Atopic dermatitis (AtD) is a condition that makes the skin red and itchy and which is common in children but can occur at any age. Atopic dermatitis is long lasting and tends to flare periodically and then subside. Lilly has conducted a Phase IIa trial to evaluate the safety and efficacy of baricitinib in patients with moderate-to-severe atopic dermatitis. The JAK-STAT pathway has been shown to play an essential role in the dysregulation of immune responses in atopic dermatitis. Therefore, we believe that inhibiting cytokine pathways dependent on JAK1 and JAK2 may lead to positive clinical outcomes in atopic dermatitis. In December 2017, Lilly announced that a Phase III program to evaluate the safety and efficacy of baricitinib in patients with moderate to severe AtD has been initiated.

*Systemic Lupus Erythematosus.* Systemic lupus erythematosus (SLE) is a chronic disease that causes inflammation. In addition to affecting the skin and joints, it can affect other organs in the body such as the kidneys, the tissue lining the lungs and heart, and the brain. Lilly has conducted a Phase II trial to evaluate the safety and efficacy of

baricitinib in patients with SLE. Baricitinib's activity profile suggests that it inhibits cytokines implicated in SLE such as type I interferon (IFN), type II IFN- $\gamma$ , IL-6, and IL-23 as well as other cytokines that may have a role in SLE, including granulocyte macrophage colony stimulating factor (GM-CSF) and IL-12. The potential impact of baricitinib on the IFN pathway is highly relevant to SLE, as clinical and preclinical studies have established that this pathway is involved in the pathogenesis of SLE.

We exercised our co-development options in rheumatoid arthritis, atopic dermatitis, and psoriatic arthritis to fund 30% of future global development costs through regulatory approval, including post-launch studies required by a regulatory authority, in exchange for increased tiered royalties ranging up to the high twenties on potential future sales. We also exercised our co-development options in systemic lupus erythematosus and axial spondyloarthritis, should Lilly decide to progress into a pivotal program in these indications.

### **Capmatinib**

Capmatinib is a potent and highly selective MET inhibitor. The investigational compound has demonstrated inhibitory activity in cell-based biochemical and functional assays that measure MET signaling and MET dependent cell proliferation, survival and migration. Under our agreement, Novartis received worldwide exclusive development and commercialization rights to capmatinib and certain back-up compounds in all indications. Capmatinib is being evaluated in patients with hepatocellular carcinoma, non-small cell lung cancer and other solid tumors, and may have potential utility as a combination agent.

MET is a clinically validated receptor kinase cancer target. Abnormal MET activation in cancer correlates with poor prognosis. Dysregulation of the MET pathway triggers tumor growth, formation of new blood vessels that supply the tumor with nutrients, and causes cancer to spread to other organs. Dysregulation of the MET pathway is seen in many types of cancers, including lung, kidney, liver, stomach, breast and brain.

	<b>Indication</b>	<b>Status Update</b>
<b>Baricitinib (JAK1/JAK2)</b> <sup>1</sup>	Rheumatoid arthritis	Approved in Europe and Japan; CRL issued by FDA
<b>Baricitinib (JAK1/JAK2)</b> <sup>1</sup>	Psoriatic arthritis	Lilly expects the Phase III program to start in 2018
<b>Baricitinib (JAK1/JAK2)</b> <sup>1</sup>	Atopic dermatitis	Phase III
<b>Baricitinib (JAK1/JAK2)</b> <sup>1</sup>	Systemic lupus erythematosus	Phase II
<b>Capmatinib (MET)</b> <sup>2</sup>	NSCLC, liver cancer	Phase II in EGFR wild-type ALK negative NSCLC patients with MET amplification and mutation

<sup>1</sup> Baricitinib licensed to Lilly

<sup>2</sup> Capmatinib licensed to Novartis

### **License Agreements and Business Relationships**

As part of our business strategy, we establish business relationships, including collaborative arrangements with other companies and medical research institutions to assist in the clinical development and/or commercialization of certain of our drugs and drug candidates and to provide support for our research programs. We also evaluate opportunities for acquiring products or rights to products and technologies that are complementary to our business from other companies and medical research institutions.

Below is a brief description of our significant business relationships and collaborations and related license agreements that expand our pipeline and provide us with certain rights to existing and potential new products and technologies.

### ***Novartis***

In November 2009, we entered into a Collaboration and License Agreement with Novartis. Under the terms of the agreement, Novartis received exclusive development and commercialization rights outside of the United States to ruxolitinib and certain back-up compounds for hematologic and oncology indications, including all hematological malignancies, solid tumors and myeloproliferative diseases. We retained exclusive development and commercialization rights to JAKAFI (ruxolitinib) in the United States and in certain other indications. Novartis also received worldwide exclusive development and commercialization rights to our MET inhibitor compound capmatinib and certain back-up compounds in all indications. We retained options to co-develop and to co-promote capmatinib in the United States.

Under this agreement, we received an upfront payment and immediate milestone payment totaling \$210.0 million and were initially eligible to receive additional payments of up to approximately \$1.2 billion if defined development and commercialization milestones are achieved. We are also eligible to receive tiered, double-digit royalties ranging from the upper-teens to the mid-twenties percent on future ruxolitinib net sales outside of the United States, and tiered, worldwide royalties on future capmatinib net sales that range from 12% to 14%. In addition, Novartis has received reimbursement and pricing approval for ruxolitinib in a specified number of countries, and we are now obligated to pay to Novartis tiered royalties in the low single-digits on future ruxolitinib net sales within the United States. Each company is responsible for costs relating to the development and commercialization of ruxolitinib in its respective territories, with costs of collaborative studies shared equally. Novartis is also responsible for all costs relating to the development and commercialization of capmatinib.

In April 2016, we amended this agreement to provide that Novartis has exclusive research, development and commercialization rights outside of the United States to ruxolitinib (excluding topical formulations) in the GVHD field. Under this amendment, we received a \$5.0 million payment in exchange for the development and commercialization rights to ruxolitinib in GVHD outside of the United States and became eligible to receive up to \$75.0 million of additional potential development and regulatory milestones relating to GVHD. In March 2017, we recognized a \$25.0 million milestone for the first patient first visit in a GVHD study and in December 2017, we recognized a \$40.0 million milestone for Novartis achieving annual net sales of a JAK licensed product of \$600.0 million.

The Novartis agreement will continue on a program-by-program basis until Novartis has no royalty payment obligations with respect to such program or, if earlier, the termination of the agreement or any program in accordance with the terms of the agreement. Royalties are payable by Novartis on a product-by-product and country-by-country basis until the latest to occur of (i) the expiration of the last valid claim of the licensed patent rights covering the licensed product in the relevant country, (ii) the expiration of regulatory exclusivity for the licensed product in such country and (iii) a specified period from first commercial sale in such country of the licensed product by Novartis or its affiliates or sublicensees. The agreement may be terminated in its entirety or on a program-by-program basis by Novartis for convenience. The agreement may also be terminated by either party under certain other circumstances, including material breach.

### ***Lilly***

In December 2009, we entered into a License, Development and Commercialization Agreement with Lilly. Under the terms of the agreement, Lilly received exclusive worldwide development and commercialization rights to baricitinib and certain back-up compounds for inflammatory and autoimmune diseases. We received an initial payment of \$90.0 million, and were initially eligible to receive additional payments of up to \$665.0 million based on the achievement of defined development, regulatory and commercialization milestones.

We retained options to co-develop our JAK1/JAK2 inhibitors with Lilly on a compound-by-compound and indication-by-indication basis. Lilly is responsible for all costs relating to the development and commercialization of the compounds unless we elect to co-develop any compounds or indications. If we elect to co-develop any compounds and/or indications, we would be responsible for funding 30% of the associated future global development costs from the initiation of a Phase IIb trial through regulatory approval, including post-launch studies required by a regulatory authority. We would receive an incremental royalty rate increase across all tiers resulting in effective royalty rates ranging up to the high twenties on potential future global net sales for compounds and/or indications that we elect to co-develop. For indications that we elect not to co-develop, we would receive tiered, double-digit royalty payments on future global net sales with rates ranging

up to 20% if the product is successfully commercialized. We previously had retained an option to co-promote products in the United States but, in March 2016, we waived our co-promotion option as part of an amendment to the agreement.

In July 2010, we elected to co-develop baricitinib with Lilly in rheumatoid arthritis and we are responsible for funding 30% of the associated future global development costs for this indication from the initiation of the Phase IIb trial through regulatory approval, including post-launch studies required by a regulatory authority. In January 2017, we elected to co-develop baricitinib with Lilly in psoriatic arthritis and atopic dermatitis. We have also exercised our co-development options in systemic lupus erythematosus and axial spondyloarthritis, should Lilly decide to progress into a pivotal program in these indications.

In March 2016, we entered into an amendment to the agreement with Lilly that allows us to engage in the development and commercialization of ruxolitinib in the GVHD field. We paid Lilly an upfront payment of \$35.0 million and Lilly is eligible to receive up to \$40.0 million in additional regulatory milestone payments relating to ruxolitinib in the GVHD field.

In February 2017, the European Commission announced the approval of baricitinib as OLUMIANT, triggering a \$65.0 million milestone payment from Lilly. In July 2017, Japan's MHLW granted marketing approval for OLUMIANT, triggering a \$15.0 million milestone payment to Incyte from Lilly. In December 2017, we recognized a \$30.0 million milestone payment for the first patient treated in the atopic dermatitis Phase III program for baricitinib.

The Lilly agreement will continue until Lilly no longer has any royalty payment obligations or, if earlier, the termination of the agreement in accordance with its terms. Royalties are payable by Lilly on a product-by-product and country-by-country basis until the latest to occur of (i) the expiration of the last valid claim of the licensed patent rights covering the licensed product in the relevant country, (ii) the expiration of regulatory exclusivity for the licensed product in such country and (iii) a specified period from first commercial sale in such country of the licensed product by Lilly or its affiliates or sublicensees. The agreement may be terminated by Lilly for convenience, and may also be terminated under certain other circumstances, including material breach.

#### *Agenus*

In January 2015, we entered into a License, Development and Commercialization Agreement with Agenus Inc. and its wholly-owned subsidiary, 4-Antibody AG (now known as Agenus Switzerland Inc.), which we collectively refer to as Agenus. Under this agreement, the parties have agreed to collaborate on the discovery of novel immuno-therapeutics using Agenus' antibody discovery platforms. In February 2017, we and Agenus amended this agreement.

Under the terms of this agreement, as amended, we received exclusive worldwide development and commercialization rights to four checkpoint modulators directed against GITR, OX40, LAG-3 and TIM-3. In addition to the initial four program targets, we and Agenus have the option to jointly nominate and pursue additional targets within the framework of the collaboration, and in November 2015, three more targets were added. Targets may be designated profit-share programs, where all costs and profits are shared equally by us and Agenus, or royalty-bearing programs, where we are responsible for all costs associated with discovery, preclinical, clinical development and commercialization activities. The programs relating to GITR and OX40 and two of the undisclosed targets were profit-share programs until February 2017, while the other targets currently under collaboration are royalty-bearing programs. The February 2017 amendment converted the programs relating to GITR and OX40 to royalty-bearing programs and removed from the collaboration the profit-share programs relating to the two undisclosed targets, with one reverting to us and one reverting to Agenus. Should any of those removed programs be successfully developed by a party, the other party will be eligible to receive the same milestone payments as the royalty-bearing programs and royalties at a 15% rate on global net sales. There are currently no profit-share programs. For each royalty-bearing product other than GITR and OX40, Agenus will be eligible to receive tiered royalties on global net sales ranging from 6% to 12%. For GITR and OX40, Agenus will be eligible to receive 15% royalties on global net sales. Under the February 2017 amendment, we paid Agenus \$20.0 million in accelerated milestones relating to the clinical development of the GITR and OX40 programs. Agenus is eligible to receive up to an additional \$510.0 million in future contingent development, regulatory and commercialization milestones across all programs in the collaboration. The agreement may be terminated by us for convenience upon 12 months' notice and may also be terminated under certain other circumstances, including material breach.

### ***Hengrui***

In September 2015, we entered into a License and Collaboration Agreement with Hengrui. Under the terms of this agreement, we received exclusive development and commercialization rights worldwide, with the exception of Mainland China, Hong Kong, Macau and Taiwan, to INCSHR1210, an investigational PD-1 monoclonal antibody, and certain back-up compounds. In February 2018, Incyte and Hengrui agreed to terminate the collaboration, pursuant to the terms of the License and Collaboration Agreement.

### ***ARIAD Pharmaceuticals (Luxembourg) S.à.r.l. Acquisition***

In June 2016, we acquired from ARIAD all of the outstanding shares of ARIAD Pharmaceuticals (Luxembourg) S.à.r.l., the parent company of ARIAD's European subsidiaries responsible for the development and commercialization of ICLUSIG in the European Union and other countries, including Switzerland, Norway, Turkey, Israel and Russia, in exchange for an upfront payment of \$147.5 million, including customary working capital adjustments. We obtained an exclusive license to develop and commercialize ICLUSIG in Europe and other select countries. ARIAD will be eligible to receive from us tiered royalties on net sales of ICLUSIG in our territory and up to \$135.0 million in potential future oncology development and regulatory approval milestone payments, together with additional milestone payments for non-oncology indications, if approved, in our territory.

### ***Merus***

In December 2016, we entered into a Collaboration and License Agreement with Merus N.V. Under this agreement, which became effective in January 2017, the parties have agreed to collaborate with respect to the research, discovery and development of bispecific antibodies utilizing Merus' technology platform. The collaboration encompasses up to eleven independent programs, including two of Merus' current preclinical immuno-oncology discovery programs. We received exclusive development and commercialization rights outside of the United States to products and product candidates resulting from one of Merus' current preclinical discovery programs, referred to as "Program 1." We also received worldwide exclusive development and commercialization rights to products and product candidates resulting from the other current Merus preclinical discovery program that is subject to the collaboration and to up to nine additional programs. Merus retained exclusive development and commercialization rights in the United States to products and product candidates resulting from Program 1 and options, subject to certain conditions, to co-fund development of products resulting from two other programs in exchange for a share of profits in the United States. Merus will also have the right to participate in a specified proportion of detailing activities in the United States for one of those co-developed programs. Should Program 1 fail to successfully complete IND-enabling toxicology studies, Merus would be granted an additional option to co-fund development of a program in exchange for a share of profits in the United States. All costs related to the collaboration are subject to joint research and development plans. Each party will share equally the costs of mutually agreed global development activities for Program 1, and fund itself any independent development activities in its territory. We will be responsible for all research, development and commercialization costs relating to all other programs, subject to Merus' election to co-fund development and co-detail described above. If Merus exercises its co-funding option for a program, Merus would be responsible for funding 35% of the associated future global development costs and, for certain of such programs, would be responsible for reimbursing us for certain development costs incurred prior to the option exercise. All products as to which Merus has exercised its option to co-fund development would be subject to joint development plans and overseen by a joint development committee, but we will have final determination as to such plans in cases of dispute.

In February 2017, we paid Merus an upfront non-refundable payment of \$120.0 million. For each program as to which Merus does not have commercialization or co-development rights, Merus will be eligible to receive up to \$100.0 million in future contingent development and regulatory milestones and up to \$250.0 million in commercialization milestones as well as tiered royalties ranging from 6% to 10% of global net sales. For each program as to which Merus exercises its option to co-fund development, Merus will be eligible to receive a 50% share of profits (or sustain 50% of any losses) in the United States and be eligible to receive tiered royalties ranging from 6% to 10% of net sales of products outside of the United States. If Merus opts to cease co-funding a program as to which it exercised its co-development option, then Merus will no longer receive a share of profits in the United States but will be eligible to receive the same milestones from the co-funding termination date and the same tiered royalties described above with respect to non-co-developed programs and, depending on the stage at which Merus chose to cease co-funding development costs, additional

royalties ranging up to 4% of net sales in the United States. For Program 1, we and Merus will each be eligible to receive tiered royalties on net sales in the other party's territory at rates ranging from 6% to 10%.

The Merus agreement will continue on a program-by-program basis until we have no royalty payment obligations with respect to such program or, if earlier, the termination of the agreement or any program in accordance with the terms of the agreement. The agreement may be terminated in its entirety or on a program-by-program basis by us for convenience. The agreement may also be terminated by either party under certain other circumstances, including material breach, as set forth in the agreement. If the agreement is terminated with respect to one or more programs, all rights in the terminated programs revert to Merus, subject to payment to us of a reverse royalty of up to 4% on sales of future products, if Merus elects to pursue development and commercialization of products arising from the terminated programs.

### ***Calithera***

In January 2017, we entered into a Collaboration and License Agreement with Calithera Biosciences, Inc. Under this agreement, we received an exclusive, worldwide license to develop and commercialize small molecule arginase inhibitors, including INCB01158 (CB-1158), which is currently in Phase I clinical trials, for hematology and oncology indications. We have agreed to co-fund 70% of the global development costs for the development of the licensed products for hematology and oncology indications. Calithera will have the right to conduct certain clinical development under the collaboration, including combination studies of a licensed product with a proprietary compound of Calithera. We will be entitled to 60% of the profits and losses from net sales of licensed product in the United States, and Calithera will have the right to co-detail licensed products in the United States, and we have agreed to pay Calithera tiered royalties ranging from the low to mid-double digits on net sales of licensed products outside the United States. Calithera may opt out of its co-funding obligation, in which case the U.S. profit sharing will no longer be in effect, and we have agreed to pay Calithera tiered royalties ranging from the low to mid-double digits on net sales of licensed products both in the United States and outside the United States, and additional royalties to reimburse Calithera for previously incurred development costs.

Calithera retains rights to certain arginase inhibitors that are not part of the collaboration for specific orphan indications outside of hematology and oncology, subject to our rights to negotiate a license for any such programs under specified circumstances if Calithera elects to out-license them.

In January 2017, we paid Calithera an upfront license fee of \$45.0 million and have agreed to pay potential development, regulatory and sales milestone payments of over \$430.0 million if the profit share is in effect, or \$750.0 million if the profit share terminates.

The Calithera agreement will continue on a product-by-product and country-by-country basis for so long as we are developing or commercializing products in the United States (if the parties are sharing profits in the United States) and until we have no further royalty payment obligations, unless earlier terminated according to the terms of the agreement. The agreement may be terminated in its entirety or on a product-by-product and/or a country-by-country basis by us for convenience. The agreement may also be terminated by us for Calithera's uncured material breach, by Calithera for our uncured material breach and by either party for bankruptcy or patent challenge. If the agreement is terminated early with respect to one or more products or countries, all rights in the terminated products and countries revert to Calithera.

### ***MacroGenics***

In October 2017, we entered into a Global Collaboration and License Agreement with MacroGenics, Inc. Under this agreement, we received exclusive development and commercialization rights worldwide to MacroGenics' MGA012, an investigational monoclonal antibody that inhibits PD-1. Except as set forth in the succeeding sentence, we will have sole authority over and bear all costs and expenses in connection with the development and commercialization of MGA012 in all indications, whether as a monotherapy or as part of a combination regimen. MacroGenics has retained the right to develop and commercialize, at its cost and expense, its pipeline assets in combination with MGA012. In addition, MacroGenics has the right to manufacture a portion of both companies' global clinical and commercial supply needs of MGA012. In December 2017, we paid MacroGenics an upfront payment of \$150.0 million. MacroGenics will be eligible to receive up to \$420.0 million in future contingent development and regulatory milestones, and up to \$330.0 million in commercial milestones as well as tiered royalties ranging from 15% to 24% of global net sales.

The MacroGenics agreement will continue until we are no longer commercializing, developing or manufacturing MGA012 or, if earlier, the termination of the agreement in accordance with its terms. The agreement may be terminated in its entirety or on a licensed product by licensed product basis by us for convenience. The agreement may also be terminated by either party under certain other circumstances, including material breach, as set forth in the agreement.

### **Syros**

In January 2018, we entered into a target discovery, research collaboration and option agreement with Syros Pharmaceuticals, Inc. Under this agreement, Syros will use its proprietary gene control platform to identify novel therapeutic targets with a focus in myeloproliferative neoplasms and we have received options to obtain exclusive worldwide rights to intellectual property resulting from the collaboration for up to seven validated targets. We will have exclusive worldwide rights to develop and commercialize any therapies under the collaboration that modulate those validated targets. We paid Syros \$2.5 million in cash for access to proprietary technology and \$7.5 million in cash for research and development services. We have agreed to pay Syros up to \$54.0 million in target selection and option exercise fees should we decide to exercise all of our options under the agreement. For products resulting from the collaboration against each of the seven selected and validated targets, we have agreed to pay up to \$50.0 million in potential development and regulatory milestones and up to \$65.0 million in potential commercial milestones. Syros is also eligible to receive low single-digit royalties on net sales of products resulting from the collaboration.

### **Incyte's Approach to Drug Discovery and Development**

Our productivity in drug discovery is primarily a result of our core competency in medicinal chemistry which is tightly integrated with, and supported by, an experienced team of biologists and pharmaceutical scientists with expertise in multiple therapeutic areas. This discovery team operates in concert with an equally experienced drug development organization with expertise in clinical sciences, statistics, and regulatory affairs. Our drug development organization manages our clinical programs and utilizes clinical research organizations (CROs), expert scientific advisory boards, and leading consultants and suppliers as appropriate to ensure our clinical trials are conducted efficiently, effectively, and in accordance with regulatory and compliance guidelines.

To succeed in our objective to discover and advance novel therapeutics that address serious unmet medical needs, we have established a broad range of discovery capabilities in-house, including target validation, high-throughput screening, medicinal chemistry, computational chemistry, and pharmacological and ADME (absorption, distribution, metabolism and excretion) assessment. We augment these capabilities through collaborations with academic and contract laboratory resources with relevant expertise.

In addition to our small molecule expertise, we have added biotherapeutic antibody discovery capabilities. The collaboration with Agenus has provided us with access to their antibody discovery platform and provided us with both clinical antibodies and pre-clinical candidates. Recently, we have expanded our discovery reach to include bispecific antibodies through a collaboration with Merus. We are complementing these collaborations by building in-house antibody discovery, pharmacology, ADME and CMC capabilities and will partner these efforts with our small molecule portfolio.

Driven by a target- and pathway-centric discovery process, our pipeline has grown and is currently focused primarily in the area of oncology. We conduct a limited number of discovery programs in parallel at any one time. This focus allows us to allocate resources to our selected programs at a level that we believe is competitive with larger pharmaceutical companies. We continually modify the resourcing of our discovery efforts with the goals of maximizing information content when and where we need it and ensuring that each program, regardless of stage, is executed in the most efficient and data-rich manner possible. We believe this approach has played a critical role in the development of our product portfolio.

Once our compounds reach clinical development, our objective is to rapidly progress the lead candidate into a proof-of-concept clinical trial to quickly assess the therapeutic potential of the clinical candidate itself as well as its underlying mechanism of action. This information is then used to evaluate the compound's development opportunities, identify the most appropriate indication or indications to pursue, and develop a clinical and regulatory plan to advance the molecule forward.

Our development teams are responsible for ensuring that our clinical candidates are expeditiously progressed through clinical safety, proof-of-concept, and formal efficacy/pivotal trials. Our development teams include employees with expertise in drug development, including clinical trial design, statistics, regulatory affairs, medical affairs, pharmacovigilance and project management. We have also built internal process chemistry and formulation teams that work closely with external GMP contract manufacturers to support our drug development efforts.

### **Incyte's Commercial Strategy**

Our strategy is to develop and commercialize our compounds on our own in selected markets where we believe a company of our size can successfully compete, such as in myelofibrosis, polycythemia vera, and other oncology indications. In November 2011, we received regulatory approval of JAKAFI (ruxolitinib) in the United States for the treatment of intermediate or high-risk myelofibrosis. Since that time, we have focused on increasing utilization of JAKAFI in this patient population. In December 2014, JAKAFI was approved for the treatment of patients with polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea. JAKAFI is the only FDA-approved product to treat these two diseases. We have expanded the marketing, medical, sales and operational infrastructure to support continued commercialization of JAKAFI in its two indications and to prepare for potential future indications of JAKAFI in the United States. We are expanding marketing, medical and operational infrastructure outside of the United States and within the United States to prepare for potential approval of other products.

For rights to ruxolitinib outside the United States as well as for pipeline compounds that are outside of our core expertise, would require expensive clinical studies, or could be used in combination with other compounds or biologics, we have established or may in the future establish collaborations or strategic relationships to support development and commercialization, such as our collaborations with Novartis and Lilly for our JAK inhibitors. We believe the key benefits to entering into strategic relationships include the potential to receive upfront payments and future milestones and royalties in exchange for certain rights to our compounds, as well as the potential to expedite the development and commercialization of certain of our compounds.

ICLUSIG is approved in the European Union for the treatment of adult patients with 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. ICLUSIG is also indicated in adult patients with Philadelphia positive AML 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. We are focused on increasing the utilization of ICLUSIG in this patient population within our territory as appropriate.

Please also see Note 16 of Notes to Consolidated Financial Statements included in this Annual Report on Form 10-K for financial information about geographic areas.

### **Patents and Other Intellectual Property**

We regard the protection of patents and other enforceable intellectual property rights that we own or license as critical to our business and competitive position. Accordingly, we rely on patent, trade secret and copyright law, as well as nondisclosure and other contractual arrangements, to protect our intellectual property. We have established a patent portfolio of patents and patent applications owned or licensed by us that cover aspects of all our drug products and drug candidates. The patents and patent applications relating to our drug products and drug candidates generally include claims directed to the compounds, methods of using the compounds, formulations of the compounds, pharmaceutical salt forms of the compounds, and methods of manufacturing the compounds. Our policy is to pursue patent applications on inventions and discoveries that we believe are commercially important to the development and growth of our business. The following table sets forth the status of the patents and patent applications in the United States, the European Union, and Japan,

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covering our drug products and drug candidates in key programs that show at least proof of concept in their respective clinical development programs:

<b>Drug/Drug Candidate (Target)</b>	<b>Status of United States Patent Estate (Earliest Anticipated Expirations, Subject to Potential Extensions and Payment of Maintenance Fees)</b>	<b>Status of European Union and Japan Patent Estate (Earliest Anticipated Expirations, Subject to Potential Extensions and Payment of Maintenance Fees)</b>
ruxolitinib (JAK)	Granted and pending (2026)	Granted and pending (2026)
baricitinib (JAK)	Granted and pending (2029)	Granted and pending (2029)
epacadostat (IDO)	Granted and pending (2029)	Granted and pending (2029)
itacitinib (JAK)	Granted and pending (2031)	Granted and pending (2031)
capmatinib (cMET)	Granted and pending (2027)	Granted and pending (2027)
INCB050465 (PI3K $\delta$ )	Granted and pending (2032)	Granted and pending (2032)
INCB054828 (FGFR)	Granted and pending (2033)	Granted and pending (2033)
ponatinib (BCR ABL)		Granted and pending (2026)

Patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country.

We may seek to license rights relating to technologies, drug candidates or drug products in connection with our drug discovery and development programs and commercialization activities. Under these licenses, such as our licenses from Agenus, ARIAD, Calithera, MacroGenics and Merus we may be required to pay up-front fees, license fees, milestone payments and royalties on sales of future products.

Although we believe our rights under patents and patent applications provide a competitive advantage, the patent positions of pharmaceutical and biotechnology companies are highly uncertain and involve complex legal and factual questions. We may not be able to develop patentable products or processes, and may not be able to obtain patents in the United States or elsewhere from pending applications. Even if patent claims are allowed, the claims may not issue, or in the event of issuance, may not be valid or enforceable or may not be sufficient to protect the technology owned by or licensed to us or provide us with a competitive advantage. Any patent or other intellectual property rights that we own or obtain may be circumvented, challenged or invalidated by our competitors. Others may have patents that relate to our business or technology and that may prevent us from marketing our drug candidates unless we are able to obtain a license to those patents. In addition, litigation or other proceedings may be necessary to defend against claims of infringement, to enforce patents, to protect our other intellectual property rights, to determine the scope and validity of the proprietary rights of third parties or to defend ourselves in patent or other intellectual property right suits brought by third parties. We could incur substantial costs in such litigation or other proceedings. An adverse outcome in any such litigation or proceeding could subject us to significant liability.

With respect to proprietary information that is not patentable, and for inventions for which patents are difficult to enforce, we rely on trade secret protection and confidentiality agreements to protect our interests. While we require all employees, consultants and potential business partners to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary information. Others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets.

### **Competition**

Our drug discovery, development and commercialization activities face, and will continue to face, intense competition from organizations such as pharmaceutical and biotechnology companies, as well as academic and research institutions and government agencies. We face significant competition from organizations, particularly fully integrated pharmaceutical companies that are pursuing pharmaceuticals that are competitive with JAKAFI, ICLUSIG and our drug candidates.

Many companies and institutions, either alone or together with their collaborative partners, have substantially greater financial resources, larger drug discovery, development and commercial staffs and significantly greater experience than we do in:

- drug discovery;
- developing products;
- undertaking preclinical testing and clinical trials;
- obtaining FDA and other regulatory approvals of products; and
- manufacturing, marketing, distributing and selling products.

Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA and other regulatory approval or commercializing products that compete with JAKAFI, ICLUSIG or our drug candidates.

In addition, any drug candidate that we successfully develop may compete with existing therapies that have long histories of safe and effective use. Competition may also arise from:

- other drug development technologies and methods of preventing or reducing the incidence of disease;
- new small molecules; or
- other classes of therapeutic agents.

We face and will continue to face intense competition from other companies for collaborative arrangements with pharmaceutical and biotechnology companies, for establishing relationships with academic and research institutions and for licenses to drug candidates or proprietary technology. These competitors, either alone or with their collaborative partners, may succeed in developing products that are more effective than ours.

Our ability to compete successfully will depend, in part, on our ability to:

- develop proprietary products;
- develop and maintain products that reach the market first, are technologically superior to and/or are of lower cost than other products in the market;
- attract and retain scientific, product development and sales and marketing personnel;
- obtain patent or other proprietary protection for our products and technologies;
- obtain required regulatory approvals; and
- manufacture, market, distribute and sell any products that we develop.

In a number of countries, including in particular, developing countries, government officials and other groups have suggested that pharmaceutical companies should make drugs available at a low cost. In some cases, governmental authorities have indicated that where pharmaceutical companies do not do so, their patents might not be enforceable to prevent generic competition. Some major pharmaceutical companies have greatly reduced prices for their drugs in certain developing countries. If certain countries do not permit enforcement of any of our patents, sales of our products in those countries, and in other countries by importation from low-price countries, could be reduced by generic competition or by parallel importation of our product. Alternatively, governments in those countries could require that we grant compulsory licenses to allow competitors to manufacture and sell their own versions of our products in those countries, thereby

reducing our product sales, or we could respond to governmental concerns by reducing prices for our products. In all of these situations, our results of operations could be adversely affected.

## **Government Regulation**

Our ongoing research and development activities and any manufacturing and marketing of our approved drug products and our drug candidates are subject to extensive regulation by numerous governmental authorities in the United States and other countries. Before marketing in the United States, any drug developed by us must undergo rigorous preclinical testing, clinical trials, and an extensive regulatory clearance process implemented by the FDA under the United States Food, Drug and Cosmetic Act and its implementing regulations and, in the case of biologics, the Public Health Service Act. The FDA regulates, among other things, the research, development, testing, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution and import and export, of these products.

### *FDA Review and Approval Process*

The regulatory review and approval process is lengthy, expensive and uncertain. The steps generally required before a drug may be marketed in the United States include:

- preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's Good Laboratory Practice and Good Manufacturing Practice regulations;
- submission to the FDA of an Investigational New Drug application (IND) for human clinical testing, which must become effective before human clinical trials may commence;
- performance of adequate and well-controlled clinical trials in three phases, as described below, to establish the safety and efficacy of the drug for each indication;
- submission of an NDA or Biologics License Application (BLA) to the FDA for review;
- random inspections of clinical sites to ensure validity of clinical safety and efficacy data;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practices;
- FDA approval of the NDA or BLA; and
- payment of user and establishment fees, if applicable.

Similar requirements exist within foreign agencies as well. The time required to satisfy FDA requirements or similar requirements of foreign regulatory agencies may vary substantially based on the type, complexity and novelty of the product or the targeted disease.

Preclinical testing includes laboratory evaluation of product pharmacology, drug metabolism, and toxicity which includes animal studies, to assess potential safety and efficacy as well as product chemistry, stability, formulation, development, and testing. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time, the FDA raises safety concerns or questions about the conduct of the clinical trial(s) included in the IND. In the latter case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. We cannot be sure that submission of an IND will result in the FDA allowing clinical trials to commence.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators and in accordance with good clinical practices regulations covering the protection of human

subjects. These regulations require all research subjects to provide informed consent. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND and each trial must be reviewed and approved by an institutional review board (IRB) before it can begin.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Phase I usually involves the initial introduction of the investigational drug into healthy volunteers to evaluate its safety, dosage tolerance, absorption, metabolism, distribution and excretion. Phase II usually involves clinical trials in a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse effects and safety risks, and evaluate and gain preliminary evidence of the efficacy of the drug for specific indications. Phase III clinical trials usually further evaluate clinical efficacy and safety by testing the drug in its final form in an expanded patient population, providing statistical evidence of efficacy and safety, and providing an adequate basis for labeling. We cannot guarantee that Phase I, Phase II or Phase III testing will be completed successfully within any specified period of time, if at all. Furthermore, we, the IRB, or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

As a separate amendment to an IND, a clinical trial sponsor may submit to the FDA a request for a Special Protocol Assessment (SPA). Under the SPA procedure, a sponsor may seek the FDA's agreement on the design and size of a clinical trial intended to form the primary basis of an effectiveness claim. If the FDA agrees in writing, its agreement may not be changed after the trial begins, except when agreed by FDA or in limited circumstances, such as when a substantial scientific issue essential to determining the safety and effectiveness of a drug candidate is identified after a Phase III clinical trial is commenced and agreement is obtained with the FDA. If the outcome of the trial is successful, the sponsor will ordinarily be able to rely on it as the primary basis for approval with respect to effectiveness. However, additional trials could also be requested by the FDA to support approval, and the FDA may make an approval decision based on a number of factors, including the degree of clinical benefit as well as safety. The FDA is not obligated to approve an NDA or BLA as a result of an SPA agreement, even if the clinical outcome is positive.

Even after initial FDA approval has been obtained, post-approval trials, or Phase IV studies, may be required to provide additional data, and will be required to obtain approval for the sale of a product as a treatment for a clinical indication other than that for which the product was initially tested and approved. Also, the FDA will require post-approval safety reporting to monitor the side effects of the drug. Results of post-approval programs may limit or expand the indication or indications for which the drug product may be marketed. Further, if there are any requests for modifications to the initial FDA approval for the drug, including changes in indication, manufacturing process, manufacturing facilities, or labeling, a supplemental NDA or BLA may be required to be submitted to the FDA.

The length of time and related costs necessary to complete clinical trials varies significantly and may be difficult to predict. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Additional factors that can cause delay or termination of our clinical trials, or cause the costs of these clinical trials to increase, include:

- slow patient enrollment due to the nature of the protocol, the proximity of patients to clinical sites, the eligibility criteria for the study, competition with clinical trials for other drug candidates or other factors;
- inadequately trained or insufficient personnel at the study site to assist in overseeing and monitoring clinical trials;
- delays in approvals from a study site's IRB;
- longer than anticipated treatment time required to demonstrate effectiveness or determine the appropriate product dose;
- lack of sufficient supplies of the drug candidate for use in clinical trials;
- adverse medical events or side effects in treated patients; and

- lack of effectiveness of the drug candidate being tested.

Any drug is likely to produce some toxicities or undesirable side effects in animals and in humans when administered at sufficiently high doses and/or for sufficiently long periods of time. Unacceptable toxicities or side effects may occur at any dose level, and at any time in the course of animal studies designed to identify unacceptable effects of a drug candidate, known as toxicological studies, or in clinical trials of our drug candidates. The appearance of any unacceptable toxicity or side effect could cause us or regulatory authorities to interrupt, limit, delay or abort the development of any of our drug candidates, and could ultimately prevent their marketing approval by the FDA or foreign regulatory authorities for any or all targeted indications.

The FDA's fast track, breakthrough therapy, accelerated approval, and priority review designation programs are intended to facilitate the development and expedite the review and approval of drug candidates intended for the treatment of serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs for these conditions. Under these programs, FDA can, for example, review portions of an NDA or BLA for a drug candidate before the entire application is complete, thus potentially beginning the review process at an earlier time.

We cannot guarantee that the FDA will grant any of our requests for any of these expedited program designations, that any such designations would affect the time of review or that the FDA will approve the NDA or BLA submitted for any of our drug candidates, whether or not these designations are granted. Additionally, FDA approval of a product can include restrictions on the product's use or distribution (such as permitting use only for specified medical conditions or limiting distribution to physicians or facilities with special training or experience). Approval of such designated products can be conditioned on additional clinical trials after approval.

Sponsors submit the results of preclinical studies and clinical trials to the FDA as part of an NDA or BLA. NDAs and BLAs must also contain extensive product manufacturing information and proposed labeling. Upon receipt, the FDA initially reviews the NDA or BLA to determine whether it is sufficiently complete to initiate a substantive review. If the FDA identifies deficiencies that would preclude substantive review, the FDA will refuse to accept the NDA or BLA and will inform the sponsor of the deficiencies that must be corrected prior to resubmission. If the FDA accepts the submission for review (then deemed a "filing"), the FDA typically completes the NDA or BLA review within a pre-determined time frame. Under the Prescription Drug User Fee Act, the FDA agrees to review NDAs and BLAs under either a standard review or priority review. FDA procedures provide for priority review of NDAs and BLAs submitted for drugs that, compared to currently marketed products, if any, offer a significant improvement in the treatment, diagnosis or prevention of a disease. The FDA seeks to review NDAs and BLAs that are granted priority status more quickly than NDAs and BLAs given standard review status. The FDA's stated policy is to act on 90% of priority NDAs and BLAs within eight months of receipt (or six months after filing, which occurs within 60 days after NDA or BLA submission). Although the FDA historically has not met these goals, the agency has made significant improvements in the timeliness of the review process. NDA and BLA review often extends beyond anticipated completion dates due to FDA requests for additional data or clarification, the FDA's decision to have an advisory committee review, and difficulties in scheduling an advisory committee meeting. The recommendations of an advisory committee are not binding on the FDA.

To obtain FDA approval to market a product, we must demonstrate that the product is safe and effective for the patient population that will be treated. If regulatory approval of a product is granted, the approval will be limited to those disease states and conditions for which the product is safe and effective, as demonstrated through clinical trials. Marketing or promoting a drug for an unapproved indication is prohibited. Furthermore, approval may entail requirements for post-marketing studies or risk evaluation and mitigation strategies, including the need for patient and/or physician education, patient registries, medication or similar guides, or other restrictions on the distribution of the product. If an NDA or BLA does not satisfy applicable regulatory criteria, the FDA may deny approval of an NDA or BLA or may issue a complete response, and require, among other things, additional clinical data or analyses.

The Orphan Drug Act provides incentives to manufacturers to develop and market drugs for rare diseases and conditions affecting fewer than 200,000 persons in the United States at the time of application for orphan drug designation. The first developer to receive FDA marketing approval for an orphan drug is entitled to a seven year exclusive marketing period in the United States for the orphan drug indication. However, a drug that the FDA considers to be clinically superior to, or different from, another approved orphan drug, even though for the same indication, may also obtain approval in the United States during the seven year exclusive marketing period.

*Regulation of Manufacturing Process*

Even when NDA or BLA approval is obtained, a marketed product, such as JAKAFI, its manufacturer and its manufacturing facilities are subject to continual review and periodic inspections by the FDA. The manufacturing process for pharmaceutical products is highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations. Discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on the product, manufacturer or facility, including costly recalls or withdrawal of the product from the market. Manufacturing facilities are always subject to inspection by the applicable regulatory authorities.

We and our third-party manufacturers are subject to current Good Manufacturing Practices, which are extensive regulations governing manufacturing processes, including but not limited to stability testing, record keeping and quality standards as defined by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, or ICH, FDA and the European Medicines Agency. Similar regulations are in effect in other countries. Manufacturing facilities are subject to inspection by the applicable regulatory authorities and are subject to manufacturing licenses where applicable. These facilities, whether our own or our contract manufacturers, must be inspected before we can use them in commercial manufacturing of our related products. We or our contract manufacturers may not be able to comply with applicable Good Manufacturing Practices and FDA or other regulatory requirements. If we or our contract manufacturers fail to comply, we or our contract manufacturers may be subject to legal or regulatory action, such as suspension of manufacturing license, seizure of product, or voluntary recall of product. Furthermore, continued compliance with applicable Good Manufacturing Practices will require continual expenditure of time, money and effort on the part of us or our contract manufacturers in the areas of production and quality control and record keeping and reporting, in order to ensure full compliance.

*Post-Approval Regulation*

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including record-keeping requirements, reporting of adverse experiences with the drug and other reporting, advertising and promotion restrictions. The FDA's rules for advertising and promotion require, among other things, that our promotion be fairly balanced and adequately substantiated by clinical studies, and that we not promote our products for unapproved uses. We must also submit appropriate new and supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. On its own initiative, the FDA may require changes to the labeling of an approved drug if it becomes aware of new safety information that the agency believes should be included in the approved drug's labeling. The FDA also enforces the requirements of the Prescription Drug Marketing Act, or PDMA, which, among other things, imposes various requirements in connection with the distribution of product samples to physicians.

In addition to inspections related to manufacturing, we are subject to periodic unannounced inspections by the FDA and other regulatory bodies related to the other regulatory requirements that apply to marketed drugs manufactured or distributed by us. The FDA also may conduct periodic inspections regarding our review and reporting of adverse events, or related to compliance with the requirements of the PDMA concerning the handling of drug samples. When the FDA conducts an inspection, the inspectors will identify any deficiencies they believe exist in the form of a notice of inspectional observations. The observations may be more or less significant. If we receive a notice of inspectional observations, we likely will be required to respond in writing, and may be required to undertake corrective and preventive actions in order to address the FDA's concerns.

There are a variety of state laws and regulations that apply in the states or localities where JAKAFI and our drug candidates are or may be marketed. For example, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in that state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Any applicable state or local regulations may hinder our ability to market, or increase the cost of marketing, our products in those states or localities.

The FDA's policies may change and additional government regulations may be enacted which could impose additional burdens or limitations on our ability to market products after approval. Moreover, increased attention to the containment of health care costs in the United States and in foreign markets could result in new government regulations which could have a material adverse effect on our business. We cannot predict the likelihood, nature or extent of adverse governmental regulation which might arise from future legislative or administrative action, either in the United States or abroad.

#### *Marketing Exclusivity*

The FDA may grant five years of exclusivity in the United States for the approval of NDAs for new chemical entities, and three years of exclusivity for supplemental NDAs, for among other things, new indications, dosages or dosage forms of an existing drug if new clinical investigations that were conducted or sponsored by the applicant are essential to the approval of the supplemental application. Additionally, six months of marketing exclusivity in the United States is available if, in response to a written request from the FDA, a sponsor submits and the agency accepts requested information relating to the use of the approved drug in the pediatric population. The six month pediatric exclusivity is added to any existing patent or non-patent exclusivity period for which the drug is eligible. Orphan drug products are also eligible for pediatric exclusivity if the FDA requests and the company completes pediatric clinical trials. Under the Biologics Price Competition and Innovation Act, the FDA may grant 12 years of data exclusivity for innovative biological products.

#### *Foreign Regulation*

Outside the United States, our ability to market a product is contingent upon receiving a marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. At present, foreign marketing authorizations are applied for at a national level, although within the European Union (EU) registration procedures are available to companies wishing to market a product in more than one EU member state. If the competent regulatory authority is satisfied that adequate evidence of safety, quality and efficacy has been presented, a marketing authorization may be granted. This foreign regulatory approval process involves all of the risks associated with FDA approval discussed above and may also include additional risks.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in non-US countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a process that requires the submission of a clinical trial application, or CTA, much like an IND prior to the commencement of human clinical trials. In Europe, a CTA must be submitted to the competent national health authority and to independent ethics committees in each country in which a company plans to conduct clinical trials. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed in that country and are conducted in accordance with GCP and other applicable regulatory requirements.

To obtain regulatory approval of an investigational drug under EU regulatory systems, we must submit a marketing authorization application (MAA). This application is similar to the NDA in the United States, with the exception of, among other things, country-specific document requirements. Drugs can be authorized in the EU by using (i) the centralized authorization procedure, (ii) the mutual recognition procedure, (iii) the decentralized procedure or (iv) national authorization procedures.

The European Medicines Agency (EMA) implemented the centralized procedure for the approval of human drugs to facilitate marketing authorizations that are valid throughout the EU. This procedure results in a single marketing authorization granted by the European Commission that is valid across the EU. Under the centralized procedure, the maximum timeframe for the evaluation of a marketing authorization application by the EMA is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the Committee for Medicinal Products for Human Use (CHMP)). A positive opinion on the MAA by the CHMP then needs to be endorsed by the European Commission. Accelerated assessment might be granted by the CHMP in exceptional cases, in which case the EMA ensures that the evaluation for the opinion of the CHMP is completed within 150 days (excluding clock stops) and the opinion issued thereafter.

The mutual recognition procedure (MRP) for the approval of human drugs is an alternative approach to facilitate individual national marketing authorizations within the EU. The MRP may be applied for all human drugs for which the centralized procedure is not obligatory. The MRP is based on the principle of the mutual recognition by EU member states of their respective national marketing authorizations. Based on a marketing authorization in the reference member state, the applicant may apply for marketing authorizations in other member states. In such case, the reference member state shall update its existing assessment report about the drug. After the assessment is completed, copies of the report are sent to all member states, together with the approved summary of product characteristics, labeling and package leaflet. The concerned member states then recognize the decision of the reference member state and the summary of product characteristics, labeling and package leaflet. National marketing authorizations shall be granted within 30 days after acknowledgement of the agreement.

Should any Member State refuse to recognize the marketing authorization by the reference member state, the member states shall make all efforts to reach a consensus. If this fails, the procedure is submitted to an EMA scientific committee for arbitration. The opinion of this EMA Committee is then forwarded to the Commission, for the start of the decision making process. As in the centralized procedure, this process entails consulting various European Commission Directorates General and the Standing Committee on Human Medicinal Products or Veterinary Medicinal Products, as appropriate.

Legislation similar to the Orphan Drug Act has been enacted in other countries outside of the United States, including the EU. The orphan legislation in the EU is available for therapies addressing conditions that affect five or fewer out of 10,000 persons, are life-threatening or chronically debilitating conditions and for which no satisfactory treatment is authorized. The market exclusivity period is for ten years, although that period can be reduced to six years if, at the end of the fifth year, available evidence establishes that the product does not justify maintenance of market exclusivity.

For other countries outside of the EU, such as non-EU countries in Eastern Europe, Latin America, Japan or other countries in Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary. In all cases, again, the clinical trials are conducted in accordance with GCP and the other applicable regulatory requirements.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

## **Manufacturing**

Our manufacturing strategy is to contract with third parties to manufacture the raw materials, our active pharmaceutical ingredients, or API, and finished dosage form for clinical and commercial uses. We currently do not operate manufacturing facilities for clinical or commercial production of JAKAFI, ICLUSIG, or our drug candidates. In addition, we expect for the foreseeable future to continue to rely on third parties for the manufacture of commercial supplies of the raw materials, API and finished drug product for any drugs that we successfully develop and are approved for commercial sale. In this manner, we continue to build and maintain our supply chain and quality assurance resources.

### *Manufacturing of our Products*

Our supply chain for manufacturing raw materials, API and drug product ready for distribution and commercialization is a multi-step international process. Establishing and managing the supply chain requires a significant financial commitment and the creation and maintenance of numerous third-party contractual relationships.

We contract with third parties to manufacture JAKAFI, ICLUSIG, and our drug candidates for clinical and commercial purposes. Third-party manufacturers supply us with raw materials, and other third-party manufacturers convert these raw materials into API or convert the API into final dosage form. For most of our drug candidates, once our raw materials are produced, we rely on one third-party to manufacture the API, another to make finished drug product and a third to package and label the finished product. For ruxolitinib phosphate, the API for JAKAFI, we have two qualified third-party contract manufacturers from which we can source drug substance. The API for ICLUSIG is sourced from Takeda in addition to one qualified third-party contract manufacturer.

We also rely on third-party contract manufacturers to tablet or capsule all of our active pharmaceutical ingredients for clinical and commercial uses. For JAKAFI, we have two qualified third-party manufacturers from which we can source commercial drug product. For ICLUSIG we have two qualified third-party manufacturers from which we can source commercial drug product. Secondary packaging of ICLUSIG is performed by a qualified third-party manufacturer. Primary packaged product for ICLUSIG can be used for clinical and commercial purposes.

We may not be able to obtain sufficient quantities of any of our raw materials, drug candidates, API, or finished goods if our designated manufacturers do not have the capacity or capability to manufacture our products according to our schedule and specifications. If any of these single source suppliers were to become unable or unwilling to supply us with API or finished product that complies with applicable regulatory requirements, we could incur significant delays in our clinical trials or interruption of commercial supply which could have a material adverse effect on our business.

We have established a quality assurance program intended to ensure that our third-party manufacturers and service providers produce materials and provide services, as applicable, in accordance with the FDA and EMA's current Good Manufacturing Practices and other applicable regulations. Our quality assurance program extends to our licensed facilities that oversee the manufacturing and distribution activities.

For our future products, we intend to continue to establish third-party suppliers to manufacture sufficient quantities of our drug candidates to undertake clinical trials and to manufacture sufficient quantities of any product that is approved for commercial sale. If we are unable to contract for large scale manufacturing with third parties on acceptable terms for our future products or develop manufacturing capabilities internally, our ability to conduct large scale clinical trials and meet customer demand for commercial products will be adversely affected.

#### *Third-party Manufacturers*

Our third-party manufacturers are independent entities, under contract with us, who are subject to their own unique operational and financial risks which are out of our control. If we or any of our third-party manufacturers fail to perform as required, this could impair our ability to deliver our products on a timely basis or cause delays in our clinical trials and applications for regulatory approval. To the extent these risks materialize and affect their performance obligations to us, our financial results may be adversely affected.

We believe the technology used to manufacture our products is proprietary. For products manufactured by our third-party manufacturers, we have licensed the necessary aspects of this manufacturing technology that we believe is proprietary to us to enable them to manufacture the products for us. We have agreements with these third-party manufacturers that are intended to restrict these manufacturers from using or revealing our technology, but we cannot be certain that these third-party manufacturers will comply with these restrictions.

While we believe there are multiple third parties capable of providing most of the materials and services we need in order to manufacture API and distribute finished goods, and that supply of materials that cannot be second sourced can be managed with inventory planning, there is always a risk that we may underestimate demand, and that our manufacturing capacity through third-party manufacturers may not be sufficient. In addition, because of the significant lead times involved in our supply chain for ruxolitinib phosphate, we may have less flexibility to adjust our supply in response to changes in demand than if we had shorter lead times. Our strategy is to maintain 24 months of safety stock of API to be able to respond to changes in demand to provide on-time supply of drug product as well as at least 6 months of brite stock bottles.

#### *Access to Supplies and Materials*

Our third-party manufacturers need access to certain supplies and products to manufacture JAKAFI, ICLUSIG, and our drug candidates. If delivery of material from their suppliers were interrupted for any reason or if they are unable to purchase sufficient quantities of raw materials used to manufacture JAKAFI, ICLUSIG, and our drug candidates, they may be unable to ship JAKAFI and ICLUSIG for commercial supply or to supply our drug candidates in development for clinical trials. For example, currently raw materials used to manufacture ruxolitinib phosphate, the API in JAKAFI, are supplied by Chinese-based companies. As a result, an international trade dispute between China and the United States or any other actions by the Chinese government that would limit or prevent Chinese companies from supplying these materials

would adversely affect our ability to manufacture and supply our products to meet market needs and have a material and adverse effect on our operating results.

#### *Agenus*

Under our collaboration with Agenus, Agenus had primary responsibility for manufacturing activities, including selecting and monitoring third-party manufacturers. Under the February 2017 amendment to our collaboration agreement, we assumed primary responsibility for manufacturing activities, including selecting and monitoring third-party manufacturers, of all products from royalty-bearing programs under the collaboration. Manufacturing antibodies and products containing antibodies is a more complex process than manufacturing small molecule drugs and subject to additional risks. The process of manufacturing antibodies and products containing antibodies is highly susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics, and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our drug candidates or in the manufacturing facilities in which our drug candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

### **Research and Development**

Since our inception, we have made substantial investments in research and technology development. During the years ended December 31, 2017, 2016 and 2015, we incurred research and development expenses of \$1.3 billion, \$581.9 million and \$479.5 million, respectively.

### **Human Resources**

As of December 31, 2017, we had 1,208 employees, including 669 in research and development, 93 in medical affairs, 256 in sales and marketing and 190 in operations support, finance and administrative positions. Geographically, 985 employees were based in the United States and 223 employees were based in Europe and Japan. None of our employees are covered by collective bargaining agreements, and management considers relations with our employees to be good.

### **Available Information**

We were incorporated in Delaware in 1991 and our website is located at [www.incyte.com](http://www.incyte.com). We make available free of charge on our website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports, as soon as reasonably practicable after we electronically file or furnish such materials to the Securities and Exchange Commission. Our website and the information contained therein or connected thereto are not intended to be incorporated into this Annual Report on Form 10-K.

### **Item 1A. Risk Factors**

#### **RISKS RELATING TO COMMERCIALIZATION OF OUR PRODUCTS**

*We depend heavily on our lead product, JAKAFI (ruxolitinib), which is marketed as JAKAVI outside the United States. If we are unable to successfully commercialize JAKAFI in its approved indications or to successfully obtain regulatory approval for and commercialize ruxolitinib for the treatment of additional indications, or if we are significantly delayed or limited in doing so, our business may be materially harmed.*

JAKAFI is our first and, currently, only product approved for sale in the United States. It was approved by the U.S. Food and Drug Administration, or FDA, in November 2011 for the treatment of patients with intermediate or high-risk myelofibrosis and in December 2014 for the treatment of patients with polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea, which we refer to as uncontrolled polycythemia vera. Although we have received regulatory approval for these indications, such approval does not guarantee future revenues. While in June 2016 we acquired exclusive rights to develop and commercialize ICLUSIG in the European Union, or EU, and other countries,

we anticipate that JAKAFI product sales will continue to contribute a significant percentage of our total revenues over the next several years.

The commercial success of JAKAFI and our ability to generate and maintain revenues from the sale of JAKAFI will depend on a number of factors, including:

- the number of patients with intermediate or high-risk myelofibrosis or uncontrolled polycythemia vera who are diagnosed with the disease and the number of such patients that may be treated with JAKAFI;
- the acceptance of JAKAFI by patients and the healthcare community;
- whether physicians, patients and healthcare payors view JAKAFI as therapeutically effective and safe relative to cost and any alternative therapies;
- the ability to obtain and maintain sufficient coverage or reimbursement by third-party payors;
- the ability of our third-party manufacturers to manufacture JAKAFI in sufficient quantities with acceptable quality;
- the ability of our company and our third-party providers to provide marketing and distribution support for JAKAFI;
- the label and promotional claims allowed by the FDA;
- the maintenance of regulatory approval for the approved indications in the United States; and
- our ability to develop, obtain regulatory approval for and commercialize ruxolitinib in the United States for additional indications.

If we are not successful in commercializing JAKAFI in the United States, or are significantly delayed or limited in doing so, our business may be materially harmed and we may need to delay other drug discovery and development initiatives or even significantly curtail operations.

In addition, our receipt of royalties under our collaboration agreement with Novartis for sales of JAKAFI outside the United States will depend on factors similar to those listed above for jurisdictions outside the United States.

***If we are unable to obtain, or maintain at anticipated levels, reimbursement for our products from government health administration authorities, private health insurers and other organizations, our pricing may be affected or our product sales, results of operations or financial condition could be harmed.***

We may not be able to sell our products on a profitable basis or our profitability may be reduced if we are required to sell our products at lower than anticipated prices or reimbursement is unavailable or limited in scope or amount. JAKAFI and ICLUSIG are expensive and almost all patients will require some form of third-party coverage to afford their cost. Our future revenues and profitability will be adversely affected if we cannot depend on government and other third-party payors to defray the cost of our products to the patient. Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country-by-country basis. Reimbursement in the EU must be negotiated on a country-by-country basis and in many countries the product cannot be commercially launched until reimbursement is approved. The timing to complete the negotiation process in each country is highly uncertain, and in some countries, we expect that it may exceed 12 months. Risks related to pricing and reimbursement are described below under “— Other Risks Relating to our Business— Health care reform measures could impact the pricing and profitability of pharmaceuticals, and adversely affect the commercial viability of our products and drug candidates. Our ability to generate revenues will be diminished if we are unable to obtain an adequate level of reimbursement from private insurers, government insurance programs or other third-party payors of health care costs, which could be affected by current and potential healthcare reform legislation.” If government and other third-party payors refuse to provide

coverage and reimbursement with respect to our products, determine to provide a lower level of coverage and reimbursement than anticipated, or reduce previously approved levels of coverage and reimbursement, then our pricing or reimbursement for our products may be affected and our product sales, results of operations or financial condition could be harmed.

***We depend upon a limited number of specialty pharmacies and wholesalers for a significant portion of any revenues from JAKAFI, and the loss of, or significant reduction in sales to, any one of these specialty pharmacies or wholesalers could adversely affect our operations and financial condition.***

We sell JAKAFI primarily to specialty pharmacies and wholesalers. Specialty pharmacies dispense JAKAFI to patients in fulfillment of prescriptions and wholesalers sell JAKAFI to hospitals and physician offices. We do not promote JAKAFI to specialty pharmacies or wholesalers, and they do not set or determine demand for JAKAFI. Our ability to successfully commercialize JAKAFI will depend, in part, on the extent to which we are able to provide adequate distribution of JAKAFI to patients. Although we have contracted with a number of specialty pharmacies and wholesalers, they are expected generally to carry a very limited inventory and may be reluctant to be part of our distribution network in the future if demand for the product does not increase. Further, it is possible that these specialty pharmacies and wholesalers could decide to change their policies or fees, or both, at some time in the future. This could result in their refusal to carry smaller volume products such as JAKAFI, or lower margins or the need to find alternative methods of distributing our product. Although we believe we can find alternative channels to distribute JAKAFI on relatively short notice, our revenue during that period of time may suffer and we may incur additional costs to replace any such specialty pharmacy or wholesaler. The loss of any large specialty pharmacy or wholesaler as part of our distribution network, a significant reduction in sales we make to specialty pharmacies or wholesalers, or any failure to pay for the products we have shipped to them could materially and adversely affect our results of 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.***

Prior to our commercialization of JAKAFI, we had no experience selling and marketing drug products and with pricing and obtaining adequate third-party reimbursement for drug products. Under our collaboration and license agreement with Novartis, we have retained commercialization rights to JAKAFI in the United States. We have established commercial capabilities in the United States, but cannot guarantee that we will be able to enter into and maintain any marketing, distribution or third-party logistics agreements with third-party providers on acceptable terms, if at all. In connection with our June 2016 acquisition from ARIAD Pharmaceuticals, Inc. we licensed rights to develop and commercialize ICLUSIG in certain countries and we acquired the European sales, marketing and distribution operations of ARIAD. We may not be able to maintain those operations or retain their personnel or distribution arrangements. We may not be able to correctly judge the size and experience of the sales and marketing force and the scale of distribution capabilities necessary to successfully market and sell our products. Establishing and maintaining sales, marketing and distribution capabilities are expensive and time consuming. Competition for personnel with experience in sales and marketing can be high. Our expenses associated with building and maintaining the sales force and distribution capabilities may be disproportional compared to the revenues we may be able to generate on sales of 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.***

We cannot guarantee that we will be able to maintain regulatory approval to market our products in the jurisdictions in which they are currently marketed. If we do not maintain our regulatory approval to market our products, in particular JAKAFI, our results of operations will be materially harmed. We and our collaborators, third-party manufacturers and suppliers are subject to rigorous and extensive regulation by the FDA and other federal and state agencies as well as foreign governmental agencies. These regulations continue to apply after product marketing approval, and cover, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, risk mitigation, and adverse event reporting requirements.

The commercialization of our products is subject to post-regulatory approval product surveillance, and our products may have to be withdrawn from the market or subject to restrictions if previously unknown problems occur. Regulatory agencies may also require additional clinical trials or testing for our products, and our products may be recalled

or may be subject to reformulation, additional studies, changes in labeling, warnings to the public and negative publicity. For example, from late 2013 through 2014, ICLUSIG was subject to review by the European Medicines Agency, or EMA, of the benefits and risks of ICLUSIG to better understand the nature, frequency and severity of events obstructing the arteries or veins, the potential mechanism that leads to these side effects and whether there needed to be a revision in the dosing recommendation, patient monitoring and a risk management plan for ICLUSIG. This review was completed in January 2015, with additional warnings in the product information but without any change in the approved indications. The EMA could take additional actions in the future that reduce the commercial potential of ICLUSIG.

Failure to comply with the laws and regulations administered by the FDA or other agencies could result in:

- administrative and judicial sanctions, including warning letters;
- fines and other civil penalties;
- suspension or withdrawal of regulatory approval to market our products;
- interruption of production;
- operating restrictions;
- product recall or seizure;
- injunctions; and
- criminal prosecution.

The occurrence of any such event may have a material adverse effect on our business.

***If the use of our products harms patients, or is perceived to harm patients even when such harm is unrelated to our products, our regulatory approvals could be revoked or otherwise negatively impacted or we could be subject to costly and damaging product liability claims.***

The testing of JAKAFI and ICLUSIG, the manufacturing, marketing and sale of JAKAFI and the marketing and sale of ICLUSIG expose us to product liability and other risks. Side effects and other problems experienced by patients from the use of our products could:

- lessen the frequency with which physicians decide to prescribe our products;
- encourage physicians to stop prescribing our products to their patients who previously had been prescribed our products;
- cause serious harm to patients that may give rise to product liability claims against us; and
- result in our need to withdraw or recall our products from the marketplace.

If our products are used by a wide patient population, new risks and side effects may be discovered, the rate of known risks or side effects may increase, and risks previously viewed as less significant could be determined to be significant.

Previously unknown risks and adverse effects of our products may also be discovered in connection with unapproved, or off-label, uses of our products. We are prohibited by law from promoting or in any way supporting or encouraging the promotion of our products for off-label uses, but physicians are permitted to use products for off-label purposes. In addition, we are studying and expect to continue to study JAKAFI in diseases for potential additional indications in controlled clinical settings, and independent investigators are doing so as well. In the event of any new risks

or adverse effects discovered as new patients are treated for intermediate or high-risk myelofibrosis or uncontrolled polycythemia vera and as JAKAFI is studied in or used by patients for off-label indications, regulatory authorities may delay or revoke their approvals, we may be required to conduct additional clinical trials, make changes in labeling of JAKAFI, reformulate JAKAFI or make changes and obtain new approvals. We may also experience a significant drop in the sales of JAKAFI, experience harm to our reputation and the reputation of JAKAFI in the marketplace or become subject to lawsuits, including class actions. Any of these results could decrease or prevent sales of JAKAFI or substantially increase the costs and expenses of commercializing JAKAFI. Similar results could occur with respect to our commercialization of ICLUSIG.

Patients who have been enrolled in our clinical trials or who may use our products in the future often have severe and advanced stages of disease and known as well as unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may or may not be related to our products. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our products, the investigation into the circumstance may be time consuming or inconclusive. These investigations may interrupt our sales efforts, impact and limit the type of regulatory approvals our products receive or maintain, or delay the regulatory approval process in other countries.

Factors similar to those listed above also apply to our collaboration partner Novartis and to ICLUSIG for jurisdictions outside the United States.

***If we market our products in a manner that violates various laws and regulations, we may be subject to civil or criminal penalties.***

In addition to FDA and related regulatory requirements, we are subject to health care “fraud and abuse” laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally- or state-financed health care programs. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities.

Although physicians are permitted, based on their medical judgment, to prescribe products for indications other than those approved by the FDA, manufacturers are prohibited from promoting their products for such off-label uses. We market JAKAFI for intermediate or high-risk myelofibrosis and uncontrolled polycythemia vera and provide promotional materials to physicians regarding the use of JAKAFI for these indications. Although we believe that our promotional materials for physicians do not constitute off-label promotion of JAKAFI, the FDA or other agencies may disagree. If the FDA or another agency determines that our promotional materials or other activities constitute off-label promotion of JAKAFI, it could request that we modify our promotional materials or other activities or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they believe that the alleged improper promotion led to the submission and payment of claims for an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. Even if it is later determined we are not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our position and have to divert significant management resources from other matters.

The European Union and member countries impose similar strict restrictions on the promotion and marketing of drug products. The off-label promotion of medicinal products is prohibited in the EU and in other territories. The promotion of medicinal products that are not subject to a marketing authorization is also prohibited in the EU. Violations of the rules governing the promotion of medicinal products in the EU and in other territories could be penalized by administrative measures, fines and imprisonment.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. In recent years, several states and localities, including California, Connecticut, the District of Columbia, Massachusetts, Minnesota, Nevada, New Mexico, Texas, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar legislation is being considered in other states. Additionally, as part of the Patient Protection and Affordable Care Act, the federal government has enacted the Physician Payment Sunshine provisions. The Sunshine provisions require manufacturers to publicly report certain payments or other transfers of value made to physicians and teaching hospitals. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity. See also “—Other Risks Relating to our Business—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” below.

***Competition for our products could harm our business and result in a decrease in our revenue.***

Present and potential competitors for JAKAFI could include major pharmaceutical and biotechnology companies, as well as specialty pharmaceutical firms. For example, in January 2018, Celgene Corporation announced an agreement to acquire Impact Biomedicines, which is developing a drug candidate for the treatment of myelofibrosis and polycythemia vera. See “—Other Risks Relating to our Business— 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” for a description of risks relating to this type of competition. In addition, JAKAFI could face competition from generic products. As a result of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, in the United States, generic manufacturers may seek approval of a generic version of an innovative pharmaceutical by filing with the FDA an Abbreviated New Drug Application, or ANDA. The Hatch-Waxman Act provides significant incentives to generic manufacturers to challenge U.S. patents on successful innovative pharmaceutical products. In February 2016, we received a notice letter regarding an ANDA that requested approval to market a generic version of JAKAFI and purported to challenge patents covering ruxolitinib phosphate and its use that expire in 2028. The notice letter does not challenge the ruxolitinib composition of matter patent, which expires in December 2027. To date, to our knowledge, the FDA has taken no action with respect to this ANDA. Separately, in January 2018 the Patent Trial and Appeal Board of United States Patent and Trademark Office denied a petition challenging our patent covering deuterated ruxolitinib analogs, although the challenging party retains the right to challenge the validity of the patent in federal court. There can be no assurance that our patents will be upheld or that any litigation in which we might engage with any such generic manufacturer would be successful in protecting JAKAFI’s exclusivity. The entry of a generic version of JAKAFI could result in a decrease in JAKAFI sales and materially harm our business, operating results and financial condition.

ICLUSIG currently competes with existing therapies that are approved for the treatment of patients with chronic myeloid leukemia, or CML, who are resistant or intolerant to prior tyrosine kinase inhibitor, or TKI, therapies, on the basis of, among other things, efficacy, cost, breadth of approved use and the safety and side-effect profile. In addition, a generic version of imatinib was launched in the United States in February 2016, and generic versions are expected to be launched in other markets. Although we currently believe that generic versions of imatinib will not materially impact our commercialization of ICLUSIG, given ICLUSIG’s various indication statements globally that are currently focused on resistant or intolerant CML, we cannot be certain how physicians, payors, patients, regulatory authorities and other market participants will respond to the availability of generic versions of imatinib.

**OTHER RISKS RELATING TO OUR BUSINESS**

***We may be unsuccessful in our efforts to discover and develop drug candidates and commercialize drug products.***

None of our drug candidates, other than JAKAFI/JAKAVI, has received regulatory approval. Our ability to discover and develop drug candidates and to commercialize additional drug products will depend on our ability to:

- hire and retain key employees;

- identify high quality therapeutic targets;
- identify potential drug candidates;
- develop products internally or license drug candidates from others;
- identify and enroll suitable human subjects, either in the United States or abroad, for our clinical trials;
- complete laboratory testing;
- commence, conduct and complete safe and effective clinical trials on humans;
- obtain and maintain necessary intellectual property rights to our products;
- obtain and maintain necessary regulatory approvals for our products, both in the United States and abroad;
- enter into arrangements with third parties to provide services or to manufacture our products on our behalf;
- deploy sales and marketing resources effectively or enter into arrangements with third parties to provide these functions in compliance with all applicable laws;
- obtain appropriate coverage and reimbursement levels for the cost of our products from governmental authorities, private health insurers and other third-party payors;
- lease facilities at reasonable rates to support our growth; and
- enter into arrangements with third parties to license and commercialize our products.

We have limited experience with many of the activities listed above and may not be successful in discovering, developing, or commercializing additional drug products. Discovery and development of drug candidates are expensive, uncertain and time-consuming, and we do not know if our efforts will lead to discovery of any drug candidates that can be successfully developed and marketed. Of the compounds or biologics that we identify as potential drug products or that we may in-license from other companies, including potential products for which we are conducting clinical trials, only a few, if any, are likely to lead to successful drug development programs and commercialized drug products.

***We depend heavily on the success of our most advanced drug candidates. We might not be able to commercialize any of our drug candidates successfully, and we may spend significant time and money attempting to do so.***

We have invested significant resources in the development of our most advanced drug candidates. Ruxolitinib is in Phase II and Phase III clinical trials for the treatment of patients with steroid-refractory acute graft-versus-host disease and is in other clinical trials. Epacadostat is in a number of Phase III clinical trials. Further, we have a number of drug candidates in Phase I and Phase II clinical trials. Our ability to generate product revenues will depend on the successful development and eventual commercialization of our most advanced drug candidates. We, or our collaborators or licensees, may decide to discontinue development of any or all of our drug candidates at any time for commercial, scientific or other reasons. For example, in early 2016, we decided to discontinue the studies of ruxolitinib in pancreatic cancer and solid tumors and itacitinib in pancreatic cancer. If a product is developed but not approved or marketed, we may have spent significant amounts of time and money on it, which could adversely affect our operating results and financial condition as well as our business plans.

***If we or our collaborators are unable to obtain regulatory approval for our drug candidates in the United States and foreign jurisdictions, we or our collaborators will not be permitted to commercialize products resulting from our research.***

In order to commercialize drug products in the United States, drug candidates will have to obtain regulatory

approval from the FDA. Satisfaction of regulatory requirements typically takes many years. To obtain regulatory approval, we or our collaborators, as the case may be, must first show that our drug candidates are safe and effective for target indications through preclinical testing (animal testing) and clinical trials (human testing). Preclinical testing and clinical development are long, expensive and uncertain processes, and we do not know whether the FDA will allow us or our collaborators to undertake clinical trials of any drug candidates in addition to our compounds currently in clinical trials. If regulatory approval of a product is granted, this approval will be limited to those disease states and conditions for which the product is demonstrated through clinical trials to be safe and effective.

Completion of clinical trials may take several years and failure may occur at any stage of testing. The length of time required varies substantially according to the type, complexity, novelty and intended use of the drug candidate. Interim results of a preclinical test or clinical trial do not necessarily predict final results, and acceptable results in early clinical trials may not be repeated in later clinical trials. For example, a drug candidate that is successful at the preclinical level may cause harmful or dangerous side effects when tested at the clinical level. Our rate of commencement and completion of clinical trials may be delayed, and existing clinical trials with our drug candidates may be stopped, due to many potential factors, including:

- the high degree of risk and uncertainty associated with drug development;
- our inability to formulate or manufacture sufficient quantities of materials for use in clinical trials;
- variability in the number and types of patients available for each study;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- unforeseen safety issues or side effects;
- poor or unanticipated effectiveness of drug candidates during the clinical trials; or
- government or regulatory delays.

Data obtained from clinical trials are susceptible to varying interpretation, which may delay, limit or prevent regulatory approval. Many companies in the pharmaceutical and biopharmaceutical industry, including our company, have suffered significant setbacks in advanced clinical trials, even after achieving promising results in earlier clinical trials. In addition, regulatory authorities may refuse or delay approval as a result of other factors, such as changes in regulatory policy during the period of product development and regulatory agency review. For example, the FDA has in the past required, and could in the future require, that we or our collaborators conduct additional trials of any of our drug candidates, which would result in delays. In April 2017, we and our collaborator Lilly announced that the FDA had issued a complete response letter for the New Drug Application (NDA) of OLUMIANT (baricitinib) as a once-daily oral medication for the treatment of moderate-to-severe rheumatoid arthritis. The letter indicated that the FDA was unable to approve the application in its current form. Specifically, the FDA indicated that additional clinical data are needed to determine the most appropriate doses. The FDA also stated that additional data are necessary to further characterize safety concerns across treatment arms.

Compounds or biologics developed by us or with or by our collaborators and licensees may not prove to be safe and effective in clinical trials and may not meet all of the applicable regulatory requirements needed to receive marketing approval. For example, in January 2016, a Phase II trial that was evaluating ruxolitinib in combination with regorafenib in patients with relapsed or refractory metastatic colorectal cancer and high C-reactive protein was stopped early after a planned analysis of interim efficacy data determined that the likelihood of the trial meeting its efficacy endpoint was insufficient. In addition, in February 2016, we made a decision to discontinue our JANUS 1 study, our JANUS 2 study, our other studies of ruxolitinib in colorectal, breast and lung cancer, and our study of INCB39110 in pancreatic cancer after a planned analysis of interim efficacy data of JANUS 1 demonstrated that ruxolitinib plus capecitabine did not show a sufficient level of efficacy to warrant continuation. If clinical trials of any of our compounds or biologics are stopped for safety, efficacy or other reasons or fail to meet their respective endpoints, our overall development plans, business, prospects, expected operating results and financial condition could be materially harmed and the value of our company could be negatively affected.

Outside the United States, our and our collaborators' ability to market a product is contingent upon receiving a marketing authorization from the appropriate regulatory authorities. This foreign regulatory approval process typically includes all of the risks associated with the FDA approval process described above and may also include additional risks. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country and may require us to perform additional testing and expend additional resources. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA.

***Health care reform measures could impact the pricing and profitability of pharmaceuticals, and adversely affect the commercial viability of our products and drug candidates. Our ability to generate revenues will be diminished if we are unable to obtain an adequate level of reimbursement from private insurers, government insurance programs or other third-party payors of health care costs, which could be affected by current and potential healthcare reform legislation.***

Our ability to commercialize our current and any future approved products successfully will depend in part on the extent to which adequate reimbursement levels for the cost of our products and related treatment are obtained from third-party payors, such as private insurers, government insurance programs, including Medicare and Medicaid, health maintenance organizations (HMOs) and other health care related organizations.

In recent years, through legislative and regulatory actions, the federal government has made substantial changes to various payment systems under the Medicare and other federal health care programs. Comprehensive reforms to the U.S. healthcare system were enacted, including changes to the methods for, and amounts of, Medicare reimbursement. While there is currently significant uncertainty regarding the implementation of some of these reforms or the scope of amended or additional reforms, the implementation of reforms could significantly reduce payments from Medicare and Medicaid. Reforms or other changes to these payment systems, may change the availability, methods and rates of reimbursements from Medicare, private insurers and other third-party payors for our current and any future approved products. Some of these changes and proposed changes could result in reduced reimbursement rates or in eliminating dual sources of payment, which could reduce the price that we or any of our collaborators or licensees receive for any products in the future, and which would adversely affect our business strategy, operations and financial results. Further federal and state proposals to regulate prices of pharmaceutical products and other health care reforms are possible, which could limit the prices that can be charged for any of our products and may further limit the commercial viability of our products and drug candidates. In certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. If reimbursement for our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed. There may be future changes that result in reductions in current coverage and reimbursement levels for our current or any future approved products, and we cannot predict the scope of any future changes or the impact that those changes would have on our operations.

Third-party payors are increasingly challenging the prices charged for medical products and services. Also, the trend toward managed health care in the United States, the organizations for which could control or significantly influence the purchase of health care services and products, as well as legislative and regulatory proposals to reform health care or reduce government insurance programs, may all result in lower prices for or rejection of our products. Adoption of our products by the medical community may be limited without adequate reimbursement for those products. Cost control initiatives may decrease coverage and payment levels for our products and, in turn, the price that we will be able to charge for any product. Our products may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a profitable basis. We are unable to predict all changes to the coverage or reimbursement methodologies that will be applied by private or government payors to our current and any future approved products.

The continuing efforts of legislatures, health agencies and third-party payors to contain or reduce the costs of health care, any denial of private or government payor coverage or inadequate reimbursement for our drug candidates could materially and adversely affect our business strategy, operations, future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers, collaborators and licensees and the availability of capital. The same risks apply to our compounds developed and marketed by our collaborators, and our future potential milestone and royalty revenues could be affected in a similar manner.

***We depend on our collaborators and licensees for the future development and commercialization of some of our drug candidates. Conflicts may arise between our collaborators and licensees and us, or our collaborators and licensees may choose to terminate their agreements with us, which may adversely affect our business.***

We have licensed to Novartis rights to ruxolitinib outside of the United States and worldwide rights to our MET inhibitor compounds and licensed to Lilly worldwide rights to baricitinib. We have also licensed to Pfizer our portfolio of CCR2 antagonist compounds. Under the terms of our agreements with these collaborators, we have no or limited control over the further clinical development of these drug candidates and any revenues we may receive if these drug candidates receive regulatory approval and are commercialized will depend primarily on the development and commercialization efforts of others. While OLUMIANT (baricitinib) was approved by the European Commission in February 2017 for the treatment of moderate-to-severe rheumatoid arthritis in adult patients and by Japan's Ministry of Health, Labor and Welfare in July 2017 for the treatment of rheumatoid arthritis in patients with inadequate response to standard-of-care therapies, if the New Drug Application for baricitinib for the treatment of moderate-to-severe rheumatoid arthritis does not receive FDA approval, we will not receive future milestone payments or royalties related to that indication in the United States under our agreement with Lilly. In addition, even if baricitinib is approved by the FDA in this indication, delays in any such approval, or any label modifications or restrictions in connection with any approval by the FDA, European or other regulatory authorities, or the existence of other risks relating to approved drug products, including those described under "Risks Relating to Commercialization of Our Products," could delay the receipt of and reduce resulting potential royalty and milestone revenue from baricitinib.

Conflicts may arise with our collaborators and licensees if they pursue alternative technologies or develop alternative products either on their own or in collaboration with others as a means for developing treatments for the diseases that we have targeted. Competing products and product opportunities may lead our collaborators and licensees to withdraw their support for our drug candidates. Any failure of our collaborators and licensees to perform their obligations under our agreements with them or otherwise to support our drug candidates could negatively impact the development of our drug candidates, lead to our loss of potential revenues from product sales and milestones and delay our achievement, if any, of profitability. Additionally, conflicts may arise if, among other things, there is a dispute about the achievement and payment of a milestone amount or the ownership of intellectual property that is developed during the course of a collaborative relationship.

Our existing collaborative and license agreements can be terminated by our collaborators and licensees for convenience, among other circumstances. If any of our collaborators or licensees terminates its agreement with us, or terminates its rights with respect to certain indications or drug candidates, we may not be able to find a new collaborator for them, and our business could be adversely affected. Should an agreement be terminated before we have realized the benefits of the collaboration or license, our reputation could be harmed, we may not obtain revenues that we anticipated receiving, and our business could be adversely affected.

***The success of our drug discovery and development efforts may depend on our ability to find suitable collaborators to fully exploit our capabilities. If we are unable to establish collaborations or if these future collaborations are unsuccessful in the development and commercialization of our drug candidates, our research, development and commercialization efforts may be unsuccessful, which could adversely affect our results of operations and financial condition.***

An important element of our business strategy is to enter into collaborative or license arrangements with other parties, under which we license our drug candidates to those parties for development and commercialization or under which we study our drug candidates in combination with other parties' compounds or biologics. For example, in addition to our Novartis, Lilly and Pfizer collaborations, we have entered into clinical study relationships with respect to epacadostat and are evaluating strategic relationships with respect to several of our other programs. However, because collaboration and license arrangements are complex to negotiate, we may not be successful in our attempts to establish these arrangements. Also, we may not have drug candidates that are desirable to other parties, or we may be unwilling to license a drug candidate to a particular party because such party interested in it is a competitor or for other reasons. The terms of any such arrangements that we establish may not be favorable to us. Alternatively, potential collaborators may decide against entering into an agreement with us because of our financial, regulatory or intellectual property position or for scientific, commercial or other reasons. If we are not able to establish collaboration or license arrangements, we may not be able to develop and commercialize a drug product, which could adversely affect our business and our revenues.

We will likely not be able to control the amount and timing of resources that our collaborators or licensees devote to our programs or drug candidates. If our collaborators or licensees prove difficult to work with, are less skilled than we originally expected, do not devote adequate resources to the program, are unable to obtain regulatory approval of our drug candidates, pursue alternative technologies or develop alternative products, or do not agree with our approach to development or manufacturing of the drug candidate, the relationship could be unsuccessful. Our collaborations with respect to epacadostat involve the study of our collaborators' drugs used in combination with epacadostat on a number of indications or tumor types, many of which are the same across multiple collaborations. We cannot assure you that potential conflicts will not arise or be alleged among these collaborations. If a business combination involving a collaborator or licensee and a third-party were to occur, the effect could be to terminate or cause delays in development of a drug candidate.

***If we fail to enter into additional licensing agreements or if these arrangements are unsuccessful, our business and operations might be adversely affected.***

In addition to establishing collaborative or license arrangements under which other parties license our drug candidates for development and commercialization or under which we study our drug candidates in combination with such parties' compounds or biologics, we may explore opportunities to develop our clinical pipeline by in-licensing drug candidates or therapeutics targets that fit within our focus on oncology, such as our collaborations with Agenus Inc., Calithera Biosciences, Inc., MacroGenics, Inc., Merus N.V., and Syros Pharmaceuticals, Inc., or explore additional opportunities to further develop and commercialize existing drug candidates in specific jurisdictions, such as our June 2016 acquisition of the development and commercialization rights to ICLUSIG in certain countries. We may be unable to enter into any additional in-licensing agreements because suitable drug candidates that are within our expertise may not be available to us on terms that are acceptable to us or because competitors with greater resources seek to in-license the same drug candidates. Drug candidates that we would like to develop or commercialize may not be available to us because they are controlled by competitors who are unwilling to license the rights to the drug candidate to us. In addition, we may enter into license agreements that are unsuccessful and our business and operations might be adversely affected if we are unable to realize the expected economic benefits of a collaboration or other licensing arrangement, by the termination of a drug candidate and termination and winding down of the related license agreement, or due to other business or regulatory issues that may adversely affect a licensor's ability to continue to perform its obligations under an in-license agreement. As discussed above under "We depend on our collaborators and licensees for the future development and commercialization of some of our drug candidates. Conflicts may arise between our collaborators and licensees and us, or our collaborators and licensees may choose to terminate their agreements with us, which may adversely affect our business," conflicts or other issues may arise with our licensors. Those conflicts could result in delays in our plans to develop drug candidates or result in the expenditure of additional funds to resolve those conflicts that could have an adverse effect on our results of operations. We may also need to license drug delivery or other technology in order to continue to develop our drug candidates. If we are unable to enter into additional agreements to license drug candidates, drug delivery technology or other technology or if these arrangements are unsuccessful, our research and development efforts could be adversely affected.

***Even if a drug candidate that we develop receives regulatory approval, we may decide not to commercialize it if we determine that commercialization of that product would require more money and time than we are willing to invest.***

Even if any of our drug candidates receives regulatory approval, it could be subject to post-regulatory surveillance, and may have to be withdrawn from the market or subject to restrictions if previously unknown problems occur. Regulatory agencies may also require additional clinical trials or testing, and the drug product may be recalled or may be subject to reformulation, additional studies, changes in labeling, warnings to the public and negative publicity. As a result, we may not continue to commercialize a product even though it has obtained regulatory approval. Further, we may decide not to continue to commercialize a product if the market does not accept the product because it is too expensive or because third parties, such as insurance companies or Medicare, have not approved it for substantial reimbursement. In addition, we may decide not to continue to commercialize a product if competitors develop and commercialize similar or superior products or have proprietary rights that preclude us from ultimately marketing our products.

***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.***

Even if we are successful in gaining regulatory approval of any of our drug candidates in addition to JAKAFI or acquire rights to approved drug products in addition to ICLUSIG, we may not generate significant product revenues and we may not become profitable if these drug products do not achieve an adequate level of acceptance. Physicians may not recommend our drug products until longer-term clinical data or other factors demonstrate the safety and efficacy of our drug products as compared to other alternative treatments. Even if the clinical safety and efficacy of our drug products is established, physicians may elect not to prescribe these drug products for a variety of reasons, including the reimbursement policies of government and other third-party payors and the effectiveness of our competitors in marketing their products.

Market acceptance of our drug products, if approved for commercial sale, will depend on a number of factors, including:

- the willingness and ability of patients and the healthcare community to use our drug products;
- the ability to manufacture our drug products in sufficient quantities with acceptable quality and to offer our drug products for sale at competitive prices;
- the perception of patients and the healthcare community, including third-party payors, regarding the safety, efficacy and benefits of our drug products compared to those of competing products or therapies;
- the label and promotional claims allowed by the FDA;
- the pricing and reimbursement of our drug products relative to existing treatments; and
- marketing and distribution support for our drug products.

***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 have limited internal resources and capacity to perform preclinical testing and clinical trials. As part of our development strategy, we often hire clinical research organizations, or CROs, to perform preclinical testing and clinical trials for drug candidates. If the CROs that we hire to perform our preclinical testing and clinical trials do not meet deadlines, do not follow proper procedures, or a conflict arises between us and our CROs, our preclinical testing and clinical trials may take longer than expected, may cost more, may be delayed or may be terminated. If we were forced to find a replacement entity to perform any of our preclinical testing or clinical trials, we may not be able to find a suitable entity on favorable terms, or at all. Even if we were able to find another company to perform a preclinical test or clinical trial, the delay in the test or trial may result in significant additional expenditures. Events such as these may result in delays in our obtaining regulatory approval for our drug candidates or our ability to commercialize our products and could result in increased expenditures that would adversely affect our operating results.

***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.***

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our drug discovery and development efforts may target diseases and conditions that are already subject to existing therapies or that are being developed by our competitors, many of which have substantially greater resources, larger research and development staffs and facilities, more experience in completing preclinical testing and clinical trials, and formulation, marketing and manufacturing capabilities. As a result of these resources, our competitors may develop drug products that render our products obsolete or noncompetitive by developing more effective drugs, developing their products more efficiently or pricing their products more competitively. Our ability to develop competitive products would be limited if our competitors succeeded in obtaining regulatory approvals for drug candidates more rapidly than we were able to or in obtaining patent protection or other intellectual property rights that limited our drug development efforts. Any drug products resulting from our research and development efforts, or from our joint efforts with collaborators

or licensees, might not be able to compete successfully with our competitors' existing and future products, or obtain regulatory approval in the United States or elsewhere. The development of products or processes by our competitors with significant advantages over those that we are developing could harm our future revenues and profitability.

***Our reliance on other parties to manufacture our drug products and drug candidates could result in a short supply of the drugs, delays in clinical trials or drug development, increased costs, and withdrawal or denial of a regulatory authority's approval.***

We do not currently operate manufacturing facilities for clinical or commercial production of JAKAFI and our other drug candidates or for ICLUSIG. We currently hire third parties to manufacture the raw materials, active pharmaceutical ingredient, or API, and finished drug product of JAKAFI, ICLUSIG and our other drug candidates for clinical trials. In addition, we expect to continue to rely on third parties for the manufacture of commercial supplies of raw materials, API and finished drug product for any drugs that we successfully develop. We also hire third parties to package and label the finished product. The FDA requires that the raw materials, API and finished product for JAKAFI and our other drug candidates be manufactured according to its current Good Manufacturing Practices regulations and regulatory authorities in other countries have similar requirements. There are only a limited number of manufacturers that comply with these requirements. Failure to comply with current Good Manufacturing Practices and the applicable regulatory requirements of other countries in the manufacture of our drug candidates and products could result in the FDA or a foreign regulatory authority halting our clinical trials, withdrawing or denying regulatory approval of our drug product, enforcing product recalls or other enforcement actions, which could have a material adverse effect on our business.

We may not be able to obtain sufficient quantities of our drug candidates or any drug products we may develop if our designated manufacturers do not have the capacity or capability to manufacture them according to our schedule and specifications. Manufacturers of pharmaceutical products often encounter difficulties in production, especially in scaling up initial production. These problems include difficulties with production costs and yields, quality control and assurance and shortages of qualified personnel. In addition, we may not be able to arrange for our drug candidates or any drug products that we may develop to be manufactured by one of these parties on reasonable terms, if at all. We generally have a single source or a limited number of suppliers that are qualified to supply each of the API and finished product of JAKAFI, ICLUSIG and our other drug candidates and, in the case of JAKAFI, we only have a single source for its raw materials. If any of these suppliers were to become unable or unwilling to supply us with raw materials, API or finished product that complies with applicable regulatory requirements, we could incur significant delays in our clinical trials or interruption of commercial supply that could have a material adverse effect on our business. If we have promised delivery of a drug candidate or drug product and are unable to meet the delivery requirement due to manufacturing difficulties, our development programs could be delayed, we may have to expend additional sums in order to ensure that manufacturing capacity is available when we need it even if we do not use all of the manufacturing capacity, and our business and operating results could be harmed.

We may not be able to adequately manage and oversee the manufacturers we choose, they may not perform as agreed or they may terminate their agreements with us. Foreign manufacturing approval processes typically include all of the risks associated with the FDA approval process for manufacturing and may also include additional risks.

A number of our collaborations involve the manufacture of antibodies. Either we or our collaborators have primary responsibility for manufacturing activities, and we are currently using third-party contract manufacturing organizations. Manufacturing antibodies and products containing antibodies is a more complex process than manufacturing small molecule drugs and subject to additional risks. The process of manufacturing antibodies and products containing antibodies is highly susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics, and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

***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.***

Our activities, and the activities of our collaborators, partners and third-party providers, are subject to extensive government regulation and oversight both in the United States and in foreign jurisdictions. The FDA and comparable agencies in other jurisdictions directly regulate many of our most critical business activities, including the conduct of preclinical and clinical studies, product manufacturing, advertising and promotion, product distribution, adverse event reporting and product risk management. States increasingly have been placing greater restrictions on the marketing practices of healthcare companies. In addition, pharmaceutical and biotechnology companies have been the target of lawsuits and investigations alleging violations of government regulations, including claims asserting submission of incorrect pricing information, impermissible off-label promotion of pharmaceutical products, payments intended to influence the referral of federal or state healthcare business, submission of false claims for government reimbursement, antitrust violations, violations of the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act and similar anti-bribery or anti-corruption laws, or violations related to environmental matters. There is also enhanced scrutiny of company-sponsored patient assistance programs, including insurance premium and co-pay assistance programs and donations to third-party charities that provide such assistance. Violations of governmental regulation by us, our vendors or donation recipients may be punishable by criminal and civil sanctions, including fines and civil monetary penalties and exclusion from participation in government programs, including Medicare and Medicaid. In addition to penalties for violation of laws and regulations, we could be required to repay amounts we received from government payors, or pay additional rebates and interest if we are found to have miscalculated the pricing information we have submitted to the government. Actions taken by federal or local governments, legislative bodies and enforcement agencies with respect to these legal and regulatory compliance matters could also result in reduced demand for our products, reduced coverage of our products by health care payors, or both. We cannot ensure that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, collaborators, partners or third-party providers that would violate the laws or regulations of the jurisdictions in which we operate. Whether or not we have complied with the law, an investigation into alleged unlawful conduct could increase our expenses, damage our reputation, divert management time and attention and adversely affect our business. Risks relating to compliance with laws and regulations may be heightened as we continue to expand our global operations and enter new therapeutic areas with different patient populations, which due to different product distribution methods, marketing programs or patient assistance programs may result in additional regulatory burdens and obligations.

***As 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.***

Our facility in Wilmington, Delaware is our headquarters and is also where we conduct all of our drug discovery, research, development and marketing activities. In addition, natural disasters or actions of activists opposed to aspects of pharmaceutical research may disrupt our experiments or our ability to access or use our facility. The loss of access to or use of our Wilmington, Delaware facility, either on a temporary or permanent basis would result in an interruption of our business and, consequently, would adversely affect our overall business.

***We depend on key employees in a competitive market for skilled personnel, and the loss of the services of any of our key employees or our inability to attract and retain additional personnel would affect our ability to expand our drug discovery and development programs and achieve our objectives.***

We are highly dependent on the members of our executive management team and principal members of our commercial, development, medical, operations and scientific staff. We experience intense competition for qualified personnel. Our future success also depends in part on the continued service of our executive management team and key personnel and our ability to recruit, train and retain essential personnel for our drug discovery and development programs, and for our medical affairs and commercialization activities. If we lose the services of any of these people or if we are unable to recruit sufficient qualified personnel, our research and product development goals, and our commercialization efforts could be delayed or curtailed. We do not maintain “key person” insurance on any of our employees.

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

We expect that if our drug discovery efforts continue to generate drug candidates, our clinical drug candidates continue to progress in development, and we continue to build our development, medical and commercial organizations, we will require significant additional investment in personnel, management and resources. Our ability to achieve our research, development and commercialization objectives depends on our ability to respond effectively to these demands and expand our internal organization, systems, controls and facilities to accommodate additional anticipated growth. If we are unable to manage our growth effectively, our business could be harmed and our ability to execute our business strategy 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.***

As part of our business strategy, we may pursue additional acquisitions of what we believe to be complementary businesses or assets or seek to enter into joint ventures. We also may pursue strategic alliances in an effort to leverage our existing infrastructure and industry experience to expand our product offerings or distribution, or make investments in other companies. For example, in June 2016, we completed the acquisition of the European operations of ARIAD and obtained the exclusive license to develop and commercialize ICLUSIG in Europe and other countries. The success of our acquisitions, joint ventures, strategic alliances and investments will depend on our ability to identify, negotiate, complete and, in the case of acquisitions, integrate those transactions and, if necessary, obtain satisfactory debt or equity financing to fund those transactions. We may not realize the anticipated benefits of any acquisition, joint venture, strategic alliance or investment. We may not be able to integrate acquisitions successfully into our existing business, maintain the key business relationships of businesses we acquire, or retain key personnel of an acquired business, and we could assume unknown or contingent liabilities or incur unanticipated expenses. Integration of acquired companies or businesses also may require management resources that otherwise would be available for ongoing development of our existing business. Any acquisitions or investments made by us also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. For example, in the year ended December 31, 2017, we recorded unrealized losses related to our investments in Agenus Inc. and Merus N.V., and we may in the future experience additional losses related to our investments. In addition, if we choose to issue shares of our stock as consideration for any acquisition, dilution to our stockholders could result.

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

Our acquisition of ARIAD's European operations significantly expanded our operations in Europe, and we plan to continue to expand our operations and conduct certain development activities outside of the United States. We have limited experience with conducting activities outside of the United States. International operations and business expansion plans are subject to numerous additional risks, including:

- multiple, conflicting and changing laws and regulations such as tax laws, privacy regulations, tariffs, export and import restrictions, employment, immigration and labor laws, regulatory requirements, and other governmental approvals, permits and licenses;
- difficulties in staffing and managing foreign operations and difficulties in connection with assimilating and integrating any operations and personnel we might acquire into our company;
- risks associated with obtaining and maintaining, or the failure to obtain or maintain, regulatory approvals for the sale or use of our products in various countries;
- complexities associated with managing government payor systems, multiple payor-reimbursement regimes or patient self-pay systems;
- financial risks, such as longer payment cycles, difficulty obtaining financing in foreign markets, difficulty enforcing contracts and intellectual property rights, difficulty collecting accounts receivable and exposure to foreign currency exchange rate fluctuations;

- general political and economic conditions in the countries in operate, including terrorism and political unrest, curtailment of trade and other business restrictions, and uncertainties associated with the future relationship between the United Kingdom and the European Union; and
- regulatory and compliance risks that relate to maintaining accurate information and control over activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its books and records provisions or its anti-bribery provisions, or similar anti-bribery or anti-corruption laws and regulations.

Although we conducted due diligence of ARIAD's European operations prior to the acquisition, we may discover or identify deficiencies or non-compliance with such laws and regulations as we complete the integration of the ARIAD business and conduct our European operations. Any of the risks described above, if encountered, could significantly increase our costs of operating internationally, prevent us from operating in certain jurisdictions, or otherwise significantly harm our future international expansion and operations, which could have a material adverse effect on our business, financial condition and results of operations.

***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.***

In addition to the risks described above under “—Risks Relating to Commercialization of Our Products—If the use of our products harms patients, or is perceived to harm patients even when such harm is unrelated to our products, our regulatory approvals could be revoked or otherwise negatively impacted or we could be subject to costly and damaging product liability claims,” the conduct of clinical trials of medical products that are intended for human use entails an inherent risk of product liability. If any product that we or any of our collaborators or licensees develops causes or is alleged to cause injury during clinical trials or commercialization, we may be held liable. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities, including substantial damages to be paid to the plaintiffs and legal costs, or we may be required to limit further development and commercialization of our products. Additionally, any product liability lawsuit could cause injury to our reputation, participants and investigators to withdraw from clinical trials, and potential collaborators or licensees to seek other partners, any of which could impact our results of operations.

Our product liability insurance policy may not fully cover our potential liabilities. In addition, we may determine that we should increase our coverage, and this insurance may be prohibitively expensive to us or our collaborators or licensees and may not fully cover our potential liabilities. Since December 30, 2017, we elected to self-insure a portion of our exposure to product liability risks through our wholly-owned captive insurance subsidiary, in tandem with third-party insurance policies. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the development or commercialization of our drug candidates and products, and if our liabilities from any such claims exceed our third-party insurance limits and self-insurance reserves, our results of operations, cash flows and financial condition could be adversely impacted.

***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 are subject to various environmental, health and safety laws and regulations governing, among other things, the use, handling, storage and disposal of regulated substances and the health and safety of our employees. Our research and development processes involve the controlled use of hazardous and radioactive materials and biological waste resulting in the production of hazardous waste products. We cannot completely eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. If any injury or contamination results from our use or the use by our collaborators or licensees of these materials, we may be sued and our liability may exceed our insurance coverage and our total assets. Further, we may be required to indemnify our collaborators or licensees against all damages and other liabilities arising out of our development activities or products produced in connection with these collaborations or licenses. Compliance with the applicable environmental and workplace laws and regulations is expensive. Future changes to environmental, health, workplace and safety laws could cause us to incur additional expense or may restrict our operations or impair our research, development and production efforts.

## RISKS RELATING TO OUR FINANCIAL RESULTS

***We may incur losses in the future and we may not achieve or maintain profitability in the future.***

Due to historical net losses, we had an accumulated deficit of \$2.0 billion as of December 31, 2017. We intend to continue to spend significant amounts on our efforts to discover and develop drugs. As a result, we may incur losses in future periods as well.

We anticipate that our drug discovery and development efforts and related expenditures will increase as we focus on the studies, including preclinical tests and clinical trials prior to seeking regulatory approval, that are required before we can sell a drug product.

The development of drug products will require us to spend significant funds on research, development, testing, obtaining regulatory approvals, manufacturing and marketing. To date, we do not have any drug products that have generated significant revenues other than from sales of JAKAFI and we cannot assure you that we will generate significant revenues from the drug candidates that we license or develop, including ICLUSIG, for several years, if ever.

We cannot be certain whether or when we will achieve profitability because of the significant uncertainties relating to our ability to generate commercially successful drug products. Even if we are successful in obtaining regulatory approvals for manufacturing and commercializing drug products in addition to JAKAFI and ICLUSIG, we may incur losses if our products do not generate significant revenues. If we achieve profitability, we may not be able to sustain or increase profitability.

***We may need additional capital in the future. If we are unable to generate sufficient funds from operations, the capital markets may not permit us to raise additional capital at the time that we require it, which could result in limitations on our research and development or commercialization efforts or the loss of certain of our rights in our technologies or drug candidates.***

Our future funding requirements will depend on many factors and we anticipate that we may need to raise additional capital to fund our business plan and research and development efforts going-forward and to repay our indebtedness.

Additional factors that may affect our future funding requirements include:

- the amount of revenues generated from our business activities;
- any changes in the breadth of our research and development programs;
- the results of research and development, preclinical testing and clinical trials conducted by us or our current or future collaborators or licensees, if any;
- our exercise of any co-development options with collaborators that may require us to fund future development;
- the acquisition of businesses, technologies, or drug candidates, or the licensing of technologies or drug candidates, if any;
- costs for future facility requirements;
- our ability to maintain and establish new corporate relationships and research collaborations;
- competing technological and market developments;

- the time and costs involved in filing, prosecuting, defending and enforcing patent and intellectual property claims;
- the receipt of contingent licensing or milestone fees or royalties on product sales from our current or future collaborative and license arrangements, if established; and
- the timing of regulatory approvals, if any.

If we require additional capital at a time when investment in companies such as ours, or in the marketplace generally, is limited due to the then prevailing market or other conditions, we may have to scale back our operations, eliminate one or more of our research or development programs, or attempt to obtain funds by entering into an agreement with a collaborator or licensee that would result in terms that are not favorable to us or relinquishing our rights in certain of our proprietary technologies or drug candidates. If we are unable to raise funds at the time that we desire or at any time thereafter on acceptable terms, we may not be able to continue to develop our drug candidates. The sale of equity or additional convertible debt securities in the future may be dilutive to our stockholders and may provide for rights, preferences or privileges senior to those of our holders of common stock, and debt financing arrangements may require us to pledge certain assets or enter into covenants that could restrict our operations or our ability to incur further indebtedness.

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

We invest our cash in accordance with an established internal policy and customarily in instruments, corporate bonds and money market funds which historically have been highly liquid and carried relatively low risk. In recent periods, similar types of investments and money market funds have experienced losses in value or liquidity issues that differ from their historical pattern.

Should a portion of our cash or marketable securities lose value or have their liquidity impaired, it could adversely affect our overall financial position by imperiling our ability to fund our operations and forcing us to seek additional financing sooner than we would otherwise. Such financing, if available, may not be available on commercially attractive terms.

As discussed under “Other Risks Relating to Our Business— 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,” any investments that we may make in companies with which we have strategic alliances, such as Agenus and Merus, could result in our recognition of losses on those investments. In addition, to the extent we may seek to sell or otherwise monetize those investments, we may not be able to do so at our desired price or valuation levels, or at all, due to the limited liquidity of some or all of those investments.

Any loss in value of our long term investments could adversely affect our financial position on the consolidated balance sheets and consolidated statements of operations.

***Our current revenues are derived from JAKAFI and ICLUSIG product sales, JAKAVI and OLUMIANT product royalties, collaborations and from licensing our intellectual property. If we are unable to achieve milestones, develop products or renew or enter into new collaborations, our revenues may decrease, and future milestone and royalty payments may not contribute significantly to revenues for several years, and may never result in revenues.***

We derived substantially all of our revenues for the year ended December 31, 2017 from JAKAFI and ICLUSIG product revenues, JAKAVI and OLUMIANT product royalties and our collaborations and licensing our intellectual property to others. Future revenues from research and development collaborations depend upon continuation of the collaborations, the achievement of milestones and royalties we earn from any future products developed from our research. If we are unable to successfully achieve milestones or our collaborators fail to develop successful products, we will not earn the future revenues contemplated under our collaborative agreements. For example, delays in or other limitations with respect to the approval of baricitinib in the United States for the treatment of moderate-to-severe rheumatoid arthritis, or the failure to obtain such approval, as discussed under “—We depend on our collaborators and licensees for the future development and commercialization of some of our drug candidates. Conflicts may arise between our collaborators and

licensees and us, or our collaborators and licensees may choose to terminate their agreements with us, which may adversely affect our business.” would affect potential future royalty and milestone revenue.

## **RISKS RELATING TO INTELLECTUAL PROPERTY AND LEGAL MATTERS**

***If we are subject to arbitration, litigation and infringement claims, they could be costly and disrupt our drug discovery and development efforts.***

The technology that we use to make and develop our drug products, the technology that we incorporate in our products, and the products we are developing may be subject to claims that they infringe the patents or proprietary rights of others. The success of our drug discovery and development efforts will also depend on our ability to develop new compounds, drugs and technologies without infringing or misappropriating the proprietary rights of others. We are aware of patents and patent applications filed in certain countries claiming intellectual property relating to some of our drug discovery targets and drug candidates. While the validity of issued patents, patentability of pending patent applications and applicability of any of them to our programs are uncertain, if any of these patents are asserted against us or if we choose to license any of these patents, our ability to commercialize our products could be harmed or the potential return to us from any product that may be successfully commercialized could be diminished.

From time to time we have received, and we may in the future receive, notices from third parties offering licenses to technology or alleging patent, trademark, or copyright infringement, claims regarding trade secrets or other contract claims. Receipt of these notices could result in significant costs as a result of the diversion of the attention of management from our drug discovery and development efforts. Parties sending these notices may have brought and in the future may bring litigation against us or seek arbitration relating to contract claims.

We may be involved in future lawsuits or other legal proceedings alleging patent infringement or other intellectual property rights or contract violations. In addition, litigation or other legal proceedings may be necessary to:

- assert claims of infringement;
- enforce our patents or trademarks;
- protect our trade secrets or know-how; or
- determine the enforceability, scope and validity of the proprietary rights of others.

We may be unsuccessful in defending or pursuing these lawsuits, claims or other legal proceedings. Regardless of the outcome, litigation or other legal proceedings can be very costly and can divert management’s efforts. An adverse determination may subject us to significant liabilities or require us or our collaborators or licensees to seek licenses to other parties’ patents or proprietary rights. We or our collaborators or licensees may also be restricted or prevented from manufacturing or selling a drug or other product that we or they develop. Further, we or our future collaborators or licensees may not be able to obtain any necessary licenses on acceptable terms, if at all. If we are unable to develop non-infringing technology or license technology on a timely basis or on reasonable terms, our business could be harmed.

***We may be unable to adequately protect or enforce our proprietary information, which may result in its unauthorized use, a loss of revenue under a collaboration agreement or loss of sales to generic versions of our products or otherwise reduce our ability to compete in developing and commercializing products.***

Our business and competitive position depends in significant part upon our ability to protect our proprietary technology, including any drug products that we create. Despite our efforts to protect this information, unauthorized parties may attempt to obtain and use information that we regard as proprietary. For example, one of our collaborators may disclose proprietary information pertaining to our drug discovery efforts. In addition, while we have filed numerous patent applications with respect to ruxolitinib and our drug candidates in the United States and in foreign countries, our patent applications may fail to result in issued patents. In addition, because patent applications can take several years to issue as patents, there may be pending patent applications of others that may later issue as patents that cover some aspect of ruxolitinib and our drug candidates. Our existing patents and any future patents we may obtain may not be broad enough

to protect our products or all of the potential uses of our products, or otherwise prevent others from developing competing products or technologies. In addition, our patents may be challenged and invalidated or may fail to provide us with any competitive advantages if, for example, others were first to invent or first to file a patent application for the technologies and products covered by our patents. As noted above under “—Risks Relating to Commercialization of Our Products—Competition for our products could potentially harm our business and result in a decrease in our revenue,” a potential generic drug company competitor has challenged certain patents relating to JAKAFI.

Additionally, when we do not control the prosecution, maintenance and enforcement of certain important intellectual property, such as a drug candidate in-licensed to us or subject to a collaboration with a third-party, the protection of the intellectual property rights may not be in our hands. If we do not control the intellectual property rights in-licensed to us with respect to a drug candidate and the entity that controls the intellectual property rights does not adequately protect those rights, our rights may be impaired, which may impact our ability to develop, market and commercialize the in-licensed drug candidate.

Our means of protecting our proprietary rights may not be adequate, and our competitors may:

- independently develop substantially equivalent proprietary information, products and techniques;
- otherwise gain access to our proprietary information; or
- design around patents issued to us or our other intellectual property.

We pursue a policy of having our employees, consultants and advisors execute proprietary information and invention agreements when they begin working for us. However, these agreements may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure. If we fail to maintain trade secret and patent protection, our potential, future revenues may be decreased.

***If the effective term of our patents is decreased due to changes in the United States patent laws 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.***

The value of our patents depends, in part, on their duration. A shorter period of patent protection could lessen the value of our rights under any patents that we obtain and may decrease the revenues we derive from our patents. The United States patent laws were amended in 1995 to change the term of patent protection from 17 years from patent issuance to 20 years from the earliest effective filing date of the application. Because the time from filing to issuance of biotechnology applications may be more than three years depending on the subject matter, a 20-year patent term from the filing date may result in substantially shorter patent protection.

Additionally, United States patent laws were amended in 2011 with the enactment of the America Invents Act and third parties are now able to challenge the validity of issued U.S. patents through various review proceedings; thus rendering the validity of U.S. patents more uncertain. We may be obligated to participate in review proceedings to determine the validity of our U.S. patents. We cannot predict the ultimate outcome of these proceedings, the conduct of which could result in substantial costs and diversion of our efforts and resources. If we are unsuccessful in these proceedings some or all of our claims in the patents may be narrowed or invalidated and the patent protection for our products and drug candidates in the United States could be substantially shortened. Further, if all of the patents covering one of our products are invalidated, the FDA could approve requests to manufacture a generic version of that product prior to the expiration date of those patents.

Other changes in the United States patent laws or changes in the interpretation of patent laws could diminish the value of our patents or narrow the scope of our patent protection. For example, the Supreme Court of the United States recently ruled that isolated DNA sequences cannot be patented. Although we no longer receive significant revenues generated from our former information products business, the majority of our gene patent portfolio from that business consists of patents on isolated DNA sequences, and this ruling limits our ability to derive additional revenues from our gene patent portfolio. Additionally, the Supreme Court recently resolved a split among the circuit courts of appeals regarding antitrust challenges to settlements of patent infringement lawsuits under the Hatch-Waxman Act between brand-name drug companies and generic drug companies. The Court rejected the “scope of the patent” test and ruled that

settlements involving “reverse payments” from brand-name drug companies to generic drug companies should be analyzed under the rule of reason. This ruling may create uncertainty and make it more difficult to settle patent litigation if a company seeking to manufacture a generic version of one of our products challenges the patents covering that product prior to the expiration date of those patents.

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

Biotechnology and pharmaceutical patent law outside the United States is even more uncertain and costly than in the United States and is currently undergoing review and revision in many countries. Further, the laws of some foreign countries may not protect our intellectual property rights to the same extent as United States laws. For example, certain countries do not grant patent claims that are directed to the treatment of humans. We have participated, and may in the future participate, in opposition proceedings to determine the validity of our foreign patents or our competitors’ foreign patents, which could result in substantial costs and diversion of our efforts. For example, there is a patent opposition proceeding in India against our Indian patent that covers the composition of matter and use of certain Janus Kinase inhibitors, including ruxolitinib phosphate, for the treatment of myeloid proliferative disorders, cancer, immune-related diseases, skin disorders, and other diseases. Successful challenges to our patent or other intellectual property rights through these proceedings could result in a loss of rights in the relevant jurisdiction and allow third parties to use our proprietary technologies without a license from us or our collaborators, which may also result in loss of future royalty payments. In addition, successful challenges may jeopardize or delay our ability to enter into new collaborations or commercialize potential products, which could harm our business and results of operations.

#### **RISKS RELATING TO INFORMATION TECHNOLOGY AND DATA PRIVACY**

***Significant disruptions of information technology systems, breaches of data security, or unauthorized disclosures of sensitive data or personally identifiable information or individually identifiable health information could adversely affect our business, and could subject us to liability or reputational damage.***

Our business is increasingly dependent on critical, complex, and interdependent information technology (IT) systems, including Internet-based systems, some of which are managed or hosted by third parties, to support business processes as well as internal and external communications. The size and complexity of our IT systems make us potentially vulnerable to IT system breakdowns, malicious intrusion, and computer viruses, which may result in the impairment of our ability to operate our business effectively.

We are currently in the process of enhancing our IT systems to address our planned growth as well as to support our planned manufacturing operations. There are inherent costs and risks associated with implementing the enhancements to our IT systems, including potential delays in access to, or errors in, critical business and financial information, substantial capital expenditures, additional administrative time and operating expenses, retention of sufficiently skilled personnel to implement and operate the enhanced systems, demands on management time, and costs of delays or difficulties in transitioning to the enhanced systems, any of which could harm our business and results of operations. In addition, the implementation of enhancements to our IT systems may not result in productivity improvements at a level that outweighs the costs of implementation, or at all.

In addition, our systems and the systems of our third-party providers and collaborators are potentially vulnerable to data security breaches which may expose sensitive data to unauthorized persons or to the public. Such data security breaches could lead to the loss of confidential information, trade secrets or other intellectual property, or could lead to the public exposure of personal information (including personally identifiable information or individually identifiable health information) of our employees, clinical trial patients, customers, business partners, and others. Data security breaches could also result in loss of clinical trial data or damage to the integrity of that data. In addition, the increased use of social media by our employees and contractors could result in inadvertent disclosure of sensitive data or personal information, including but not limited to, confidential information, trade secrets and other intellectual property.

Any such disruption or security breach, as well as any action by us or our employees or contractors that might be inconsistent with the rapidly evolving data privacy and security laws and regulations applicable within the United States and elsewhere where we conduct business, could result in enforcement actions by U.S. states, the U.S. Federal government

or foreign governments, liability or sanctions under data privacy laws that protect personally identifiable information, regulatory penalties, other legal proceedings such as but not limited to private litigation, the incurrence of significant remediation costs, disruptions to our operations and collaborations, and damage to our reputation, which could harm our business and operations. Because of the rapidly moving nature of technology and the increasing sophistication of cybersecurity threats, our measures to prevent, respond to and minimize such risks may be unsuccessful.

***Increasing use of social media could give rise to liability, breaches of data security, or reputational damage.***

We and our employees are increasingly utilizing social media tools as a means of communication both internally and externally. Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us or our employees to communicate about our products or business may cause us to be found in violation of applicable requirements. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our social media policy or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial patients, customers, and others. Furthermore, negative posts or comments about us or our products in social media could seriously damage our reputation, brand image, and goodwill.

**Item 1B. *Unresolved Staff Comments* .**

None.

**Item 2. *Properties***

Our global headquarters is in Wilmington, Delaware, which is where our principal drug discovery and development operations are also located. We own two buildings comprising approximately 344,000 square feet of laboratory and office space at this site. In March 2017, we acquired additional adjacent land with a view toward further expanding our headquarters facilities.

We lease approximately 160,000 square feet of office space in Chadds Ford, Pennsylvania and approximately 100,000 square feet of additional laboratory and office space in Wilmington, Delaware.

We conduct our European clinical development operations from our offices in Geneva, Switzerland and Lausanne, Switzerland, and have recently opened our Japanese office in Tokyo.

**Item 3. *Legal Proceedings***

From time to time, we are party to legal proceedings in the course of our business. The outcome of any such proceedings, regardless of the merits, is inherently uncertain. We do not expect any such current legal proceedings to have a material adverse impact on our business or financial condition.

**Item 4. *Mine Safety Disclosure* s**

Not applicable.

**Executive Officers of the Registrant**

Our executive officers are as follows:

*Hervé Hoppenot*, age 58, joined Incyte as President and Chief Executive Officer and a Director, in January 2014 and was appointed Chairman of the Board in May 2015. Mr. Hoppenot served as the President of Novartis Oncology, Novartis Pharmaceuticals Corporation, the U.S. subsidiary of Novartis AG, a pharmaceutical company, from January 2010 to January 2014. Prior to that, Mr. Hoppenot served in other executive positions at Novartis Pharmaceuticals Corporation, serving from September 2006 to January 2010 as Executive Vice President, Chief Commercial Officer of Novartis Oncology and Head of Global Product Strategy & Scientific Development of Novartis Pharmaceuticals Corporation and

from 2003 to September 2006 as Senior Vice President, Head of Global Marketing of Novartis Oncology. Prior to joining Novartis, Mr. Hoppenot served in various increasingly senior roles at Aventis S.A. (formerly Rhône-Poulenc S.A.), a pharmaceutical company, including as Vice President Oncology US of Aventis Pharmaceuticals, Inc. from 2000 to 2003 and Vice President US Oncology Operations of Rhone-Poulenc Rorer Pharmaceuticals, Inc. from 1998 to 2000. Mr. Hoppenot holds a Diploma from ESSEC International Business School. Mr. Hoppenot is also a director of Cellectis S.A.

*Barry P. Flannelly*, age 60, has served as Executive Vice President and General Manager US since June 2015 and joined Incyte as Executive Vice President, Business Development and Strategic Planning in August 2014. Prior to joining Incyte, he served as Chief Executive Officer of OSS Healthcare Inc., a biotechnology start-up company, from August 2013 to July 2014. He served as Vice President, Global Product Strategy and Commercial Planning of Nektar Therapeutics, a biopharmaceutical company, from April 2011 until April 2013, and as Senior Vice President, Commercial, of Onyx Pharmaceuticals, Inc., a biopharmaceutical company, from August 2008 until January 2011. Prior thereto, Dr. Flannelly held key positions at biopharmaceutical and pharmaceutical companies such as Abraxis BioScience, Inc. and Novartis. Dr. Flannelly earned his doctorate in pharmacy from the University of Maryland, School of Pharmacy, his master's degree in business administration from the University of Baltimore, and his B.S. degree in Pharmacy from Massachusetts College of Pharmacy.

*David W. Gryska*, age 61, joined Incyte as Executive Vice President and Chief Financial Officer in October 2014. Prior to joining Incyte, Mr. Gryska served as an independent consultant and as a member of several public company boards of directors. Mr. Gryska served as the Chief Operating Officer and a Director of Myrexis, Inc., a biotechnology company, from May 2012 to December 2012. From December 2006 to October 2010, Mr. Gryska served as Senior Vice President and Chief Financial Officer of Celgene Corporation, a biopharmaceutical company. From October 2004 to December 2006, Mr. Gryska was a principal at Strategic Consulting Group. Previously, Mr. Gryska served at Scios, Inc., a biopharmaceutical company, as Senior Vice President and Chief Financial Officer from 2000 to 2004, and as Vice President of Finance and Chief Financial Officer from 1998 to 2000. From 1993 to 1998, Mr. Gryska served as Vice President, Finance and Chief Financial Officer at Cardiac Pathways. Prior to Cardiac Pathways, Mr. Gryska served as a partner at Ernst & Young LLP. Mr. Gryska is a CPA, and holds a B.A. in Accounting and Finance from Loyola University and an M.B.A. from Golden Gate University.

*Reid M. Huber*, age 46, has served as Executive Vice President, Chief Scientific Officer since April 2014. Dr. Huber joined Incyte as Associate Director, Applied Technology in January 2002 and held roles of increasing responsibility in both drug discovery and clinical development at Incyte. Prior to joining Incyte, Dr. Huber held scientific research positions with DuPont Pharmaceuticals Company from 1998 to 2002. Dr. Huber held intramural pre-doctoral and post-doctoral fellowships at the National Institutes of Health from 1997 to 1998. Dr. Huber received his B.S. in biochemistry/molecular genetics from Murray State University and his Ph.D. in molecular genetics from Washington University.

*Vijay Iyengar*, age 45, joined Incyte in May 2016 as Executive Vice President, Global Strategy and Corporate Development. Prior to joining Incyte, from April 2014 to April 2016, he was the President of Genoptix Corporation, a Novartis Company. From December 2011 to March 2014, he was the Vice President and Rare Diseases Franchise Head at Novartis Oncology and from July 2009 to December 2011, he was the Vice President and Oncology General Manager of Novartis Greece. From October 2007 to June 2009, he was the Global Brand Executive Director at Novartis Pharmaceuticals, and from January 2006 to October 2007, he was the Global Brand Director, Oncology at Novartis Pharmaceuticals. Dr. Iyengar received his B.S. degree in Biology from Stanford University and earned his M.D. from Harvard Medical School.

*Steven Stein*, age 51, has served as Executive Vice President and Chief Medical Officer since May 2016 and joined Incyte as Senior Vice President and Chief Medical Officer in March 2015. Prior to joining Incyte, from May 2011 to February 2015, he was the Senior Vice President, US Clinical Development & Medical Affairs at Novartis Pharmaceuticals. From February 2004 to April 2011, Dr. Stein was the Vice President, Global Oncology, Clinical Development and the Head of Medicines Development for Hematology and Supportive Care for GlaxoSmithKline. Dr. Stein held a post-doctoral fellowship in hematology/oncology at the University of Pennsylvania from 1998 to 2001, and earned his M.D. from the University of Witwatersrand in Johannesburg, South Africa in 1990.

*Paula J. Swain*, age 60, has served as Executive Vice President, Human Resources since August 2002 and joined Incyte as Senior Vice President of Human Resources in January 2002. Ms. Swain served as Senior Vice President of Human Resources at Bristol-Myers Squibb Company from October 2001 to January 2002, after it acquired DuPont Pharmaceuticals Company. From July 1998 to October 2001, Ms. Swain was Senior Vice President of Human Resources at DuPont Pharmaceuticals. From October 1992 to July 1998, Ms. Swain held a variety of human resources positions of increasing responsibility at DuPont Pharmaceuticals. Ms. Swain received her B.A. in Psychology and Industrial Relations from Rockhurst University.

*Wenqing Yao*, age 55, has served as Executive Vice President, Head of Discovery Chemistry since October 2014. Dr. Yao joined Incyte as Director, Chemistry in February 2002 and held roles of increasing responsibility at Incyte. Prior to joining Incyte, Dr. Yao held scientific research positions with DuPont Pharmaceuticals and Bristol-Myers Squibb Company from 1996 to 2002. Dr. Yao received his B.S. in chemistry from Xuzhou Normal University, his M.S. in organic chemistry from NanKai University and his Ph.D. in organic/medicinal chemistry from the University of Pennsylvania.

## PART II

### **Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities**

Our common stock, \$.001 par value per share, is traded on The Nasdaq Global Select Market (Nasdaq) under the symbol "INCY." The following table sets forth, for the periods indicated, the range of high and low sales prices for our common stock on Nasdaq, as reported in its consolidated transaction reporting system.

	<u>High</u>	<u>Low</u>
<b>2016</b>		
First Quarter	\$ 106.81	\$ 55.00
Second Quarter	87.88	68.03
Third Quarter	95.39	75.52
Fourth Quarter	109.95	83.01
<b>2017</b>		
First Quarter	\$ 153.15	\$ 100.41
Second Quarter	144.32	114.03
Third Quarter	140.11	107.79
Fourth Quarter	118.32	92.91

As of December 31, 2017, our common stock was held by 154 stockholders of record. We have never declared or paid dividends on our capital stock and do not anticipate paying any dividends in the foreseeable future.

**Item 6. Selected Financial Data**

**Selected Consolidated Financial Data  
(in thousands, except per share data)**

The data set forth below should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in Item 7 and the Consolidated Financial Statements and related Notes included in Item 8 of this Report.

	Year Ended December 31,				
	2017	2016	2015	2014	2013
<b>Consolidated Statements of Operations Data:</b>					
Revenues:					
Product revenues, net <sup>(1)</sup>	\$ 1,200,312	\$ 882,404	\$ 601,015	\$ 357,562	\$ 235,443
Product royalty revenues <sup>(2)</sup>	160,791	110,711	74,821	48,966	28,251
Milestone and contract revenues <sup>(3)</sup>	175,000	112,512	77,857	104,857	91,047
Other revenues	113	92	58	110	206
<b>Total revenues</b>	<b>1,536,216</b>	<b>1,105,719</b>	<b>753,751</b>	<b>511,495</b>	<b>354,947</b>
Costs and expenses:					
Cost of product revenues (including definite-lived intangible amortization)	79,479	58,187	26,972	3,004	630
Research and development	1,326,361	581,861	479,514	347,523	260,436
Selling, general and administrative	366,406	303,251	196,614	165,772	109,983
Change in fair value of acquisition-related contingent consideration	7,704	17,422	—	—	—
<b>Total costs and expenses</b>	<b>1,779,950</b>	<b>960,721</b>	<b>703,100</b>	<b>516,299</b>	<b>371,049</b>
Income (loss) from operations	(243,734)	144,998	50,651	(4,804)	(16,102)
Interest and other income, net	17,500	4,412	7,089	3,350	1,324
Interest expense	(6,900)	(38,745)	(45,603)	(46,828)	(38,652)
Unrealized loss on long term investment	(24,275)	(3,261)	(4,581)	—	—
Expense related to senior note conversions	(54,881)	—	—	(265)	(11,484)
Loss on repurchase of convertible senior notes	—	—	—	—	(17,934)
Income (loss) before provision (benefit) for income taxes	(312,290)	107,404	7,556	(48,547)	(82,848)
Provision (benefit) for income taxes	852	3,182	1,025	(66)	299
<b>Net income (loss)</b>	<b>\$ (313,142)</b>	<b>\$ 104,222</b>	<b>\$ 6,531</b>	<b>\$ (48,481)</b>	<b>\$ (83,147)</b>
Net income (loss) per share:					
Basic	\$ (1.53)	\$ 0.55	\$ 0.04	\$ (0.29)	\$ (0.56)
Diluted	\$ (1.53)	\$ 0.54	\$ 0.03	\$ (0.29)	\$ (0.56)
Shares used in computing net income (loss) per share:					
Basic	204,580	187,873	179,601	167,947	148,403
Diluted	204,580	194,125	187,302	167,947	148,403

(1) 2017 and 2016 product revenues, net, relate to our product sales of JAKAFI and product sales of ICLUSIG from the date of acquisition on June 1, 2016. 2015, 2014, and 2013 product revenues, net, relate to our product sales of JAKAFI.

(2) 2017 product royalty revenues relate to Novartis net sales of JAKAVI outside of the United States and Lilly net sales of OLUMIANT outside of the United States. 2016, 2015, 2014 and 2013 product royalty revenues relate to Novartis net sales of JAKAVI outside the United States.

(3) Milestone and contract revenues relate to our collaborative research and license agreements with Novartis and Lilly.

	December 31,				
	2017	2016	2015	2014	2013
<b>Consolidated Balance Sheets Data:</b>					
Cash, cash equivalents, and marketable securities	\$ 1,169,645	\$ 808,546	\$ 707,783	\$ 600,263	\$ 509,004
Working capital	1,129,458	720,677	674,368	458,512	446,862
Total assets	2,302,582	1,638,597	1,007,440	796,477	611,589
Convertible senior notes	24,001	651,481	619,893	675,167	644,483
Stockholders' equity (deficit)	1,630,629	419,467	171,155	(81,628)	(193,108)

### **Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with "Selected Consolidated Financial Data" and the Consolidated Financial Statements and related Notes included elsewhere in this Report.

#### **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 operations from our offices in Geneva, Switzerland and Lausanne, Switzerland, and have recently opened our Japanese office in Tokyo.

JAKAFI (ruxolitinib) is our first product to be approved for sale in the United States. It is an oral JAK1 and JAK2 inhibitor and was approved by the U.S. Food and Drug Administration (FDA) in November 2011 for the treatment of patients with intermediate or high-risk myelofibrosis and in December 2014 for the treatment of patients with polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea. Myelofibrosis and polycythemia vera are both rare blood cancers.

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 April 2016, we amended this agreement to provide that Novartis has exclusive research, development and commercialization rights outside of the United States to ruxolitinib (excluding topical formulations) in the graft-versus-host-disease field.

We have a second oral JAK1 and JAK2 inhibitor, baricitinib, which is subject to a collaboration agreement with Eli Lilly and Company in which Lilly received exclusive worldwide development and commercialization rights for the compound for inflammatory and autoimmune diseases. In January 2016, Lilly submitted a New Drug Application (NDA) to the FDA and a Marketing Authorization Application (MAA) to the European Medicines Agency for baricitinib as treatment for rheumatoid arthritis. In March 2016, we entered into an amendment to the agreement with Lilly that amended the non-compete provision of the agreement to allow us to engage in the development and commercialization of ruxolitinib in the graft-versus-host-disease field. In February 2017, we and Lilly announced that the European Commission approved baricitinib as OLUMIANT for the treatment of moderate-to-severe rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to, one or more disease-modifying antirheumatic drugs (DMARDs). In July 2017, Japan's Ministry of Health, Labor and Welfare (MHLW) granted marketing approval for OLUMIANT for the treatment of rheumatoid arthritis (including the prevention of structural injury of joints) in patients with inadequate response to standard-of-care therapies. In April 2017, we and Lilly announced that the FDA had issued a complete response letter for the New Drug Application of baricitinib as a once-daily oral medication for the treatment of moderate-to-severe rheumatoid arthritis. The letter indicated that the FDA was unable to approve the application in its current form. Specifically, the FDA indicated that additional clinical data are needed to determine the most appropriate doses. The FDA also stated that additional data are necessary to further characterize safety concerns across treatment arms. In December 2017, Lilly announced that the NDA for baricitinib had been resubmitted and included new safety and efficacy data. The FDA classified the application as a Class II resubmission, which started a new six-month review cycle.

In June 2016, we acquired (the “Acquisition”) from ARIAD Pharmaceuticals, Inc. all of the outstanding shares of ARIAD Pharmaceuticals (Luxembourg) S.à.r.l., the parent company of ARIAD’s European subsidiaries responsible for the development and commercialization of ICLUSIG in the European Union and other countries, including Switzerland, Norway, Turkey, Israel and Russia. We obtained an exclusive license to develop and commercialize ICLUSIG in those countries. ICLUSIG is approved in the European Union for the treatment of patients with chronic myeloid leukemia and Philadelphia-positive acute lymphoblastic leukemia who are resistant to or intolerant of certain second-generation BCR-ABL inhibitors and all patients who have the T3151 mutation.

Since we began our drug-discovery and development activities in early 2002, we have filed Investigational New Drug (IND) applications and progressed multiple internally developed proprietary compounds into clinical development. As of February 15, 2018, our development portfolio, including ruxolitinib, was comprised of 17 candidates against 14 molecular targets.

### **License Agreements and Business Relationships**

As part of our business strategy, we establish business relationships, including collaborative arrangements with other companies and medical research institutions to assist in the clinical development and/or commercialization of certain of our drugs and drug candidates and to provide support for our research programs. We also evaluate opportunities for acquiring products or rights to products and technologies that are complementary to our business from other companies and medical research institutions.

Below is a brief description of our significant business relationships and collaborations and related license agreements that expand our pipeline and provide us with certain rights to existing and potential new products and technologies.

#### ***Novartis***

In November 2009, we entered into a Collaboration and License Agreement with Novartis. Under the terms of the agreement, Novartis received exclusive development and commercialization rights outside of the United States to ruxolitinib and certain back-up compounds for hematologic and oncology indications, including all hematological malignancies, solid tumors and myeloproliferative diseases. We retained exclusive development and commercialization rights to JAKAFI (ruxolitinib) in the United States and in certain other indications. Novartis also received worldwide exclusive development and commercialization rights to our MET inhibitor compound capmatinib and certain back-up compounds in all indications. We retained options to co-develop and to co-promote capmatinib in the United States.

Under this agreement, we received an upfront payment and immediate milestone payment totaling \$210.0 million and were initially eligible to receive additional payments of up to approximately \$1.2 billion if defined development and commercialization milestones are achieved. We are also eligible to receive tiered, double-digit royalties ranging from the upper-teens to the mid-twenties percent on future ruxolitinib net sales outside of the United States, and tiered, worldwide royalties on future capmatinib net sales that range from 12% to 14%. In addition, Novartis has received reimbursement and pricing approval for ruxolitinib in a specified number of countries, and we are now obligated to pay to Novartis tiered royalties in the low single-digits on future ruxolitinib net sales within the United States. Each company is responsible for costs relating to the development and commercialization of ruxolitinib in its respective territories, with costs of collaborative studies shared equally. Novartis is also responsible for all costs relating to the development and commercialization of capmatinib.

In April 2016, we amended this agreement to provide that Novartis has exclusive research, development and commercialization rights outside of the United States to ruxolitinib (excluding topical formulations) in the GVHD field. Under this amendment, we received a \$5.0 million payment in exchange for the development and commercialization rights to ruxolitinib in GVHD outside of the United States and became eligible to receive up to \$75.0 million of additional potential development and regulatory milestones relating to GVHD. In March 2017, we recognized a \$25.0 million milestone payment for the first patient first visit in a GVHD study and in December 2017, we recognized a \$40.0 million milestone for Novartis achieving annual net sales of a JAK licensed product of \$600.0 million.

The Novartis agreement will continue on a program-by-program basis until Novartis has no royalty payment obligations with respect to such program or, if earlier, the termination of the agreement or any program in accordance with the terms of the agreement. Royalties are payable by Novartis on a product-by-product and country-by-country basis until the latest to occur of (i) the expiration of the last valid claim of the licensed patent rights covering the licensed product in the relevant country, (ii) the expiration of regulatory exclusivity for the licensed product in such country and (iii) a specified period from first commercial sale in such country of the licensed product by Novartis or its affiliates or sublicensees. The agreement may be terminated in its entirety or on a program-by-program basis by Novartis for convenience. The agreement may also be terminated by either party under certain other circumstances, including material breach.

### ***Lilly***

In December 2009, we entered into a License, Development and Commercialization Agreement with Lilly. Under the terms of the agreement, Lilly received exclusive worldwide development and commercialization rights to baricitinib and certain back-up compounds for inflammatory and autoimmune diseases. We received an initial payment of \$90.0 million, and were initially eligible to receive additional payments of up to \$665.0 million based on the achievement of defined development, regulatory and commercialization milestones.

We retained options to co-develop our JAK1/JAK2 inhibitors with Lilly on a compound-by-compound and indication-by-indication basis. Lilly is responsible for all costs relating to the development and commercialization of the compounds unless we elect to co-develop any compounds or indications. If we elect to co-develop any compounds and/or indications, we would be responsible for funding 30% of the associated future global development costs from the initiation of a Phase IIb trial through regulatory approval, including post-launch studies required by a regulatory authority. We would receive an incremental royalty rate increase across all tiers resulting in effective royalty rates ranging up to the high-twenties on potential future global net sales for compounds and/or indications that we elect to co-develop. For indications that we elect not to co-develop, we would receive tiered, double-digit royalty payments on future global net sales with rates ranging up to 20% if the product is successfully commercialized. We previously had retained an option to co-promote products in the United States but, in March 2016, we waived our co-promotion option as part of an amendment to the agreement.

In July 2010, we elected to co-develop baricitinib with Lilly in rheumatoid arthritis and we are responsible for funding 30% of the associated future global development costs for this indication from the initiation of the Phase IIb trial through regulatory approval, including post-launch studies required by a regulatory authority. In January 2017, we elected to co-develop baricitinib with Lilly in psoriatic arthritis and atopic dermatitis. We have also exercised our co-development options in systemic lupus erythematosus and axial spondyloarthritis, should Lilly decide to progress into a pivotal program in these indications.

In March 2016, we entered into an amendment to the agreement with Lilly that allows us to engage in the development and commercialization of ruxolitinib in the GVHD field. We paid Lilly an upfront payment of \$35.0 million and Lilly is eligible to receive up to \$40.0 million in additional regulatory milestone payments relating to ruxolitinib in the GVHD field.

In February 2017, the European Commission announced the approval of baricitinib as OLUMIANT, triggering a \$65.0 million milestone payment from Lilly. In July 2017, Japan's MHLW granted marketing approval for OLUMIANT, triggering a \$15.0 million milestone payment to Incyte from Lilly. In December 2017, we recognized a \$30.0 million milestone payment for the first patient treated in the atopic dermatitis Phase III program for baricitinib.

The Lilly agreement will continue until Lilly no longer has any royalty payment obligations or, if earlier, the termination of the agreement in accordance with its terms. Royalties are payable by Lilly on a product-by-product and country-by-country basis until the latest to occur of (i) the expiration of the last valid claim of the licensed patent rights covering the licensed product in the relevant country, (ii) the expiration of regulatory exclusivity for the licensed product in such country and (iii) a specified period from first commercial sale in such country of the licensed product by Lilly or its affiliates or sublicensees. The agreement may be terminated by Lilly for convenience, and may also be terminated under certain other circumstances, including material breach.

### ***Agenus***

In January 2015, we entered into a License, Development and Commercialization Agreement with Agenus Inc. and its wholly-owned subsidiary, 4-Antibody AG (now known as Agenus Switzerland Inc.), which we collectively refer to as Agenus. Under this agreement, the parties have agreed to collaborate on the discovery of novel immuno-therapeutics using Agenus' antibody discovery platforms. In February 2017, we and Agenus amended this agreement.

Under the terms of this agreement, as amended, we received exclusive worldwide development and commercialization rights to four checkpoint modulators directed against GITR, OX40, LAG-3 and TIM-3. In addition to the initial four program targets, we and Agenus have the option to jointly nominate and pursue additional targets within the framework of the collaboration, and in November 2015, three more targets were added. Targets may be designated profit-share programs, where all costs and profits are shared equally by us and Agenus, or royalty-bearing programs, where we are responsible for all costs associated with discovery, preclinical, clinical development and commercialization activities. The programs relating to GITR and OX40 and two of the undisclosed targets were profit-share programs until February 2017, while the other targets currently under collaboration are royalty-bearing programs. The February 2017 amendment converted the programs relating to GITR and OX40 to royalty-bearing programs and removed from the collaboration the profit-share programs relating to the two undisclosed targets, with one reverting to us and one reverting to Agenus. Should any of those removed programs be successfully developed by a party, the other party will be eligible to receive the same milestone payments as the royalty-bearing programs and royalties at a 15% rate on global net sales. There are currently no profit-share programs. For each royalty-bearing product other than GITR and OX40, Agenus will be eligible to receive tiered royalties on global net sales ranging from 6% to 12%. For GITR and OX40, Agenus will be eligible to receive 15% royalties on global net sales. Under the February 2017 amendment, we paid Agenus \$20.0 million in accelerated milestones relating to the clinical development of the GITR and OX40 programs. Agenus is eligible to receive up to an additional \$510.0 million in future contingent development, regulatory and commercialization milestones across all programs in the collaboration. The agreement may be terminated by us for convenience upon 12 months' notice and may also be terminated under certain other circumstances, including material breach.

### ***Hengrui***

In September 2015, we entered into a License and Collaboration Agreement with Hengrui. Under the terms of this agreement, we received exclusive development and commercialization rights worldwide, with the exception of Mainland China, Hong Kong, Macau and Taiwan, to INCSHR1210, an investigational PD-1 monoclonal antibody, and certain back-up compounds. In February 2018, Incyte and Hengrui agreed to terminate the collaboration, pursuant to the terms of the License and Collaboration Agreement.

### ***ARIAD Pharmaceuticals (Luxembourg) S.à.r.l. Acquisition***

In June 2016, we completed the Acquisition. ARIAD will be eligible to receive from us tiered royalties on net sales of ICLUSIG in our territory and up to \$135.0 million in potential future oncology development and regulatory approval milestone payments, together with additional milestone payments for non-oncology indications, if approved, in our territory.

### ***Merus***

In December 2016, we entered into a Collaboration and License Agreement with Merus N.V. Under this agreement, which became effective in January 2017, the parties have agreed to collaborate with respect to the research, discovery and development of bispecific antibodies utilizing Merus' technology platform. The collaboration encompasses up to eleven independent programs, including two of Merus' current preclinical immuno-oncology discovery programs. We received exclusive development and commercialization rights outside of the United States to products and product candidates resulting from one of Merus' current preclinical discovery programs, referred to as "Program 1." We also received worldwide exclusive development and commercialization rights to products and product candidates resulting from the other current Merus preclinical discovery program that is subject to the collaboration and to up to nine additional programs. Merus retained exclusive development and commercialization rights in the United States to products and product candidates resulting from Program 1 and options, subject to certain conditions, to co-fund development of products resulting from two other programs in exchange for a share of profits in the United States. Merus will also have the right to

participate in a specified proportion of detailing activities in the United States for one of those co-developed programs. Should Program 1 fail to successfully complete IND-enabling toxicology studies, Merus would be granted an additional option to co-fund development of a program in exchange for a share of profits in the United States. All costs related to the collaboration are subject to joint research and development plans. Each party will share equally the costs of mutually agreed global development activities for Program 1, and fund itself any independent development activities in its territory. We will be responsible for all research, development and commercialization costs relating to all other programs, subject to Merus' election to co-fund development and co-detail described above. If Merus exercises its co-funding option for a program, Merus would be responsible for funding 35% of the associated future global development costs and, for certain of such programs, would be responsible for reimbursing us for certain development costs incurred prior to the option exercise. All products as to which Merus has exercised its option to co-fund development would be subject to joint development plans and overseen by a joint development committee, but we will have final determination as to such plans in cases of dispute.

In February 2017, we paid Merus an upfront, non-refundable payment of \$120.0 million. For each program as to which Merus does not have commercialization or co-development rights, Merus will be eligible to receive up to \$100.0 million in future contingent development and regulatory milestones and up to \$250.0 million in commercialization milestones as well as tiered royalties ranging from 6% to 10% of global net sales. For each program as to which Merus exercises its option to co-fund development, Merus will be eligible to receive a 50% share of profits (or sustain 50% of any losses) in the United States and be eligible to receive tiered royalties ranging from 6% to 10% of net sales of products outside of the United States. If Merus opts to cease co-funding a program as to which it exercised its co-development option, then Merus will no longer receive a share of profits in the United States but will be eligible to receive the same milestones from the co-funding termination date and the same tiered royalties described above with respect to non-co-developed programs and, depending on the stage at which Merus chose to cease co-funding development costs, additional royalties ranging up to 4% of net sales in the United States. For Program 1, we and Merus will each be eligible to receive tiered royalties on net sales in the other party's territory at rates ranging from 6% to 10%.

The Merus agreement will continue on a program-by-program basis until we have no royalty payment obligations with respect to such program or, if earlier, the termination of the agreement or any program in accordance with the terms of the agreement. The agreement may be terminated in its entirety or on a program-by-program basis by us for convenience. The agreement may also be terminated by either party under certain other circumstances, including material breach, as set forth in the agreement. If the agreement is terminated with respect to one or more programs, all rights in the terminated programs revert to Merus, subject to payment to us of a reverse royalty of up to 4% on sales of future products, if Merus elects to pursue development and commercialization of products arising from the terminated programs.

### ***Calithera***

In January 2017, we entered into a Collaboration and License Agreement with Calithera Biosciences, Inc. Under this agreement, we received an exclusive, worldwide license to develop and commercialize small molecule arginase inhibitors, including INCB01158 (CB-1158), which is currently in Phase I clinical trials, for hematology and oncology indications. We have agreed to co-fund 70% of the global development costs for the development of the licensed products for hematology and oncology indications. Calithera will have the right to conduct certain clinical development under the collaboration, including combination studies of a licensed product with a proprietary compound of Calithera. We will be entitled to 60% of the profits and losses from net sales of licensed product in the United States, and Calithera will have the right to co-detail licensed products in the United States, and we have agreed to pay Calithera tiered royalties ranging from the low to mid-double digits on net sales of licensed products outside the United States. Calithera may opt out of its co-funding obligation, in which case the U.S. profit sharing will no longer be in effect, and we have agreed to pay Calithera tiered royalties ranging from the low to mid-double digits on net sales of licensed products both in the United States and outside the United States, and additional royalties to reimburse Calithera for previously incurred development costs.

Calithera retains rights to certain arginase inhibitors that are not part of the collaboration for specific orphan indications outside of hematology and oncology, subject to our rights to negotiate a license for any such programs under specified circumstances if Calithera elects to out-license them.

In January 2017, we paid Calithera an upfront license fee of \$45.0 million and have agreed to pay potential development, regulatory and sales milestone payments of over \$430.0 million if the profit share is in effect, or \$750.0 million if the profit share terminates.

The Calithera agreement will continue on a product-by-product and country-by-country basis for so long as we are developing or commercializing products in the United States (if the parties are sharing profits in the United States) and until we have no further royalty payment obligations, unless earlier terminated according to the terms of the agreement. The agreement may be terminated in its entirety or on a product-by-product and/or a country-by-country basis by us for convenience. The agreement may also be terminated by us for Calithera's uncured material breach, by Calithera for our uncured material breach and by either party for bankruptcy or patent challenge. If the agreement is terminated early with respect to one or more products or countries, all rights in the terminated products and countries revert to Calithera.

### ***MacroGenics***

In October 2017, we entered into a Global Collaboration and License Agreement with MacroGenics, Inc. Under this agreement, we received exclusive development and commercialization rights worldwide to MacroGenics' MGA012, an investigational monoclonal antibody that inhibits PD-1. Except as set forth in the succeeding sentence, we will have sole authority over and bear all costs and expenses in connection with the development and commercialization of MGA012 in all indications, whether as a monotherapy or as part of a combination regimen. MacroGenics has retained the right to develop and commercialize, at its cost and expense, its pipeline assets in combination with MGA012. In addition, MacroGenics has the right to manufacture a portion of both companies' global clinical and commercial supply needs of MGA012. In December 2017, we paid MacroGenics an upfront payment of \$150.0 million. MacroGenics will be eligible to receive up to \$420.0 million in future contingent development and regulatory milestones, and up to \$330.0 million in commercial milestones as well as tiered royalties ranging from 15% to 24% of global net sales.

The MacroGenics agreement will continue until we are no longer commercializing, developing or manufacturing MGA012 or, if earlier, the termination of the agreement in accordance with its terms. The agreement may be terminated in its entirety or on a licensed product by licensed product basis by us for convenience. The agreement may also be terminated by either party under certain other circumstances, including material breach, as set forth in the agreement.

### ***Syros***

In January 2018, we entered into a target discovery, research collaboration and option agreement with Syros Pharmaceuticals, Inc. Under this agreement, Syros will use its proprietary gene control platform to identify novel therapeutic targets with a focus in myeloproliferative neoplasms and we have received options to obtain exclusive worldwide rights to intellectual property resulting from the collaboration for up to seven validated targets. We will have exclusive worldwide rights to develop and commercialize any therapies under the collaboration that modulate those validated targets. We paid Syros \$2.5 million in cash for access to proprietary technology and \$7.5 million in cash for research and development services. We have agreed to pay Syros up to \$54.0 million in target selection and option exercise fees should we decide to exercise all of our options under the agreement. For products resulting from the collaboration against each of the seven selected and validated targets, we have agreed to pay up to \$50.0 million in potential development and regulatory milestones and up to \$65.0 million in potential commercial milestones. Syros is also eligible to receive low single-digit royalties on net sales of products resulting from the collaboration.

### **Critical Accounting Policies and Significant Estimates**

The preparation of financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances, the results of which form our basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates under different assumptions or conditions.

We believe the following critical accounting policies affect the more significant judgments and estimates used in the preparation of our consolidated financial statements:

- Revenue recognition;
- Research and development costs;
- Stock compensation;
- Convertible debt accounting;
- Income taxes;
- Business combinations;
- Acquisition-related contingent consideration; and
- Long term investments.

**Revenue Recognition.** Revenues are recognized when (1) persuasive evidence of an arrangement exists, (2) delivery has occurred or services have been rendered, (3) the price is fixed or determinable and (4) collectability is reasonably assured. Revenues are deferred for fees received before earned or until no further obligations exist. We exercise judgment in determining that collectability is reasonably assured or that services have been delivered in accordance with the arrangement. We assess whether the fee is fixed or determinable based on the payment terms associated with the transaction and whether the sales price is subject to refund or adjustment. We assess collectability based primarily on the customer's payment history and on the creditworthiness of the customer.

#### Product Revenues

Our product revenues consist of U.S. sales of JAKAFI and European sales of ICLUSIG. Product revenues are recognized once we meet all four revenue recognition criteria described above. In November 2011, we began shipping JAKAFI to our customers in the U.S., which include specialty pharmacies and wholesalers. In June 2016, we acquired the right to and began shipping ICLUSIG to our customers in the European Union and certain other jurisdictions, which include retail pharmacies, hospital pharmacies and distributors.

We recognize revenues for product received by our customers net of allowances for customer credits, including estimated rebates, chargebacks, discounts, returns, distribution service fees, patient assistance programs, and government rebates, such as Medicare Part D coverage gap reimbursements in the U.S. Product shipping and handling costs are included in cost of product revenues.

**Customer Credits:** Our customers are offered various forms of consideration, including allowances, service fees and prompt payment discounts. We expect our customers will earn prompt payment discounts and, therefore, we deduct the full amount of these discounts from total product sales when revenues are recognized. Service fees are also deducted from total product sales as they are earned.

**Rebates and Discounts:** Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program in the U.S. and mandated discounts in Europe in markets where government-sponsored healthcare systems are the primary payers for healthcare. Rebate amounts are based upon contractual agreements or legal requirements with public sector benefit providers. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements or legal requirements with public sector benefit providers. The accrual for rebates is based on statutory discount rates and expected utilization as well as historical data we have accumulated since product launch. Our estimates for expected utilization of rebates are based on data received from our customers. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarters' unpaid rebates. If actual future

rebates vary from estimates, we may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

*Chargebacks:* Chargebacks are discounts that occur when certain contracted customers, which currently consist primarily of group purchasing organizations, Public Health Service institutions, non-profit clinics, and Federal government entities purchasing via the Federal Supply Schedule, purchase directly from our wholesalers. Contracted customers generally purchase the product at a discounted price. The wholesalers, in turn, charges back to us the difference between the price initially paid by the wholesalers and the discounted price paid by the contracted customers. In addition to actual chargebacks received, we maintain an accrual for chargebacks based on the estimated contractual discounts on the inventory levels on hand in our distribution channel. If actual future chargebacks vary from these estimates, we may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

*Medicare Part D Coverage Gap:* Medicare Part D prescription drug benefit mandates manufacturers to fund 50% of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients. Our estimates for the expected Medicare Part D coverage gap are based on historical invoices received and in part from data received from our customers. Funding of the coverage gap is generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarters. If actual future funding varies from estimates, we may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

*Co-payment Assistance:* Patients who have commercial insurance and meet certain eligibility requirements may receive co-payment assistance. We accrue a liability for co-payment assistance based on actual program participation and estimates of program redemption using data provided by third-party administrators.

#### Product Royalty Revenues

Royalty revenues on commercial sales for JAKAVI by Novartis are estimated based on information provided by Novartis. Royalty revenues on commercial sales for OLUMIANT by Lilly are estimated based on information provided by Lilly. We exercise judgment in determining whether the information provided is sufficiently reliable for us to base our royalty revenue recognition thereon. If actual royalties vary from estimates, we may need to adjust the prior period which would affect royalty revenue in the period of adjustment.

#### Cost of Product Revenues

Cost of product revenues includes all JAKAFI related product costs as well as ICLUSIG related product costs. The ICLUSIG inventories were recorded at fair value less costs to sell in connection with the Acquisition, which resulted in a higher cost of ICLUSIG product revenues over a one year period from the acquisition date. In addition, cost of product revenues include low single-digit royalties under our collaboration and license agreement to Novartis on all future sales of JAKAFI in the United States. Subsequent to the Acquisition on June 1, 2016, cost of product revenues also includes the amortization of our licensed intellectual property for ICLUSIG using the straight-line method over the estimated useful life of 12.5 years.

#### Contract and License Revenues

Under agreements involving multiple deliverables, services and/or rights to use assets that we entered into prior to January 1, 2011, the multiple elements are divided into separate units of accounting when certain criteria are met, including whether the delivered items have stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. When separate units of accounting exist, consideration is allocated among the separate elements based on their respective fair values. The determination of fair value of each element is based on objective evidence from historical sales of the individual elements by us to other customers. If such evidence of fair value for each undelivered element of the arrangement does not exist, all revenue from the arrangement is deferred until such time that evidence of fair value for each undelivered element does exist or until all elements of the arrangement are delivered. When elements are specifically tied to a separate earnings process, revenue is recognized when the specific performance obligation tied to the element is completed. When revenues for an element are not specifically tied to a separate earnings process, they are recognized ratably over the term of the agreement. We assess whether a substantive

milestone exists at the inception of our agreements. For all milestones within our arrangements that are considered substantive, we recognize revenue upon the achievement of the associated milestone. If a milestone is not considered substantive, we would recognize the applicable milestone payment over the remaining period of performance under the arrangement. As of December 31, 2017, all remaining potential milestones under our collaborative arrangements are considered substantive.

On January 1, 2011, updated guidance on the recognition of revenues for agreements with multiple deliverables became effective and applies to any agreements we may enter into on or after January 1, 2011. This updated guidance (i) relates to whether multiple deliverables exist, how the deliverables in a revenue arrangement should be separated and how the consideration should be allocated; (ii) requires companies to allocate revenues in an arrangement using estimated selling prices of deliverables if a vendor does not have vendor-specific objective evidence or third-party evidence of selling price; and (iii) eliminates the use of the residual method and requires companies to allocate revenues using the relative selling price method. During the years ended December 31, 2017, 2016, and 2015, we did not enter into any agreements that are subject to this updated guidance. If we enter into an agreement with multiple deliverables after January 1, 2011 or amend existing agreements, this updated guidance could have a material effect on our financial statements.

Our collaborations often include contractual milestones, which typically relate to the achievement of pre-specified development, regulatory and commercialization events. These three categories of milestone events reflect the three stages of the life-cycle of our drugs, which we describe in more detail in the following paragraphs.

The regulatory review and approval process, which includes preclinical testing and clinical trials of each drug candidate, is lengthy, expensive and uncertain. Securing approval by the U.S. Food and Drug Administration (FDA) requires the submission of extensive preclinical and clinical data and supporting information to the FDA for each indication to establish a drug candidate's safety and efficacy. The approval process takes many years, requires the expenditure of substantial resources, involves post-marketing surveillance and may involve ongoing requirements for post-marketing studies. Before commencing clinical investigations of a drug candidate in humans, we must submit an Investigational New Drug application (IND), which must be reviewed by the FDA.

The steps generally required before a drug may be marketed in the United States include preclinical laboratory tests, animal studies and formulation studies, submission to the FDA of an IND for human clinical testing, performance of adequate and well-controlled clinical trials in three phases, as described below, to establish the safety and efficacy of the drug for each indication, submission of a new drug application (NDA) or biologics license application (BLA) to the FDA for review and FDA approval of the NDA or BLA.

Similar requirements exist within foreign regulatory agencies as well. The time required satisfying the FDA requirements or similar requirements of foreign regulatory agencies may vary substantially based on the type, complexity and novelty of the product or the targeted disease.

Preclinical testing includes laboratory evaluation of product pharmacology, drug metabolism, and toxicity, which includes animal studies, to assess potential safety and efficacy, as well as product chemistry, stability, formulation, development, and testing. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND. The FDA may raise safety concerns or questions about the conduct of the clinical trials included in the IND, and any of these concerns or questions must be resolved before clinical trials can proceed. We cannot be sure that submission of an IND will result in the FDA allowing clinical trials to commence. Clinical trials involve the administration of the investigational drug or the marketed drug to human subjects under the supervision of qualified investigators and in accordance with good clinical practices regulations covering the protection of human subjects. Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Phase I usually involves the initial introduction of the investigational drug into healthy volunteers to evaluate its safety, dosage tolerance, absorption, metabolism, distribution and excretion. Phase II usually involves clinical trials in a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse effects and safety risks, and evaluate and gain preliminary evidence of the efficacy of the drug for specific indications. Phase III clinical trials usually further evaluate clinical efficacy and safety by testing the drug in its final form in an expanded patient population, providing statistical evidence of efficacy and safety, and providing an adequate basis for labeling. We cannot guarantee that Phase I, Phase II or Phase III testing will be completed successfully within any specified period of time, if at all. Furthermore, we,

the institutional review board for a trial, or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Generally, the milestone events contained in our collaboration agreements coincide with the progression of our drugs from development, to regulatory approval and then to commercialization. The process of successfully discovering a new development candidate, having it approved and successfully commercialized is highly uncertain. As such, the milestone payments we may earn from our partners involve a significant degree of risk to achieve. Therefore, as a drug candidate progresses through the stages of its life-cycle, the value of the drug candidate generally increases.

**Research and Development Costs.** Our policy is to expense research and development costs as incurred. We often contract with clinical research organizations (CROs) to facilitate, coordinate and perform agreed upon research and development of a new drug. To ensure that research and development costs are expensed as incurred, we record monthly accruals for clinical trials and preclinical testing costs based on the work performed under the contract.

These CRO contracts typically call for the payment of fees for services at the initiation of the contract and/or upon the achievement of certain clinical trial milestones. In the event that we prepay CRO fees, we record the prepayment as a prepaid asset and amortize the asset into research and development expense over the period of time the contracted research and development services are performed. Most professional fees, including project and clinical management, data management, monitoring, and medical writing fees are incurred throughout the contract period. These professional fees are expensed based on their percentage of completion at a particular date. Our CRO contracts generally include pass through fees. Pass through fees include, but are not limited to, regulatory expenses, investigator fees, travel costs, and other miscellaneous costs, including shipping and printing fees. We expense the costs of pass through fees under our CRO contracts as they are incurred, based on the best information available to us at the time. The estimates of the pass through fees incurred are based on the amount of work completed for the clinical trial and are monitored through correspondence with the CROs, internal reviews and a review of contractual terms. The factors utilized to derive the estimates include the number of patients enrolled, duration of the clinical trial, estimated patient attrition, screening rate and length of the dosing regimen. CRO fees incurred to set up the clinical trial are expensed during the setup period.

Under our clinical trial collaboration agreements, we may be reimbursed for certain development costs incurred. Such costs are recorded as a reduction of research and development expense in the period in which the related expense is incurred.

**Stock Compensation.** Share-based payment transactions with employees, which include stock options, restricted stock units (RSUs) and performance shares (PSUs), are recognized as compensation expense over the requisite service period based on their estimated fair values as well as expected forfeiture rates. The stock compensation process requires significant judgment and the use of estimates, particularly surrounding Black-Scholes assumptions such as stock price volatility over the option term and expected option lives, as well as expected forfeiture rates and the probability of PSUs vesting. The fair value of stock options, which are subject to graded vesting, are recognized as compensation expense over the requisite service period using the accelerated attribution method. The fair value of RSUs that are subject to cliff vesting are recognized as compensation expense over the requisite service period using the straight-line attribution method, and the fair value of RSUs that are subject to graded vesting are recognized as compensation expense over the requisite service period using the accelerated attribution method. The fair value of PSUs are recognized as compensation expense beginning at the time in which the performance conditions are deemed probable of achievement, over the remaining requisite service period. We recorded \$133.1 million, \$96.2 million and \$69.9 million of stock compensation expense for the years ended December 31, 2017, 2016 and 2015, respectively.

**Convertible Debt Accounting.** We perform an assessment of all embedded features of a debt instrument to determine if (i) such features should be bifurcated and separately accounted for, and (ii) if bifurcation requirements are met, whether such features should be classified and accounted for as equity or liability instruments. If the embedded feature meets the requirements to be bifurcated and accounted for as a liability, the fair value of the embedded feature is measured initially, included as a liability on the consolidated balance sheets and re-measured to fair value at each reporting period. Any changes in fair value are recorded in the consolidated statement of operations. We monitor, on an ongoing basis, whether events or circumstances could give rise to a change in our classification of embedded features.

We determined the embedded conversion options in the 0.375% convertible senior notes due 2018 (the 2018 Notes) and the 1.25% convertible senior notes due 2020 (the 2020 Notes) are not required to be separately accounted for as derivatives. However, since the 2018 Notes and the 2020 Notes can be settled in cash or common shares, or a combination of cash and common shares at our option, we are required to separate the 2018 Notes and 2020 Notes into a liability and equity component. The carrying amount of the liability component is calculated by measuring the fair value of a similar liability that does not have an associated equity component. The carrying amount of the equity component representing the embedded conversion option is determined by deducting the fair value of the liability component from the initial proceeds. The excess of the principal amount of the liability component over its carrying amount is amortized to interest expense over the expected life of the 2018 Notes and 2020 Notes using the effective interest method. The equity component is not re-measured as long as it continues to meet the conditions for equity classification for contracts in an entity's own equity.

The fair value of the liability component of the 2018 Notes was estimated at \$299.4 million at issuance. Therefore, the difference between the \$375.0 million face value of the 2018 Notes at issuance and the \$299.4 million estimated fair value of the liability component will be amortized to interest expense over the term of the 2018 Notes through November 15, 2018 using the effective interest method.

The fair value of the liability component of the 2020 Notes was estimated at \$274.8 million at issuance. Therefore, the difference between the \$375.0 million face value of the 2020 Notes at issuance and the \$274.8 million estimated fair value of the liability component will be amortized to interest expense over the term of the 2020 Notes through November 15, 2020 using the effective interest method.

The estimated fair value of the liability components at the date of issuance for the 2018 Notes and 2020 Notes were determined using valuation models and are complex and subject to judgment. Significant assumptions within the valuation models included an implied credit spread, the expected volatility and dividend yield of our common stock and the risk-free interest rate for notes with a similar term.

Prior to May 14, 2014, the 2018 Notes and 2020 Notes were not convertible except in connection with a make-whole fundamental change, as defined in the respective indentures. Beginning on, and including, May 15, 2014, the 2018 Notes and 2020 Notes are convertible prior to the close of business on the business day immediately preceding May 15, 2018, in the case of the 2018 Notes, and May 15, 2020, in the case of the 2020 Notes, only under the following circumstances: (i) during any calendar quarter commencing after the calendar quarter ending on March 31, 2014 (and only during such calendar quarter), if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price for the 2018 Notes or 2020 Notes, as applicable, on each applicable trading day; (ii) during the five business day period after any five consecutive trading day period (the measurement period) in which the trading price per \$1,000 principal amount of 2018 Notes or 2020 Notes, as applicable, for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate for the 2018 Notes or 2020 Notes, as applicable, on each such trading day; or (iii) upon the occurrence of specified corporate events. On or after May 15, 2018, in the case of the 2018 Notes, and May 15, 2020, in the case of the 2020 Notes, until the close of business on the second scheduled trading day immediately preceding the relevant maturity date, the Notes are convertible at any time, regardless of the foregoing circumstances. Upon conversion we will pay or deliver, as the case may be, cash, shares of common stock, or a combination of cash and shares of common stock, at our election.

Upon an induced conversion, we allocate the fair value of the consideration transferred to the convertible debt holder to the liability component equal to the fair value of the liability immediately before extinguishment. The difference between the consideration allocated to the liability component and the net carrying amount of the liability component is recorded as expense related to senior note conversions.

On a quarterly basis, we perform an assessment in order to determine whether the 2018 Notes or 2020 Notes have become convertible at the option of the holder, based on meeting any of the conversion criteria described above. Should either the 2018 Notes or the 2020 Notes become convertible, we then assess our intent and ability to settle the 2018 Notes or the 2020 Notes in cash, shares of common stock, or a combination of cash and shares of common stock, in order to determine the appropriate classification of the 2018 Notes and the 2020 Notes at the balance sheet date. On January 1,

2018, the 2018 Notes and 2020 Notes became convertible through at least March 31, 2018, based on meeting the conversion criteria related to the sale price of our common stock during the calendar quarter ended December 31, 2017 as described above. The 2018 Notes will mature in November 2018, and accordingly, are classified in short term liabilities on the consolidated balance sheet at December 31, 2017. The 2020 Notes are reflected in long term liabilities on the consolidated balance sheet at December 31, 2017 as management's intent is to settle any conversions of the 2020 Notes during this period in shares of our common stock.

**Income Taxes.** We account for income taxes using an asset and liability approach to financial accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax bases of assets and liabilities using enacted tax rates in effect for years in which the basis differences are expected to reverse. We periodically assess the likelihood of the realization of deferred tax assets, and reduce the carrying amount of these deferred tax assets to an amount that is considered more-likely-than-not to be realizable. Our assessment considers recent cumulative earnings experience, projections of future taxable income (losses) and ongoing prudent and feasible tax planning strategies. When performing our assessment on projections of future taxable income (losses), we consider factors such as the likelihood of regulatory approval and commercial success of products currently under development, among other factors. Significant judgment is required in making this assessment and, to the extent that a reversal of any portion of our valuation allowance against our deferred tax assets is deemed appropriate, a tax benefit will be recognized against our income tax provision in the period of such reversal.

We do not recognize a tax benefit for an uncertain tax position unless it is more-likely-than-not that the position will be sustained upon examination based on the technical merits of the position. The tax benefit that is recorded for these positions is measured at the largest amount of benefit that is greater than 50 percent likely of being realized upon ultimate settlement. We adjust the level of the liability to reflect any subsequent changes in the relevant facts surrounding the uncertain positions. Any interest and penalties on uncertain tax positions are included within the tax provision.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 was signed into law making significant changes to the Internal Revenue Code. These changes include a federal corporate tax rate decrease from 35% to 21% for tax years beginning after December 31, 2017, the transition of U.S. international taxation from a worldwide tax system to a territorial system, and temporary full expensing of certain business assets. We have recognized in our financial statements for the year ended December 31, 2017 the provisional tax impacts related to the revaluation of deferred tax assets and liabilities as well as the temporary full-expensing of certain business assets. The ultimate impact may differ from these provisional amounts, due to additional analysis, changes in interpretations and assumptions we have made, and additional regulatory guidance that may be issued. The accounting is expected to be complete when our 2017 U.S. corporate income tax return is filed in 2018.

**Business combinations.** Acquired businesses are accounted for using the acquisition method of accounting, which requires that assets acquired and liabilities assumed be recorded at fair value, with limited exceptions. Any excess of the purchase price over the fair value of the net assets acquired is recorded as goodwill. Transaction costs are expensed as incurred. The operating results of the acquired business are reflected in our consolidated financial statements after the date of acquisition. Acquired in-process research and development ("IPR&D") is recognized at fair value and initially characterized as an indefinite-lived intangible asset, irrespective of whether the acquired IPR&D has an alternative future use. When the related research and development is completed, the asset will be assigned a useful life and amortized. Acquired intellectual property rights are recognized at fair value and amortized over the estimated useful life.

The fair value of an IPR&D intangible asset acquired in the Acquisition was determined using an income approach. The assumptions used to estimate the cash flows of the IPR&D (which relates to the potential approval of ICLUSIG as a second line treatment) included a probability of technical success ("PTS") of 25%, discount rate of 16%, estimated gross margins of 98%, income tax rates ranging from 7.8% in periods in which we have established tax holidays to 13.8% thereafter, and operating expenses consisting of direct costs based on the anticipated level of revenues as well as probability-weighted milestone payments estimated for 2020 related to the clinical results and potential approval of ICLUSIG in second line.

The fair value of licensed intellectual property rights acquired in the Acquisition was determined using an income approach. The assumptions used to estimate the cash flows of the licensed intellectual property from the Acquisition included a discount rate of 15%, estimated gross margins of 98%, income tax rates ranging from 7.8% in periods in which

we have established tax holidays to 13.8% thereafter, and operating expenses consisting of direct costs based on the anticipated level of revenues as well as the \$7.0 million of research and development cost sharing payments we have agreed to fund in 2016 and 2017.

Indefinite-lived intangible assets, including IPR&D, are tested for impairment annually or more frequently if events or changes in circumstances between annual tests indicate that the asset may be impaired. Impairment losses on indefinite-lived intangible assets are recognized based solely on a comparison of the fair value of the asset to its carrying value. Due to the discontinuation of the OPTIC-2L study, we considered our indefinite-lived IPR&D asset to be impaired and recorded \$12.0 million of research and development expense on the consolidated statements of operations during the year ended December 31, 2017.

Long-lived assets, including licensed intellectual property rights, with finite lives are tested for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. If indicators of impairment are present, the asset is tested for recoverability by comparing the carrying value of the asset to the related estimated undiscounted future cash flows expected to be derived from the asset. If the expected cash flows are less than the carrying value of the asset, then the asset is considered to be impaired and its carrying value is written down to fair value, based on the related estimated discounted future cash flows.

Goodwill is calculated as the difference between the acquisition date fair value of the consideration transferred and the values assigned to the assets acquired and liabilities assumed. Goodwill is not amortized but is tested for impairment at least annually at the reporting unit level. A reporting unit is the same as, or one level below, an operating segment. Our operations are currently comprised of a single, entity-wide reporting unit.

**Acquisition-related contingent consideration.** Acquisition-related contingent consideration, which consists of our future royalty and certain potential milestone obligations to ARIAD, was recorded on the acquisition date at the estimated fair value of the obligation, in accordance with the acquisition method of accounting. The fair value measurement is based on significant inputs that are unobservable in the market and thus represents a Level 3 measurement.

The fair value of the acquisition-related contingent consideration was determined using an income approach based on estimated ICLUSIG revenues in our licensed territory for both the approved third line treatment, as well as the second line treatment that until the three months ended September 30, 2017 was under development. The PTS of the second line indication was estimated at 25% based on the early stage of development and competitive market landscape, and the estimated future cash flows for the second line indication were probability weighted accordingly. The total projected cash flows of the third line and second line indications were estimated over 18 years, and discounted to present value using a discount rate of 10%. In addition, based on the believed limited effectiveness of ICLUSIG beyond the existing oncology indications, the fact that no development is currently ongoing for any new oncology or any non-oncology indications, and the lack of intention by us and ARIAD to develop ICLUSIG in additional oncology or non-oncology indications, the fair value of any cash flows for any new oncology or non-oncology was determined to be nil.

The fair value of the acquisition-related contingent consideration is remeasured each reporting period, with changes in fair value recorded in the consolidated statements of operations. Changes in the fair value of the acquisition-related contingent consideration can result from changes to one or multiple inputs including projected revenues, discount rates and the PTS of the second line indication for ICLUSIG, and a benefit of \$24.0 million was recorded during the year ended December 31, 2017 related to the lack of expected future sales royalties payable due to the discontinued OPTIC-2L clinical trial for the second line indication for ICLUSIG. These inputs are analyzed on a quarterly basis as changes to the inputs could have a material impact on the amount of acquisition-related contingent consideration recorded during the reporting period.

**Long term investments.** Our long term investments consist of investments in common stock of publicly held companies with whom we have entered into collaboration and license agreements. The investments in companies over which we have significant influence, but not controlling interest, are accounted for using the equity method (fair value option). The investments in companies over which we do not have significant influence are accounted for as available-for-sale securities. We classify all of our investments in common stock of publicly held companies with whom we have entered into collaboration and license agreements as long term investments.

In circumstances where we have the ability to exercise significant influence over the operating and financial policies of a company in which we have an investment, the investment is accounted for either (i) under the equity method of accounting or (ii) at fair value by electing the fair value option under U.S. GAAP. In assessing whether we exercise significant influence, we consider the nature and magnitude of our investment, any voting and protective rights we hold, any participation in the governance of the other company, and other relevant factors such as the presence of a collaboration or other business relationship. Under the equity method of accounting, we record within our results of operations our share of income or loss of the investee company. Under the fair value option, our investment is carried at fair value on our consolidated balance sheets as a long term investment and all changes in fair value are reported in our consolidated statements of operations as an unrealized gain (loss) on long term investments.

We perform an initial and ongoing evaluation of the entities with which we have variable interests, such as equity ownership, in order to identify entities (i) that do not have sufficient equity investment at risk to permit the entity to finance its activities without additional subordinated financial support or (ii) in which the equity investors lack an essential characteristic of a controlling financial interest as variable interest entities (“VIE” or “VIEs”). If an entity is identified as a VIE, we perform an assessment to determine whether we have both (i) the power to direct activities that most significantly impact the VIE’s economic performance and (ii) have the obligation to absorb losses from or the right to receive benefits of the VIE that could potentially be significant to the VIE. If both of these criteria are satisfied, we are identified as the primary beneficiary of the VIE. As of December 31, 2017, there were no entities in which we held a variable interest which we determined to be VIEs.

## Results of Operations

### *Years Ended December 31, 2017 and 2016*

We recorded a net loss for the year ended December 31, 2017 of \$313.1 million and net income for the year ended December 31, 2016 of \$104.2 million. On a per share basis, basic and diluted net loss was \$1.53 for the year ended December 31, 2017. On a per share basis, basic net income was \$0.55 and diluted net income was \$0.54 for the year ended December 31, 2016.

### *Revenues*

	For the Year Ended, December 31,	
	2017	2016
	(in millions)	
JAKAFI revenues, net	\$ 1,133.4	\$ 852.8
ICLUSIG revenues, net	66.9	29.6
Total product revenues, net	\$ 1,200.3	\$ 882.4
Product royalty revenues	160.8	110.7
Milestone and contract revenues	175.0	112.5
Other revenues	0.1	0.1
Total revenues	\$ 1,536.2	\$ 1,105.7

Our product revenues, net for the years ended December 31, 2017 and 2016, were \$1.2 billion and \$882.4 million, respectively. The increase in JAKAFI product revenues was comprised of a volume increase of \$204.6 million and a price increase of \$76.0 million. ICLUSIG product revenues commenced in June 2016 following the Acquisition. Product revenues are recorded net of estimated product returns, pricing discounts including rebates offered pursuant to mandatory federal and state government programs and chargebacks, prompt pay discounts and distribution fees and co-pay assistance. Our revenue recognition policies require estimates of the aforementioned sales allowances each period.

The following table provides a summary of activity with respect to our sales allowances and accruals for the year ended December 31, 2017:

<b>Year Ended December 31, 2017</b>	<b>Discounts and Distribution Fees</b>	<b>Government Rebates and Chargebacks</b>	<b>Co-Pay Assistance and Other Discounts</b>	<b>Product Returns</b>	<b>Total</b>
Balance at January 1, 2017	\$ 2,818	\$ 22,412	\$ 199	\$1,211	\$ 26,640
Allowances for current period sales	32,822	141,884	4,051	1,861	180,618
Allowances for prior period sales	(59)	(1,883)	(10)	(353)	(2,305)
Credits/payments for current period sales	(30,701)	(114,312)	(3,885)	(91)	(148,989)
Credits/payments for prior period sales	(800)	(17,163)	(17)	(936)	(18,916)
Balance at December 31, 2017	<u>\$ 4,080</u>	<u>\$ 30,938</u>	<u>\$ 338</u>	<u>\$1,692</u>	<u>\$ 37,048</u>

Government rebates and chargebacks are the most significant component of our sales allowances. Increases in certain government reimbursement rates are limited to a measure of inflation, and when the price of a drug increases faster than this measure of inflation it will result in a penalty adjustment factor that causes a larger sales allowance to those government related entities. We expect government rebates and chargebacks as a percentage of our gross product sales will continue to increase in connection with any future JAKAFI price increases greater than the rate of inflation, and any such increase in these government rebates and chargebacks will have a negative impact on our reported product revenues, net. We adjust our estimates for government rebates and chargebacks based on new information regarding actual rebates as it becomes available. Claims by third-party payors for rebates and chargebacks are frequently submitted after the period in which the related sales occurred, which may result in adjustments to prior period accrual balances in the period in which the new information becomes available. We also adjust our allowance for product returns based on new information regarding actual returns as it becomes available.

We expect our sales allowances to fluctuate from quarter to quarter as a result of the Medicare Part D Coverage Gap, the volume of purchases eligible for government mandated discounts and rebates as well as changes in discount percentages which are impacted by potential future price increases, rate of inflation, and other factors.

Product royalty revenues on commercial sales of JAKAVI by Novartis are based on net sales of licensed products in licensed territories as provided by Novartis. Our JAKAVI product royalty revenues for the years ended December 31, 2017 and 2016, were \$151.7 million and \$110.7 million, respectively. Product royalty revenues on commercial sales of OLUMIANT by Lilly are based on net sales of licensed products in licensed territories as provided by Lilly. Our OLUMIANT product royalty revenues for the years ended December 31, 2017 and 2016, were \$9.1 million and \$0.0 million, respectively.

Our milestone and contract revenues were \$175.0 million and \$112.5 million for the years ended December 31, 2017 and 2016, respectively. For the year ended December 31, 2017, milestone and contract revenues were derived from milestone payments from Lilly and Novartis earned during the period. For the year ended December 31, 2016, milestone and contract revenues were derived from the straight-line recognition of revenue associated with the Lilly upfront fees over the estimated performance period as well as milestone payments from Lilly and Novartis earned during the period. The upfront fees related to the Lilly agreement consisted of a \$90.0 million upfront payment received in 2010. The increase in milestone and contract revenues from 2016 to 2017 primarily relates to the recognition of \$45.0 million in milestone payments from Novartis, \$55.0 million in milestone payments from Lilly and \$12.5 million in revenue from the Lilly upfront fees in 2016 compared to the recognition of \$65.0 million in milestone payments from Novartis and \$110.0 million in milestone payments from Lilly in 2017.

**Cost of Product Revenues**

	For the Year Ended, December 31,	
	2017	2016
	(in millions)	
Product costs	\$ 7.5	\$ 8.8
Royalty expense	50.5	36.8
Amortization of definite-lived intangible assets	21.5	12.6
Total cost of product revenues	<u>\$ 79.5</u>	<u>\$ 58.2</u>

Cost of product revenues includes all JAKAFI related product costs, all ICLUSIG related product costs and low single-digit royalties to Novartis on all sales of JAKAFI in the United States. The ICLUSIG inventories were recorded at fair value less costs to sell in connection with the Acquisition, which resulted in a higher cost of ICLUSIG product revenues over a one year period from the acquisition date. Subsequent to the Acquisition on June 1, 2016, cost of product revenues also includes the amortization of our licensed intellectual property for ICLUSIG using the straight-line method over the estimated useful life of 12.5 years.

Cost of product revenues was \$79.5 million and \$58.2 million for the years ended December 31, 2017 and 2016, respectively. Cost of product revenues increased from 2016 to 2017 due primarily to an increase of \$13.7 million in royalties to Novartis on all JAKAFI sales in the United States and amortization of \$8.9 million of our licensed intellectual property acquired on June 1, 2016.

**Operating Expenses**

*Research and development expenses*

	For the Years Ended, December 31,	
	2017	2016
	(in millions)	
Salary and benefits related	\$ 198.4	\$ 138.1
Stock compensation	90.4	59.6
Clinical research and outside services	956.8	328.0
Occupancy and all other costs	80.8	56.2
Total research and development expenses	<u>\$ 1,326.4</u>	<u>\$ 581.9</u>

We currently account for research and development costs by natural expense line and not costs by project. Salary and benefits related expense increased from 2016 to 2017 due primarily to increased development headcount to sustain our development pipeline. Stock compensation expense may fluctuate from period to period based on the number of awards granted, stock price volatility and expected award lives, as well as expected award forfeiture rates which are used to value equity-based compensation.

The increase in clinical research and outside services expense from 2016 to 2017 was primarily due to upfront and milestone expenses related to our collaborative agreements, as well as an overall increase in development costs to advance our clinical pipeline. Specifically, we recorded \$359.1 million in charges for the new Calithera, MacroGenics and Merus agreements, and the amended Agenus agreement, during the year ended December 31, 2017. Research and development expenses for the years ended December 31, 2017 and 2016 were net of \$18.6 million and \$13.4 million, respectively, of costs reimbursed by our collaborative partners. In addition to one-time expenses resulting from upfront fees in connection with the entry into any new or amended collaboration agreements, research and development expenses may fluctuate from period to period depending upon the stage of certain projects, the level of pre-clinical and clinical trial related activities, and results of clinical trials. Many factors can affect the cost and timing of our clinical trials, including requests by regulatory agencies for more information, inconclusive results requiring additional clinical trials, slow patient enrollment, adverse side effects among patients, insufficient supplies for our clinical trials and real or perceived lack of effectiveness or safety of our investigational drugs in our clinical trials. In addition, the development of all of our products

will be subject to extensive governmental regulation. These factors make it difficult for us to predict the timing and costs of the further development and approval of our products.

In July 2010, we elected to co-develop baricitinib with Lilly in rheumatoid arthritis and we are responsible for funding 30% of the associated future global development costs for this indication from the initiation of the Phase IIb trial through regulatory approval. In January 2017, we exercised our co-development options in psoriatic arthritis and atopic dermatitis to fund 30% of future global development costs through regulatory approval, including post-launch studies required by a regulatory authority. We have also exercised our co-development options in systemic lupus erythematosus and axial spondyloarthritis, should Lilly decide to progress into a pivotal program in these indications. Research and development expenses recorded under the Lilly agreement representing 30% of the global development costs for baricitinib for the treatment of rheumatoid arthritis were \$40.8 million and \$27.3 million for the years ended December 31, 2017 and 2016, respectively. We have retained certain mechanisms to give us cost protection as baricitinib advances in clinical development. We can defer our portion of co-development study costs by indication if they exceed a predetermined level. This deferment would be credited against future milestones or royalties and we would still be eligible for the full incremental royalties related to the co-development option. In addition, even if we have started co-development funding for any indication, we can at any time opt out, which will stop future co-development cost sharing. If we elect to do this we would still be eligible for our base royalties plus an incremental pro-rated royalty commensurate with our contribution to the total co-development cost for those indications for which we contributed funding.

During the year ended December 31, 2017, we wrote-off the acquired IPR&D asset of \$12.0 million due to the discontinuation of the OPTIC-2L study, which was recorded in research and development expense on the consolidated statements of operations.

*Selling, general and administrative expenses*

	<b>For the Years Ended, December 31,</b>	
	<b>2017</b>	<b>2016</b>
	<b>(in millions)</b>	
Salary and benefits related	\$ 105.7	\$ 80.8
Stock compensation	42.7	36.6
Other contract services and outside costs	218.0	185.9
Total selling, general and administrative expenses	<u>\$ 366.4</u>	<u>\$ 303.3</u>

Salary and benefits related expense increased from 2016 to 2017 due to increased headcount. This increased headcount was due primarily to the ongoing commercialization efforts related to JAKAFI for intermediate or high-risk myelofibrosis and uncontrolled polycythemia vera, as well as increased headcount related to the Acquisition on June 1, 2016 and subsequent expansion of our European commercial and development operations. Stock compensation expense may fluctuate from period to period based on the number of awards granted, stock price volatility and expected award lives, as well as expected award forfeiture rates which are used to value equity-based compensation. The increase in other contract services and outside costs was primarily the result of marketing activities for JAKAFI for intermediate or high-risk myelofibrosis and uncontrolled polycythemia vera in addition to an increase in donations to independent non-profit patient assistance organizations in the United States. As our drug candidates progress closer to marketing approvals, we expect to incur increased selling, general and administrative expenses associated with the preparation for and launch of commercialization efforts. Selling, general and administrative expenses for the year ended December 31, 2016 includes expenses related to the Acquisition on June 1, 2016.

*Change in fair value of acquisition-related contingent consideration*

Acquisition-related contingent consideration, which consists of our future royalty and certain potential milestone obligations to ARIAD, was recorded on the acquisition date, June 1, 2016, at the estimated fair value of the obligation, in accordance with the acquisition method of accounting. The fair value of the acquisition-related contingent consideration was remeasured as of December 31, 2017, resulting in expense of \$7.7 million which is recorded in change in fair value of acquisition-related contingent consideration on the consolidated statements of operations. The change in fair value of the contingent consideration for the year ended December 31, 2017 is due to the passage of time and a benefit of \$24.0 million recorded during the third quarter of 2017 related to the lack of expected future sales royalties payable due to the

discontinued OPTIC-2L clinical trial. The change in fair value of the acquisition-related contingent consideration for the year ended December 31, 2016 was \$17.4 million. The change in fair value of the contingent consideration as of December 31, 2016 is primarily due to the time value of money as there were no other significant changes in the key assumptions used in the fair value calculation at the date of acquisition, including the discount rate utilized and the estimated future projections of ICLUSIG revenues.

**Other income (expense)**

*Interest and other income, net.* Interest and other income, net, for the years ended December 31, 2017 and 2016 was \$17.5 million and \$4.4 million, respectively. The increase in interest and other income, net primarily relates to refundable research and development credits from the state of Delaware.

*Interest expense.* Interest expense for the years ended December 31, 2017 and 2016, was \$6.9 million and \$38.7 million, respectively. Included in interest expense for the years ended December 31, 2017 and 2016 was \$6.1 million and \$31.6 million, respectively, of non-cash charges to amortize the discounts on the 2018 Notes and the 2020 Notes.

*Unrealized loss on long term investments.* Unrealized gains and losses on long term investments will fluctuate from period to period, based on the change in fair value of the securities we hold in our publicly held collaboration partners. With respect to our long term investment in Agenus, the unrealized loss on investment for the years ended December 31, 2017 and 2016, was \$13.6 million and \$3.3 million, respectively. The unrealized loss on our long term investment in Merus for the year ended December 31, 2017 was \$10.7 million.

*Expense related to senior note conversions.* Expense related to senior note conversions for the year ended December 31, 2017 was \$54.9 million on the conversions of our 2018 Notes and 2020 Notes.

*Provision for income taxes.* The provision for income taxes for the years ended December 31, 2017 and 2016, was \$0.9 million and \$3.2 million, respectively. The decrease in provision for income taxes primarily relates to a decrease in state taxes due to lower taxable income in 2017 sourced to certain states partially offset by increased foreign tax expense on our first full year of ICLUSIG product revenues.

**Years Ended December 31, 2016 and 2015**

We recorded net income for the year ended December 31, 2016 of \$104.2 million and net income for the year ended December 31, 2015 of \$6.5 million. On a per share basis, basic net income was \$0.55 and diluted net income was \$0.54 for the year ended December 31, 2016. On a per share basis, basic net income was \$0.04 and diluted net income was \$0.03 for the year ended December 31, 2015.

**Revenues**

	For the Year Ended, December 31,	
	2016	2015
	(in millions)	
JAKAFI revenues, net	\$ 852.8	\$ 601.0
ICLUSIG revenues, net	29.6	—
Total product revenues, net	\$ 882.4	\$ 601.0
Product royalty revenues	110.7	74.8
Milestone and contract revenues	112.5	77.9
Other revenues	0.1	0.1
Total revenues	\$ 1,105.7	\$ 753.8

Our product revenues, net for the years ended December 31, 2016 and 2015, were \$882.4 million and \$601.0 million, respectively. The increase in JAKAFI product revenues was comprised of a volume increase of \$195.5 million and a price increase of \$56.3 million. ICLUSIG product revenues commenced in June 2016 following the Acquisition.

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The following table provides a summary of activity with respect to our sales allowances and accruals for the year ended December 31, 2016:

<b>Year Ended December 31, 2016</b>	<b>Discounts and Distribution Fees</b>	<b>Government Rebates and Chargebacks</b>	<b>Co-Pay Assistance and Other Discounts</b>	<b>Product Returns</b>	<b>Total</b>
Balance at January 1, 2016	\$ 2,818	\$ 22,412	\$ 199	\$ 1,211	\$ 26,640
Allowances for current period sales	23,936	106,331	3,401	668	134,336
Allowances for prior period sales	(59)	(971)	(10)	(353)	(1,393)
Credits/payments for current period sales	(21,759)	(82,363)	(3,225)	(34)	(107,381)
Credits/payments for prior period sales	(800)	(16,964)	(17)	(404)	(18,185)
Balance at December 31, 2016	\$ 4,136	\$ 28,445	\$ 348	\$ 1,088	\$ 34,017

Government rebates and chargebacks are the most significant component of our sales allowances. Increases in certain government reimbursement rates are limited to a measure of inflation, and when the price of a drug increases faster than this measure of inflation it will result in a penalty adjustment factor that causes a larger sales allowance to those government related entities.

Product royalty revenues on commercial sales of JAKAVI by Novartis are based on net sales of licensed products in licensed territories as provided by Novartis. Our net product royalty revenues for the years ended December 31, 2016 and 2015, were \$110.7 million and \$74.8 million, respectively.

Our milestone and contract revenues were \$112.5 million and \$77.9 million for the years ended December 31, 2016 and 2015, respectively. For the years ended December 31, 2016 and 2015, milestone and contract revenues were derived from the straight-line recognition of revenue associated with the Lilly upfront fees over the estimated performance period as well as milestone payments from Lilly and Novartis earned during the periods. The upfront fees related to the Lilly agreement consisted of a \$90.0 million upfront payment received in 2010. The increase in milestone and contract revenues from 2015 to 2016 primarily relates to the recognition of \$65.0 million in milestone payments from Novartis in 2015 compared to the recognition of \$45.0 million in milestone payments from Novartis and \$55.0 million in milestone payments from Lilly in 2016.

**Cost of Product Revenues**

	<b>For the Year Ended, December 31,</b>	
	<b>2016</b>	<b>2015</b>
	(in millions)	
Product costs	\$ 8.8	\$ 2.6
Royalty expense	36.8	24.4
Amortization of definite-lived intangible assets	12.6	—
Total cost of product revenues	\$ 58.2	\$ 27.0

We began capitalizing inventory in mid-November 2011 once the FDA approved JAKAFI as the related costs were expected to be recoverable through the commercialization of the product. Costs incurred prior to FDA approval of \$9.6 million were recorded as research and development expenses in our statements of operations prior to commercialization of JAKAFI. At December 31, 2016, inventory with \$0.8 million of product costs incurred prior to FDA approval had not yet been sold. In addition, cost of product revenues included low single-digit royalties to Novartis on all sales of JAKAFI in the United States. Subsequent to the Acquisition on June 1, 2016, cost of product revenues also included the amortization of our licensed intellectual property for ICLUSIG using the straight-line method over the estimated useful life of 12.5 years.

Cost of product revenues was \$58.2 million and \$27.0 million for the years ended December 31, 2016 and 2015, respectively. Cost of product revenues increased from 2015 to 2016 due primarily to an increase of \$12.4 million in royalties to Novartis on all JAKAFI sales in the United States and amortization of \$12.6 million of our licensed intellectual property acquired on June 1, 2016.

**Operating Expenses***Research and development expenses*

	For the Years Ended, December 31,	
	2016	2015
	(in millions)	
Salary and benefits related	\$ 138.1	\$ 109.2
Stock compensation	59.6	39.9
Clinical research and outside services	328.0	287.0
Occupancy and all other costs	56.2	43.4
Total research and development expenses	<u>\$ 581.9</u>	<u>\$ 479.5</u>

Salary and benefits related expense increased from 2015 to 2016 due primarily to increased development headcount to sustain our development pipeline. Stock compensation expense may fluctuate from period to period based on the number of awards granted, stock price volatility and expected award lives, as well as expected award forfeiture rates which are used to value equity-based compensation. The increase in clinical research and outside services expense from 2015 to 2016 was primarily the result of increased development costs to advance our clinical pipeline and the \$35.0 million payment to acquire the rights from Lilly to develop ruxolitinib for the treatment of patients with graft-versus-host-disease, as well as an additional \$27.3 million of research and development costs incurred under the Agenus and Hengrui arrangements through December 31, 2016. Research and development expenses for the years ended December 31, 2016 and 2015 were net of \$13.4 million and \$6.8 million, respectively, of costs reimbursed by our collaborative partners.

Research and development expenses recorded under the Lilly agreement representing 30% of the global development costs for baricitinib for the treatment of rheumatoid arthritis were \$27.3 million and \$36.0 million for the years ended December 31, 2016 and 2015, respectively.

*Selling, general and administrative expenses*

	For the Years Ended, December 31,	
	2016	2015
	(in millions)	
Salary and benefits related	\$ 80.8	\$ 60.1
Stock compensation	36.6	29.9
Other contract services and outside costs	185.9	106.6
Total selling, general and administrative expenses	<u>\$ 303.3</u>	<u>\$ 196.6</u>

Salary and benefits related expense increased from 2015 to 2016 due to increased headcount. This increased headcount was due primarily to the ongoing commercialization efforts related to JAKAFI for intermediate or high-risk myelofibrosis and uncontrolled polycythemia vera, as well as increased headcount related to the Acquisition on June 1, 2016. Stock compensation expense may fluctuate from period to period based on the number of awards granted, stock price volatility and expected award lives, as well as expected award forfeiture rates which are used to value equity-based compensation. The increase in other contract services and outside costs was primarily the result of marketing activities for JAKAFI for intermediate or high-risk myelofibrosis and uncontrolled polycythemia vera in addition to an increase in donations to independent non-profit patient assistance organizations in the United States. Selling, general and administrative expenses for the year ended December 31, 2016 includes expenses related to the Acquisition on June 1, 2016.

*Change in fair value of acquisition-related contingent consideration*

Acquisition-related contingent consideration, which consists of our future royalty and certain potential milestone obligations to ARIAD, was recorded on the acquisition date, June 1, 2016, at the estimated fair value of the obligation, in accordance with the acquisition method of accounting. The fair value of the acquisition-related contingent consideration was remeasured as of December 31, 2016, resulting in a change in fair value of \$17.4 million which is recorded in change in fair value of acquisition-related contingent consideration on the consolidated statements of operations. The change in fair value of the contingent consideration as of December 31, 2016 was primarily due to the time value of money as there were no other significant changes in the key assumptions used in the fair value calculation at the date of acquisition, including the discount rate utilized and the estimated future projections of ICLUSIG revenues.

**Other income (expense)**

*Interest and other income, net.* Interest and other income, net, for the years ended December 31, 2016 and 2015 was \$4.4 million and \$7.1 million, respectively.

*Interest expense.* Interest expense for the years ended December 31, 2016 and 2015, was \$38.7 million and \$45.6 million, respectively. Included in interest expense for the year ended December 31, 2016 was \$31.6 million of non-cash charges to amortize the discounts on the 2018 Notes and the 2020 Notes. Included in interest expense for the year ended December 31, 2015 was \$33.8 million of non-cash charges to amortize the discounts on our 4.75% convertible senior notes due 2015 (the 2015 Notes), the 2018 Notes and the 2020 Notes.

*Unrealized loss on long term investment.* The unrealized loss on our long term investment in Agenus for the years ended December 31, 2016 and 2015, was \$3.3 million and \$4.6 million, respectively. The unrealized loss on long term investment was based on the change in fair value of Agenus' common stock during the period.

*Provision for income taxes.* The provision for income taxes for the years ended December 31, 2016 and 2015, was \$3.2 million and \$1.0 million, respectively. The increase in provision for income taxes primarily related to an increase in state taxes due to higher income in 2016 sourced to certain states and foreign tax expense on ICLUSIG product revenues.

**Liquidity and Capital Resources**

	2017	2016	2015
	(in millions)		
<b>December 31:</b>			
Cash, cash equivalents, and marketable securities	\$ 1,169.6	\$ 808.5	\$ 707.8
Working capital	\$ 1,129.5	\$ 720.7	\$ 674.4
<b>Year ended December 31:</b>			
Cash provided by (used in):			
Operating activities	\$ (93.0)	\$ 304.8	\$ 89.4
Investing activities	\$ (350.0)	\$ (232.5)	\$ (105.0)
Financing activities	\$ 690.2	\$ 58.6	\$ 84.7
Capital expenditures (included in investing activities above)	\$ (111.0)	\$ (120.3)	\$ (26.0)

*Sources and Uses of Cash.*

Due to historical net losses, we had an accumulated deficit of \$2.0 billion as of December 31, 2017. We have funded our research and development operations through sales of equity securities, the issuance of convertible notes, cash received from customers, and collaborative arrangements. At December 31, 2017, we had available cash, cash equivalents and marketable securities of \$1.2 billion. Our cash and marketable securities balances are held in a variety of interest-bearing instruments, including money market accounts, corporate debt securities and U.S. government securities. Available cash is invested in accordance with our investment policy's primary objectives of liquidity, safety of principal and diversity of investments.

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*Cash provided by (used in) operating activities.* The \$397.8 million decrease in cash provided by operating activities from 2016 to 2017 was due primarily to the payments made to our collaborative partners for new or amended arrangements and changes in working capital during the 2017 period. The \$215.4 million increase in cash provided by operating activities from 2015 to 2016 was due primarily to net income in 2016, which was driven in part by the recognition of milestones from Novartis of \$45.0 million and Eli Lilly of \$55.0 million, increased non-cash depreciation and amortization, and changes in working capital.

*Cash used in investing activities.* Our investing activities, other than purchases, sales and maturities of marketable securities, have consisted predominantly of capital expenditures and purchases of long term investments. During 2017, net cash used in investing activities was \$350.0 million, which represents purchases of marketable securities of \$260.8 million, capital expenditures of \$111.0 million, and purchases of long term investments of \$123.9 million, offset in part by the sale and maturity of marketable securities of \$145.7 million. During 2016, net cash used in investing activities was \$232.5 million, which represents purchases of marketable securities of \$57.4 million, capital expenditures of \$120.3 million, and acquisition of ARIAD Pharmaceuticals (Luxembourg) S.à.r.l. for net cash of \$142.9 million, offset in part by the sale and maturity of marketable securities of \$88.0 million. During 2015, net cash used in investing activities was \$105.0 million, which represents purchases of marketable securities of \$108.2 million, capital expenditures of \$26.0 million, and our long term investment in Agenus of \$39.8 million, offset in part by the sale and maturity of marketable securities of \$69.0 million. In the future, net cash used by investing activities may fluctuate significantly from period to period due to the timing of strategic equity investments, acquisitions, capital expenditures and maturities/sales and purchases of marketable securities.

*Cash provided by financing activities.* During 2017, net cash provided by financing activities was \$690.2 million, consisting primarily of proceeds from issuance of common stock in our September 2017 public offering and, to a lesser extent, proceeds from the issuance of common stock under our stock plans and employee stock purchase plan, offset in part by cash paid to ARIAD for contingent consideration and cash paid in connection with senior note conversions. During 2016, net cash provided by financing activities was \$58.6 million, consisting primarily of proceeds from issuance of common stock under our stock plans and employee stock purchase plan. During 2015, net cash provided by financing activities was \$84.7 million, consisting primarily of proceeds from issuance of common stock under our stock plans and employee stock purchase plan.

The following summarizes our significant contractual obligations as of December 31, 2017 and the effect those obligations are expected to have on our liquidity and cash flow in future periods (in millions):

	Total	Less Than 1 Year	Years 2 - 3	Years 4 - 5	Over 5 Years
<b>Contractual Obligations:</b>					
Principal on convertible senior debt	\$ 26.8	\$ 7.7	\$ 19.1	\$ —	\$ —
Interest on convertible senior debt	0.8	0.3	0.5	—	—
Non-cancelable lease obligations	21.7	12.0	8.6	1.0	0.1
Total contractual obligations	<u>\$ 49.3</u>	<u>\$ 20.0</u>	<u>\$ 28.2</u>	<u>\$ 1.0</u>	<u>\$ 0.1</u>

We have entered into and may in the future seek to license additional rights relating to technologies or drug development candidates in connection with our drug discovery and development programs. Under these licenses, we may be required to pay upfront fees, milestone payments, and royalties on sales of future products, which are not reflected in the table above.

We believe that our cash flow from operations, together with our cash, cash equivalents and marketable securities, will be adequate to satisfy our capital needs for at least the next twelve months. Our cash requirements depend on numerous factors, including our expenditures in connection with our drug discovery and development programs and commercialization operations; expenditures in connection with litigation or other legal proceedings; competing technological and market developments; the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; costs for future facility requirements; our receipt of any milestone or other payments under any collaborative agreements we may enter into, including the agreements with Novartis and Lilly; expenditures in connection with potential exchanges of our outstanding convertible senior notes; and expenditures in connection with strategic relationships and license agreements, including our agreements with Agenus, ARIAD, Calithera, Lilly, MacroGenics, Merus and Syros, strategic equity investments or potential acquisitions. Changes in our research and development or

commercialization plans or other changes affecting our operating expenses may result in changes in the timing and amount of expenditures of our capital resources. To the extent we seek to augment our existing cash resources and cash flow from operations to satisfy our cash requirements, we expect that additional funding can be obtained primarily through public or private equity offerings, debt financings, borrowings or strategic collaborations. The sale of equity or additional convertible debt securities in the future may be dilutive to our stockholders, and may provide for rights, preferences or privileges senior to those of our holders of common stock. Debt financing arrangements may require us to pledge certain assets or enter into covenants that could restrict our operations or our ability to incur further indebtedness.

#### **Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements other than those that are discussed above.

#### **Item 7A. *Quantitative and Qualitative Disclosures About Market Risk***

Our investments in marketable securities, which are composed primarily of corporate debt securities and U.S. government securities, are subject to default, changes in credit rating and changes in market value. These investments are also subject to interest rate risk and will decrease in value if market interest rates increase. As of December 31, 2017, marketable securities were \$270.1 million. Due to the nature of these investments, if market interest rates were to increase immediately and uniformly by 10% from levels as of December 31, 2017, the decline in fair value would not be material.

**Item 8. Financial Statements and Supplementary Data**

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Incyte Corporation

### Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Incyte Corporation (the Company) as of December 31, 2017 and 2016, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2017, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2017, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 15, 2018 expressed an unqualified opinion thereon.

### Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 1991.

Philadelphia, Pennsylvania  
February 15, 2018

**INCYTE CORPORATION**  
**CONSOLIDATED BALANCE SHEETS**  
(in thousands, except number of shares and par value)

	<u>December 31,</u>	
	<u>2017</u>	<u>2016</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 899,509	\$ 652,343
Marketable securities—available-for-sale	270,136	156,203
Accounts receivable	266,299	148,758
Inventory	6,482	4,106
Prepaid expenses and other current assets	62,428	32,768
Total current assets	<u>1,504,854</u>	<u>994,178</u>
Restricted cash and investments	925	886
Long term investments	134,356	31,987
Inventory	7,966	15,193
Property and equipment, net	259,763	167,679
Other intangible assets, net	236,901	258,437
In-process research and development	—	12,000
Goodwill	155,593	155,593
Other assets, net	2,224	2,644
Total assets	<u>\$ 2,302,582</u>	<u>\$ 1,638,597</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 67,671	\$ 75,599
Accrued compensation	74,550	50,904
Interest payable	33	762
Accrued and other current liabilities	198,901	126,697
Convertible senior notes	7,393	—
Acquisition-related contingent consideration	26,848	19,539
Total current liabilities	<u>375,396</u>	<u>273,501</u>
Convertible senior notes	16,608	651,481
Acquisition-related contingent consideration	260,152	281,461
Other liabilities	19,797	12,687
Total liabilities	<u>671,953</u>	<u>1,219,130</u>
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; none issued or outstanding as of December 31, 2017 and December 31, 2016	—	—
Common stock, \$0.001 par value; 400,000,000 shares authorized; 211,262,906 and 188,848,752 shares issued and outstanding as of December 31, 2017 and December 31, 2016, respectively	211	189
Additional paid-in capital	3,627,433	2,096,929
Accumulated other comprehensive loss	(7,010)	(2,886)
Accumulated deficit	(1,990,005)	(1,674,765)
Total stockholders' equity	<u>1,630,629</u>	<u>419,467</u>
Total liabilities and stockholders' equity	<u>\$ 2,302,582</u>	<u>\$ 1,638,597</u>

See accompanying notes.

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

	Year Ended December 31,		
	2017	2016	2015
<b>Revenues:</b>			
Product revenues, net	\$ 1,200,312	\$ 882,404	\$ 601,015
Product royalty revenues	160,791	110,711	74,821
Milestone and contract revenues	175,000	112,512	77,857
Other revenues	113	92	58
<b>Total revenues</b>	<b>1,536,216</b>	<b>1,105,719</b>	<b>753,751</b>
<b>Costs and expenses:</b>			
Cost of product revenues (including definite-lived intangible amortization)	79,479	58,187	26,972
Research and development	1,326,361	581,861	479,514
Selling, general and administrative	366,406	303,251	196,614
Change in fair value of acquisition-related contingent consideration	7,704	17,422	—
<b>Total costs and expenses</b>	<b>1,779,950</b>	<b>960,721</b>	<b>703,100</b>
Income (loss) from operations	(243,734)	144,998	50,651
Interest and other income, net	17,500	4,412	7,089
Interest expense	(6,900)	(38,745)	(45,603)
Unrealized loss on long term investments	(24,275)	(3,261)	(4,581)
Expense related to senior note conversions	(54,881)	—	—
<b>Income (loss) before provision for income taxes</b>	<b>(312,290)</b>	<b>107,404</b>	<b>7,556</b>
Provision for income taxes	852	3,182	1,025
<b>Net income (loss)</b>	<b>\$ (313,142)</b>	<b>\$ 104,222</b>	<b>\$ 6,531</b>
<b>Net income (loss) per share:</b>			
Basic	(1.53)	0.55	0.04
Diluted	(1.53)	0.54	0.03
<b>Shares used in computing net income (loss) per share:</b>			
Basic	204,580	187,873	179,601
Diluted	204,580	194,125	187,302

See accompanying notes.

**INCYTE CORPORATION**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)**  
**(in thousands)**

	<u>Year Ended December 31,</u>		
	<u>2017</u>	<u>2016</u>	<u>2015</u>
Net income (loss)	\$ (313,142)	\$ 104,222	\$ 6,531
Other comprehensive loss:			
Foreign currency translation	(39)	(9)	—
Unrealized gain (loss) on marketable securities and long term investment, net of tax	1,615	504	(794)
Reclassification adjustment for realized (gain) loss on marketable securities	—	178	(1,830)
Defined benefit pension obligations, net of tax	(5,700)	(2,750)	—
Other comprehensive loss	(4,124)	(2,077)	(2,624)
Comprehensive income (loss)	<u>\$ (317,266)</u>	<u>\$ 102,145</u>	<u>\$ 3,907</u>

See accompanying notes.

**INCYTE CORPORATION**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**  
(in thousands, except number of shares)

	Common Stock	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balances at December 31, 2014	\$ 171	\$ 1,701,904	\$ 1,815	\$ (1,785,518)	\$ (81,628)
Issuance of 5,220,474 shares of Common Stock upon exercise of stock options and settlement of employee restricted stock units and 194,453 shares of Common Stock under the ESPP	5	86,755	—	—	86,760
Issuance of 10,352,784 shares of Common Stock upon conversion of Convertibles Senior Notes due 2015	11	88,963	—	—	88,974
Issuance of 3,902 shares of Common Stock upon conversion of Convertible Senior Notes due 2020	—	180	—	—	180
Issuance of 2,017 shares of Common Stock for services rendered	—	218	—	—	218
Excess tax provision from stock based compensation	—	2,872	—	—	2,872
Stock compensation expense	—	69,872	—	—	69,872
Other comprehensive loss	—	—	(2,624)	—	(2,624)
Net income	—	—	—	6,531	6,531
Balances at December 31, 2015	\$ 187	\$ 1,950,764	\$ (809)	\$ (1,778,987)	\$ 171,155
Issuance of 2,068,226 shares of Common Stock upon exercise of stock options and settlement of employee restricted stock units and 126,648 shares of Common Stock under the ESPP	2	49,661	—	—	49,663
Issuance of 77 shares of Common Stock upon conversion of Convertible Senior Notes due 2020	—	4	—	—	4
Issuance of 114 shares of Common Stock upon conversion of Convertible Senior Notes due 2018	—	5	—	—	5
Issuance of 3,438 shares of Common Stock for services rendered	—	294	—	—	294
Stock compensation expense	—	96,201	—	—	96,201
Other comprehensive loss	—	—	(2,077)	—	(2,077)
Net income	—	—	—	104,222	104,222
Balances at December 31, 2016	\$ 189	\$ 2,096,929	\$ (2,886)	\$ (1,674,765)	\$ 419,467
Issuance of 3,012,937 shares of Common Stock upon exercise of stock options and settlement of employee restricted stock units and performance shares and 157,277 shares of Common Stock under the ESPP	3	66,732	—	—	66,735
Issuance of 7,095,350 shares of Common Stock upon conversion of Convertible Senior Notes due 2020	7	330,004	—	—	330,011
Issuance of 7,201,058 shares of Common Stock upon conversion of Convertible Senior Notes due 2018	7	351,037	—	—	351,044
Issuance of 2,532 shares of Common Stock for services rendered	—	294	—	—	294
Issuance of 4,945,000 shares of Common Stock	5	649,382	—	—	649,387
Stock compensation expense	—	133,055	—	—	133,055
Other comprehensive loss	—	—	(4,124)	—	(4,124)
Adoption of accounting standard (Note 1)	—	—	—	(2,098)	(2,098)
Net loss	—	—	—	(313,142)	(313,142)
Balances at December 31, 2017	\$ 211	\$ 3,627,433	\$ (7,010)	\$ (1,990,005)	\$ 1,630,629

See accompanying notes.

**INCYTE CORPORATION**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(in thousands)

	Year Ended December 31,		
	2017	2016	2015
<b>Cash flows from operating activities :</b>			
Net income (loss)	\$ (313,142)	\$ 104,222	\$ 6,531
Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities:			
Depreciation and amortization	52,178	58,425	44,883
In-process research and development impairment	12,000	—	—
Stock-based compensation	133,055	96,201	69,872
Expense related to senior note conversions	54,881	—	—
Other, net	290	472	(1,612)
Unrealized loss on long term investments	24,275	3,261	4,581
Change in fair value of acquisition-related contingent consideration	7,704	17,422	—
Changes in operating assets and liabilities:			
Accounts receivable	(117,541)	(23,947)	(56,517)
Prepaid expenses and other assets	(31,367)	(13,069)	3,583
Inventory	4,851	4,047	98
Accounts payable	(7,928)	43,758	5,623
Accrued and other liabilities	87,756	26,476	25,245
Deferred revenue—collaborative agreements	—	(12,512)	(12,879)
Net cash (used in) provided by operating activities	<u>(92,988)</u>	<u>304,756</u>	<u>89,408</u>
<b>Cash flows from investing activities :</b>			
Acquisition of business, net of cash acquired	—	(142,856)	—
Purchase of long term investments	(123,891)	—	(39,829)
Capital expenditures	(111,021)	(120,277)	(26,003)
Purchases of marketable securities	(260,780)	(57,372)	(108,152)
Sale and maturities of marketable securities	145,714	88,017	68,974
Net cash used in investing activities	<u>(349,978)</u>	<u>(232,488)</u>	<u>(105,010)</u>
<b>Cash flows from financing activities :</b>			
Restricted investments, net	(39)	14,023	7
Proceeds from issuance of common stock under stock plans	66,764	49,973	86,436
Proceeds from issuance of common stock, net	649,387	—	—
Cash paid in connection with senior note conversions	(8,934)	—	—
Direct financing arrangements repayments	—	(445)	(1,699)
Payment of contingent consideration	(17,007)	(4,906)	—
Net cash provided by financing activities	<u>690,171</u>	<u>58,645</u>	<u>84,744</u>
Effect of exchange rates on cash and cash equivalents	(39)	(9)	—
Net increase in cash and cash equivalents	247,166	130,904	69,142
Cash and cash equivalents at beginning of period	652,343	521,439	452,297
Cash and cash equivalents at end of period	<u>\$ 899,509</u>	<u>\$ 652,343</u>	<u>\$ 521,439</u>
<b>Supplemental Schedule of Cash Flow Information</b>			
Interest paid	\$ 314	\$ 7,218	\$ 12,746
Income taxes paid	\$ 6,305	\$ 927	\$ 62
Reclassification to common stock and additional paid in capital in connection with conversions of 4.75% convertible senior notes due 2015	\$ —	\$ —	\$ 88,974
Reclassification to common stock and additional paid in capital in connection with conversions of 0.375% convertible senior notes due 2018	\$ 351,044	\$ 5	\$ —
Reclassification to common stock and additional paid in capital in connection with conversions of 1.25% convertible senior notes due 2020	\$ 330,011	\$ 4	\$ 180
Unpaid purchases of property and equipment	\$ 5,643	\$ 10,989	\$ —

See accompanying notes.

## **Note 1. Organization and Summary of Significant Accounting Policies**

*Organization and Business.* Incyte Corporation (including its subsidiaries, “Incyte,” “we,” “us,” or “our”) is a biopharmaceutical company focused on developing and commercializing proprietary therapeutics. Our portfolio includes compounds in various stages, ranging from preclinical to late stage development, and commercialized products JAKAFI® (ruxolitinib) and ICLUSIG® (ponatinib). Our operations are treated as one operating segment.

On June 1, 2016, we acquired (the “Acquisition”), pursuant to a Share Purchase Agreement dated as of May 9, 2016 (the “Share Purchase Agreement”), all of the outstanding shares of ARIAD Pharmaceuticals (Luxembourg) S.à.r.l., since renamed Incyte Biosciences Luxembourg S.à.r.l., the parent company of certain European subsidiaries of ARIAD Pharmaceuticals, Inc. (“ARIAD”). Refer to Note 2 for further information regarding the Acquisition.

*Principles of Consolidation.* The consolidated financial statements include the accounts of Incyte Corporation and our wholly owned subsidiaries. All inter-company accounts, transactions, and profits have been eliminated in consolidation.

*Acquisitions .* Acquired businesses are accounted for using the acquisition method of accounting, which requires that assets acquired and liabilities assumed be recorded at fair value, with limited exceptions. Any excess of the purchase price over the fair value of the net assets acquired is recorded as goodwill. Transaction costs are expensed as incurred. The operating results of the acquired business are reflected in our consolidated financial statements after the date of acquisition. Acquired in-process research and development (“IPR&D”) is recognized at fair value and initially characterized as an indefinite-lived intangible asset, irrespective of whether the acquired IPR&D has an alternative future use.

*Foreign Currency Translation .* Operations in non-U.S. entities are recorded in the functional currency of each entity. For financial reporting purposes, the functional currency of an entity is determined by a review of the source of an entity's most predominant cash flows. The results of operations for any non-U.S. dollar functional currency entities are translated from functional currencies into U.S. dollars using the average currency rate during each month. Assets and liabilities are translated using currency rates at the end of the period. Adjustments resulting from translating the financial statements of our foreign entities that use their local currency as the functional currency into U.S. dollars are reflected as a component of other comprehensive income (loss). Transaction gains and losses are recorded in interest and other income, net, in the consolidated statements of operations. To date, both the translation gains or losses in other comprehensive income (loss) and the transaction gains or losses in foreign exchange gain (loss) have been immaterial.

*Use of Estimates.* The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

*Concentrations of Credit Risk.* Cash, cash equivalents, marketable securities, trade receivables and restricted investments are financial instruments which potentially subject us to concentrations of credit risk. The estimated fair value of financial instruments approximates the carrying value based on available market information. We primarily invest our excess available funds in debt securities and, by policy, limit the amount of credit exposure to any one issuer and to any one type of investment, other than securities issued or guaranteed by the U.S. government and money market funds that meet certain guidelines. Our receivables mainly relate to our product sales of JAKAFI, ICLUSIG and collaborative agreements with pharmaceutical companies. We have not experienced any significant credit losses on cash, cash equivalents, marketable securities, trade receivables or restricted investments to date and do not require collateral on receivables.

*Cash and Cash Equivalents.* Cash and cash equivalents are held in banks or in custodial accounts with banks. Cash equivalents are defined as all liquid investments and money market funds with maturity from date of purchase of 90 days or less that are readily convertible into cash.

*Marketable Securities—Available-for-Sale.* Available -for-sale securities are carried at fair value, based on quoted market prices and observable inputs, with unrealized gains and losses, net of tax, reported as a separate component of stockholders’ equity. We classify marketable securities that are available for use in current operations as current assets on

the consolidated balance sheets. Realized gains and losses and declines in value judged to be other than temporary for available-for-sale securities are included in "Interest and other income, net." The cost of securities sold is based on the specific identification method.

*Accounts Receivable.* As of December 31, 2017 and 2016, we had no allowance for doubtful accounts. We provide an allowance for doubtful accounts based on experience and specifically identified risks. Accounts receivable are carried at fair value and charged off against the allowance for doubtful accounts when we determine that recovery is unlikely and we cease collection efforts.

*Inventory.* Inventories are determined at the lower of cost and net realizable value with cost determined under the specific identification method and may consist of raw materials, work in process and finished goods.

JAKAFI raw materials and work-in-process inventory is not subject to expiration and the shelf life of finished goods inventory is 36 months from the start of manufacturing of the finished goods. ICLUSIG raw materials and work-in-process inventory is not subject to expiration and finished goods inventory has a shelf life of 24 months from the start of manufacturing of the finished goods. We evaluate for potential excess inventory by analyzing current and future product demand relative to the remaining product shelf life. We build demand forecasts by considering factors such as, but not limited to, overall market potential, market share, market acceptance and patient usage. We classify inventory as current on the consolidated balance sheets when we expect inventory to be consumed for commercial use within the next twelve months.

The ICLUSIG inventories were recorded at fair value less costs to sell in connection with the Acquisition, which resulted in a higher cost of ICLUSIG product revenues over a one year period from the acquisition date.

*Variable Interest Entities.* We perform an initial and ongoing evaluation of the entities with which we have variable interests, such as equity ownership, in order to identify entities (i) that do not have sufficient equity investment at risk to permit the entity to finance its activities without additional subordinated financial support or (ii) in which the equity investors lack an essential characteristic of a controlling financial interest as variable interest entities ("VIE" or "VIEs"). If an entity is identified as a VIE, we perform an assessment to determine whether we have both (i) the power to direct activities that most significantly impact the VIE's economic performance and (ii) have the obligation to absorb losses from or the right to receive benefits of the VIE that could potentially be significant to the VIE. If both of these criteria are satisfied, we are identified as the primary beneficiary of the VIE. As of December 31, 2017, there were no entities in which we held a variable interest which we determined to be VIEs.

*Long Term Investments.* Our long term investments consist of investments in common stock of publicly held companies with whom we have entered into collaboration and license agreements. The investments in companies over which we have significant influence, but not controlling interest, are accounted for using the equity method (fair value option). The investments in companies over which we do not have significant influence are accounted for as available-for-sale securities. We classify all of our investments in common stock of publicly held companies with whom we have entered into collaboration and license agreements as long term investments.

*Equity Method Investments.* In circumstances where we have the ability to exercise significant influence over the operating and financial policies of a company in which we have an investment, the investment is accounted for either (i) under the equity method of accounting or (ii) at fair value by electing the fair value option under U.S. GAAP. In assessing whether we exercise significant influence, we consider the nature and magnitude of our investment, any voting and protective rights we hold, any participation in the governance of the other company, and other relevant factors such as the presence of a collaboration or other business relationship. Under the equity method of accounting, we record within our results of operations our share of income or loss of the investee company. Under the fair value option, our investment is carried at fair value on our consolidated balance sheets as a long term investment and all changes in fair value are reported in our consolidated statements of operations as an unrealized gain (loss) on long term investments.

*Property and Equipment.* Property and equipment is stated at cost, less accumulated depreciation and amortization. Depreciation is recorded using the straight-line method over the estimated useful lives of the respective assets. Leasehold improvements are amortized over the shorter of the estimated useful life of the assets or lease term.

Management continually reviews the estimated useful lives of technologically sensitive equipment and believes that those estimates appropriately reflect the current useful life of our assets. In the event that a currently unknown significantly advanced technology became commercially available, we would re-evaluate the value and estimated useful lives of our existing equipment, possibly having a material impact on the financial statements.

*Lease Accounting.* We account for operating leases by recording rent expense on a straight-line basis over the expected life of the lease, commencing on the date we gain possession of leased property. We include tenant improvement allowances and rent holidays received from landlords and the effect of any rent escalation clauses to determine the straight-line rent expense over the expected life of the lease.

Capital leases are reflected as a liability at the inception of the lease based on the present value of the minimum lease payments or, if lower, the fair value of the property. Assets under capital leases are recorded in property and equipment, net on the consolidated balance sheets and depreciated in a manner similar to other property and equipment.

*Other Intangible Assets, net.* Other intangible assets, net consist of licensed intellectual property rights acquired in business combinations, which are reported at fair value, less accumulated amortization. Intangible assets with finite lives are amortized over their estimated useful lives using the straight-line method.

*In-Process Research and Development.* The fair value of in-process research and development (“IPR&D”) acquired through business combinations is capitalized as an indefinite-lived intangible asset until the completion or abandonment of the related research and development activities. When the related research and development is completed, the asset will be assigned a useful life and amortized.

*Impairment of Long-Lived Assets.* Long-lived assets with finite lives are tested for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. If indicators of impairment are present, the asset is tested for recoverability by comparing the carrying value of the asset to the related estimated undiscounted future cash flows expected to be derived from the asset. If the expected cash flows are less than the carrying value of the asset, then the asset is considered to be impaired and its carrying value is written down to fair value, based on the related estimated discounted future cash flows.

Indefinite-lived intangible assets, including IPR&D, are tested for impairment annually as of October 1 or more frequently if events or changes in circumstances between annual tests indicate that the asset may be impaired. Impairment losses on indefinite-lived intangible assets are recognized based solely on a comparison of the fair value of the asset to its carrying value. Due to the discontinuation of the OPTIC-2L study described in Note 2 below, we considered our indefinite-lived IPR&D asset to be impaired and recorded a \$12.0 million impairment charge in research and development expense on the consolidated statements of operations during the third quarter of 2017.

*Goodwill.* Goodwill is calculated as the difference between the acquisition date fair value of the consideration transferred and the values assigned to the assets acquired and liabilities assumed. Goodwill is not amortized but is tested for impairment at the reporting unit level at least annually as of October 1 or when a triggering event occurs that could indicate a potential impairment by assessing qualitative factors or performing a quantitative analysis in determining whether it is more likely than not that the fair value of net assets are below their carrying amounts. A reporting unit is the same as, or one level below, an operating segment. Our operations are currently comprised of a single, entity wide reporting unit. We completed our most recent annual impairment assessment as of October 1, 2017 and determined that the carrying value of our reporting unit was not impaired.

*Income Taxes.* We account for income taxes using the asset and liability approach which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and amounts reportable for income tax purposes. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more-likely-than-not that some portion or all of the deferred tax assets will not be realized.

In addition, we follow the guidance related to accounting for uncertainty in income taxes. This guidance creates a single model to address uncertainty in tax positions and clarifies the accounting for income taxes by prescribing the minimum recognition threshold a tax position is required to meet before it is recognized in the financial statements.

*Financing Costs Related to Long-term Debt.* Costs associated with obtaining long-term debt are deferred and amortized over the term of the related debt using the effective interest method. Such costs are presented as a direct deduction from the carrying amount of the long-term debt liability, consistent with debt discounts, on the consolidated balance sheets.

*Grant Accounting.* Grant amounts received from government agencies for operations are deferred and are amortized into income over the service period of the grant. Grant amounts received for purchases of capital assets are deferred and amortized into interest and other income, net over the useful life of the related capital assets. Such amounts are recorded in other liabilities on the consolidated balance sheets.

*Net Income (Loss) Per Share.* Our basic and diluted net income (loss) per share is calculated by dividing the net income (loss) by the weighted average number of shares of common stock outstanding during all periods presented. Options to purchase stock, restricted stock units and shares issuable upon the conversion of convertible debt are included in diluted earnings per share calculations, unless the effects are anti-dilutive.

*Accumulated Other Comprehensive Income (Loss).* Accumulated other comprehensive income (loss) consists of realized and unrealized gains or losses on marketable securities that are classified as available-for-sale, a long-term investment classified as available-for-sale, foreign currency translation gains or losses and defined benefit pension obligations.

*Revenue Recognition.* Revenues are recognized when (1) persuasive evidence of an arrangement exists, (2) delivery has occurred or services have been rendered, (3) the price is fixed or determinable and (4) collectability is reasonably assured. Revenues are deferred for fees received before earned or until no further obligations exist. We exercise judgment in determining that collectability is reasonably assured or that services have been delivered in accordance with the arrangement. We assess whether the fee is fixed or determinable based on the payment terms associated with the transaction and whether the sales price is subject to refund or adjustment. We assess collectability based primarily on the customer's payment history and on the creditworthiness of the customer.

#### Product Revenues

Our product revenues consist of U.S. sales of JAKAFI and European sales of ICLUSIG. Product revenues are recognized once we meet all four revenue recognition criteria described above. In November 2011, we began shipping JAKAFI to our customers in the U.S., which include specialty pharmacies and wholesalers. In June 2016, we acquired the right to and began shipping ICLUSIG to our customers in the European Union and certain other jurisdictions (Note 2), which include retail pharmacies, hospital pharmacies and distributors.

We recognize revenues for product received by our customers net of allowances for customer credits, including estimated rebates, chargebacks, discounts, returns, distribution service fees, patient assistance programs, and government rebates, such as Medicare Part D coverage gap reimbursements in the U.S. Product shipping and handling costs are included in cost of product revenues.

*Customer Credits:* Our customers are offered various forms of consideration, including allowances, service fees and prompt payment discounts. We expect our customers will earn prompt payment discounts and, therefore, we deduct the full amount of these discounts from total product sales when revenues are recognized. Service fees are also deducted from total product sales as they are earned.

*Rebates and Discounts:* Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program in the U.S. and mandated discounts in Europe in markets where government-sponsored healthcare systems are the primary payers for healthcare. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements or legal requirements with public sector benefit providers. The accrual for rebates is based on statutory discount rates and expected utilization as well as historical data we have accumulated since product launches. Our estimates for expected utilization of rebates are based on data received from our customers. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarters' unpaid

rebates. If actual future rebates vary from estimates, we may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

*Chargebacks:* Chargebacks are discounts that occur when certain contracted customers, which currently consist primarily of group purchasing organizations, Public Health Service institutions, non-profit clinics, and Federal government entities purchasing via the Federal Supply Schedule, purchase directly from our wholesalers. Contracted customers generally purchase the product at a discounted price. The wholesalers, in turn, charges back to us the difference between the price initially paid by the wholesalers and the discounted price paid by the contracted customers. In addition to actual chargebacks received we maintain an accrual for chargebacks based on the estimated contractual discounts on the inventory levels on hand in our distribution channel. If actual future chargebacks vary from these estimates, we may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

*Medicare Part D Coverage Gap:* Medicare Part D prescription drug benefit mandates manufacturers to fund 50% of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients. Our estimates for the expected Medicare Part D coverage gap are based on historical invoices received and in part from data received from our customers. Funding of the coverage gap is generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarters. If actual future funding varies from estimates, we may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

*Co-payment Assistance:* Patients who have commercial insurance and meet certain eligibility requirements may receive co-payment assistance. We accrue a liability for co-payment assistance based on actual program participation and estimates of program redemption using data provided by third-party administrators.

#### Product Royalty Revenues

Royalty revenues on commercial sales for ruxolitinib (marketed as JAKAVI<sup>®</sup> outside the United States) by Novartis Pharmaceutical International Ltd. ("Novartis") are based on net sales of licensed products in licensed territories as provided by Novartis. Royalty revenues on commercial sales for baricitinib (marketed as OLUMIANT) by Eli Lilly and Company ("Lilly") are based on net sales of licensed products in licensed territories as provided by Lilly. We recognize royalty revenues in the period the sales occur.

#### Cost of Product Revenues

Cost of product revenues includes all JAKAFI related product costs as well as ICLUSIG related product costs. The acquired ICLUSIG inventories were recorded at fair value less costs to sell in connection with the Acquisition, and will result in a higher cost of ICLUSIG product revenues over the period in which this inventory is sold, which is expected to be over a one year period from the acquisition date. In addition, cost of product revenues include low single-digit royalties under our collaboration and license agreement to Novartis on all future sales of JAKAFI in the United States. Subsequent to the Acquisition on June 1, 2016, cost of product revenues also includes the amortization of our licensed intellectual property for ICLUSIG using the straight-line method over the estimated useful life of 12.5 years.

#### Contract and License Revenues

Under agreements involving multiple deliverables, services and/or rights to use assets that we entered into prior to January 1, 2011, the multiple elements are divided into separate units of accounting when certain criteria are met, including whether the delivered items have stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. When separate units of accounting exist, consideration is allocated among the separate elements based on their respective fair values. The determination of fair value of each element is based on objective evidence from historical sales of the individual elements by us to other customers. If such evidence of fair value for each undelivered element of the arrangement does not exist, all revenue from the arrangement is deferred until such time that evidence of fair value for each undelivered element does exist or until all elements of the arrangement are delivered. When elements are specifically tied to a separate earnings process, revenue is recognized when the specific performance obligation tied to the element is completed. When revenues for an element are not specifically tied to a separate earnings process, they are recognized ratably over the term of the agreement. We assess whether a substantive

milestone exists at the inception of our agreements. For all milestones within our arrangements that are considered substantive, we recognize revenue upon the achievement of the associated milestone. If a milestone is not considered substantive, we would recognize the applicable milestone payment over the remaining period of performance under the arrangement. As of December 31, 2017, all remaining potential milestones under our collaborative arrangements are considered substantive.

On January 1, 2011, updated guidance on the recognition of revenues for agreements with multiple deliverables became effective and applies to any agreements we may enter into on or after January 1, 2011. This updated guidance (i) relates to whether multiple deliverables exist, how the deliverables in a revenue arrangement should be separated and how the consideration should be allocated; (ii) requires companies to allocate revenues in an arrangement using estimated selling prices of deliverables if a vendor does not have vendor-specific objective evidence or third-party evidence of selling price; and (iii) eliminates the use of the residual method and requires companies to allocate revenues using the relative selling price method. During the years ended December 31, 2017, 2016 and 2015, we did not enter into any agreements that are subject to this updated guidance. If we enter into an agreement with multiple deliverables after January 1, 2011 or amend existing agreements, this updated guidance could have a material effect on our financial statements.

Our collaborations often include contractual milestones, which typically relate to the achievement of pre-specified development, regulatory and commercialization events. These three categories of milestone events reflect the three stages of the life-cycle of our drugs, which we describe in more detail in the following paragraphs.

The regulatory review and approval process, which includes preclinical testing and clinical trials of each drug candidate, is lengthy, expensive and uncertain. Securing approval by the U.S. Food and Drug Administration (the “FDA”) requires the submission of extensive preclinical and clinical data and supporting information to the FDA for each indication to establish a drug candidate’s safety and efficacy. The approval process takes many years, requires the expenditure of substantial resources, involves post-marketing surveillance and may involve ongoing requirements for post-marketing studies. Before commencing clinical investigations of a drug candidate in humans, we must submit an Investigational New Drug application (“IND”), which must be reviewed by the FDA.

The steps generally required before a drug may be marketed in the United States include preclinical laboratory tests, animal studies and formulation studies, submission to the FDA of an IND for human clinical testing, performance of adequate and well-controlled clinical trials in three phases, as described below, to establish the safety and efficacy of the drug for each indication, submission of a new drug application (“NDA”) or biologics license application (“BLA”) to the FDA for review and FDA approval of the NDA or BLA.

Similar requirements exist within foreign regulatory agencies as well. The time required satisfying the FDA requirements or similar requirements of foreign regulatory agencies may vary substantially based on the type, complexity and novelty of the product or the targeted disease.

Preclinical testing includes laboratory evaluation of product pharmacology, drug metabolism, and toxicity, which includes animal studies, to assess potential safety and efficacy as well as product chemistry, stability, formulation, development, and testing. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND. The FDA may raise safety concerns or questions about the conduct of the clinical trials included in the IND, and any of these concerns or questions must be resolved before clinical trials can proceed. We cannot be sure that submission of an IND will result in the FDA allowing clinical trials to commence. Clinical trials involve the administration of the investigational drug or the marketed drug to human subjects under the supervision of qualified investigators and in accordance with good clinical practices regulations covering the protection of human subjects. Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Phase I usually involves the initial introduction of the investigational drug into healthy volunteers to evaluate its safety, dosage tolerance, absorption, metabolism, distribution and excretion. Phase II usually involves clinical trials in a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse effects and safety risks, and evaluate and gain preliminary evidence of the efficacy of the drug for specific indications. Phase III clinical trials usually further evaluate clinical efficacy and safety by testing the drug in its final form in an expanded patient population, providing statistical evidence of efficacy and safety, and providing an adequate basis for labeling. We cannot guarantee that Phase I, Phase II or Phase III testing will be completed successfully within any specified period of time, if at all. Furthermore, we,

the institutional review board for a trial, or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Generally, the milestone events contained in our collaboration agreements coincide with the progression of our drugs from development, to regulatory approval and then to commercialization. The process of successfully discovering a new development candidate, having it approved and successfully commercialized is highly uncertain. As such, the milestone payments we may earn from our partners involve a significant degree of risk to achieve. Therefore, as a drug candidate progresses through the stages of its life-cycle, the value of the drug candidate generally increases.

*Research and Development Costs.* Our policy is to expense research and development costs as incurred. We often contract with clinical research organizations (“CROs”) to facilitate, coordinate and perform agreed upon research and development of a new drug. To ensure that research and development costs are expensed as incurred, we record monthly accruals for clinical trials and preclinical testing costs based on the work performed under the contract.

These CRO contracts typically call for the payment of fees for services at the initiation of the contract and/or upon the achievement of certain clinical trial milestones. In the event that we prepay CRO fees, we record the prepayment as a prepaid asset and amortize the asset into research and development expense over the period of time the contracted research and development services are performed. Most professional fees, including project and clinical management, data management, monitoring, and medical writing fees are incurred throughout the contract period. These professional fees are expensed based on their percentage of completion at a particular date. Our CRO contracts generally include pass through fees. Pass through fees include, but are not limited to, regulatory expenses, investigator fees, travel costs, and other miscellaneous costs, including shipping and printing fees. We expense the costs of pass through fees under our CRO contracts as they are incurred, based on the best information available to us at the time. The estimates of the pass through fees incurred are based on the amount of work completed for the clinical trial and are monitored through correspondence with the CROs, internal reviews and a review of contractual terms. The factors utilized to derive the estimates include the number of patients enrolled, duration of the clinical trial, estimated patient attrition, screening rate and length of the dosing regimen. CRO fees incurred to set up the clinical trial are expensed during the setup period.

Under our clinical trial collaboration agreements we may be reimbursed for certain development costs incurred. Such costs are recorded as a reduction of research and development expense in the period in which the related expense is incurred.

*Stock Compensation.* Share-based payment transactions with employees, which include stock options, restricted stock units (“RSUs”) and performance shares (“PSUs”), are recognized as compensation expense over the requisite service period based on their estimated fair values as well as expected forfeiture rates. The stock compensation process requires significant judgment and the use of estimates, particularly surrounding Black-Scholes assumptions such as stock price volatility over the option term and expected option lives, as well as expected forfeiture rates and the probability of PSUs vesting. The fair value of stock options, which are subject to graded vesting, are recognized as compensation expense over the requisite service period using the accelerated attribution method. The fair value of RSUs that are subject to cliff vesting are recognized as compensation expense over the requisite service period using the straight-line attribution method, and the fair value of RSUs that are subject to graded vesting are recognized as compensation expense over the requisite service period using the accelerated attribution method. The fair value of PSUs are recognized as compensation expense beginning at the time in which the performance conditions are deemed probable of achievement, over the remaining requisite service period. We recorded \$133.1 million, \$96.2 million and \$69.9 million of stock compensation expense for the years ended December 31, 2017, 2016 and 2015, respectively.

*Acquisition-Related Contingent Consideration.* Acquisition-related contingent consideration, which consists of our future royalty and certain potential milestone obligations to ARIAD, is recorded on the acquisition date at the estimated fair value of the obligation, in accordance with the acquisition method of accounting. The fair value measurement is based on significant inputs that are unobservable in the market and thus represents a Level 3 measurement. The fair value of the acquisition-related contingent consideration is remeasured each reporting period, with changes in fair value recorded in the consolidated statements of operations.

## Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-09, “Revenue from Contracts with Customers,” which will replace numerous requirements in U.S. GAAP, including industry-specific requirements. This guidance provides a five step model to be applied to all contracts with customers, with an underlying principle that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services. ASU No. 2014-09 requires extensive quantitative and qualitative disclosures covering the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including disclosures on significant judgments made when applying the guidance. This guidance is effective for annual reporting periods beginning after December 15, 2017 and interim periods therein.

We performed an impact assessment which consisted of a review of a representative sample of contracts, discussions with key stakeholders, and a cataloging of potential impacts on our financial statements, accounting policies, financial controls, and operations. The guidance will not have a material impact on our revenue recognition practices for product and royalty revenues. The adoption of ASU 2014-09 will have primarily two impacts on our future milestone and contract revenues generated by our collaborative research and license agreements:

- (i) Changes in the model for distinct licenses of functional intellectual property which may result in a timing difference of revenue recognition. Whereas revenue from these arrangements was previously recognized over a period of time pursuant to revenue recognition guidance that was in place for our arrangements at the time such arrangements commenced, revenue from new arrangements we enter into may now be recognized at a point in time under the new guidance.
- (ii) Assessments of milestone payments, which are linked to events that are in our control, will result in variable consideration that may be recognized at an earlier point in time under the new guidance, when it is probable that the milestone will be achieved without a significant future reversal of cumulative revenue expected.

We completed our assessment of the impact of this guidance with the cumulative effect of initially applying the standard to be recognized at the date of initial application in retained earnings (also referred to as a “modified retrospective” adoption methodology). The impact under this methodology to our previously reported revenues is insignificant in the periods reported, with no effect to reported revenues in the fiscal year ended December 31, 2017. We will adopt the new standard effective for the fiscal period beginning January 1, 2018, and will report new disclosures required by this guidance within our Form 10-Q for the interim period ending March 31, 2018. Although the adoption of this new standard is anticipated to have an immaterial impact on our revenues and net income on an ongoing basis, we have implemented a controls process to identify and evaluate new revenue-generating contracts with third-party customers. We continue to monitor additional changes, modifications, clarifications or interpretations being undertaken by the FASB, which may impact our current conclusions. The standard will not impact assets or liabilities reported in our consolidated balance sheet; revenues or expenses within the consolidated statement of operations; cash from or used in operating, financing or investing activities on our consolidated cash flows statement upon adoption.

In February 2016, the FASB issued ASU No. 2016-02, “Leases,” that requires lessees to recognize assets and liabilities on the balance sheet for most leases including operating leases. Lessees now classify leases as either finance or operating leases and lessors classify all leases as sales-type, direct financing or operating leases. The statement of operations presentation and expense recognition for lessees for finance leases is similar to that of capital leases under Accounting Standards Codification (“ASC”) 840 with separate interest and amortization expense with higher periodic expense in the earlier periods of a lease. For operating leases, the statement of operations presentation and expense recognition is similar to that of operating leases under ASC 840 with single lease cost recognized on a straight-line basis. This guidance is to be applied using a modified retrospective approach at the beginning of the earliest comparative period presented in the financial statements and is effective for annual periods beginning after December 15, 2018 and interim periods therein. Early adoption is permitted. We are currently analyzing the impact of ASU No. 2016-02 and, at this time, are unable to determine the impact of the new standard, on our consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, “Restricted Cash,” which requires entities to show the changes in total of cash, cash equivalents, restricted cash and restricted cash equivalents in the statement of cash flows. As

a result, entities will no longer present transfers between cash and cash equivalents and restricted cash in the statement of cash flows. When cash, cash equivalents, restricted cash and restricted cash equivalents are presented in more than one line item on the balance sheet, the new guidance requires a reconciliation of the totals in the statement of cash flows to the related captions on the balance sheet. The reconciliation can be presented either on the face of the statement of cash flows or in the notes to the financial statements. The new standard is effective for public business entities for fiscal years beginning after December 15, 2017 and interim periods therein and is to be applied retrospectively. The guidance will be applied for the annual period beginning January 1, 2018 and presentation of reconciliations between cash and cash equivalents, and restricted cash balances will be applied retrospectively within the consolidated statement of cash flows.

In January 2017, the FASB issued ASU No. 2017-04, “Intangibles–Goodwill and Other,” which eliminates the requirement to calculate the implied fair value of goodwill to measure a goodwill impairment charge. Under the new standard, entities will record an impairment charge based on the excess of a reporting unit’s carrying amount over its fair value. The new standard is effective for public business entities that are SEC filers for annual or any interim goodwill impairment tests in fiscal years beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The standard is to be applied on a prospective basis. We are currently analyzing the impact of ASU No. 2017-04 on our consolidated financial statements.

In March 2017, the FASB issued ASU No. 2017-07, “Compensation–Retirement Benefits,” which requires the presentation of the service cost component of the net periodic benefit cost in the same income statement line as other employee compensation costs arising from services rendered during the period. In addition, only the service cost component will be eligible for capitalization in assets. Disclosure of the line(s) used to present the other components of net periodic benefit cost, if the components are not presented separately in the income statement, is also required. The new standard is effective for public business entities for fiscal years beginning after December 15, 2017 and interim periods therein. The guidance on the presentation of the components of net periodic benefit cost in the income statement is to be applied retrospectively. The guidance limiting the capitalization of net periodic benefit cost in assets to the service cost component is to be applied prospectively. We are currently analyzing the impact of ASU No. 2017-07 on our consolidated financial statements.

In October 2016, the FASB issued ASU No. 2016-16, “Intra-Entity Transfers of Assets Other Than Inventory,” which requires companies to account for the income tax effects of intercompany sales and transfers of assets other than inventory in the period in which the transfer occurs. The new standard is effective for public business entities for annual periods beginning after December 15, 2017 (i.e. 2018 for a calendar-year entity). The guidance will be applied for the annual period beginning January 1, 2018 using a modified retrospective approach with a cumulative catch-up adjustment to opening retained earnings.

We elected to adopt ASU No. 2016-16 as of the first quarter of 2017, which required us to reflect any adjustments as of January 1, 2017. The primary impact of adoption was the recognition of a deferred tax asset of \$34.9 million related to the excess of the tax basis over the consolidated book value basis in the intellectual property rights that were licensed from the U.S. parent company to our wholly-owned subsidiary in Switzerland during 2015 and a \$2.1 million reversal of long-term prepaid taxes. Under previous guidance, companies were prohibited from recognizing an increase in tax basis and any income taxes incurred as a result of a sale or transfer of assets to companies that are part of a consolidated reporting entity. Given the full valuation allowance placed on the additional \$34.9 million of deferred tax assets, the recognition upon adoption only required a \$2.1 million adjustment to our retained earnings as of January 1, 2017 due to the adjustment of the prepaid tax asset.

In January 2016, the FASB issued ASU No. 2016-01, “Financial Instruments–Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities.” The standard requires several changes including that equity investments (except those accounted for under the equity method of accounting, or those that result in consolidation of the investee) be measured at fair value with changes in fair value recognized in results of operations. These provisions will not impact the accounting for our investments in debt securities. The new guidance also changes certain disclosure requirements and other aspects of current U.S. GAAP. Amendments are to be applied as a cumulative-effect adjustment to the balance sheet as of the beginning of the fiscal year of adoption. The new standard will be effective for us on January 1, 2018. Based on our current investment holdings, the adoption of this standard will result in the reclassification of our investment in Calithera Biosciences, Inc. which is not expected to have a material impact on our financial position or results.

In July 2015, the FASB issued ASU No. 2015-11, “Simplifying the Measurement of Inventory,” which requires inventory to be measured at the lower of cost and net realizable value rather than at the lower of cost or market value. The new standard is effective for public business entities for fiscal years beginning after December 15, 2016 and interim periods therein. The guidance is to be applied prospectively. We adopted ASU No. 2015-11 as of the first quarter of 2017 and the adoption had no impact on our consolidated financial statements.

In December 2017, the FASB issued Staff Accounting Bulletin No. 118 (“SAB 118”) to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Cuts and Jobs Act of 2017 (the “Act”). In accordance with SAB 118, we have recorded provisional tax impacts related to the revaluation of deferred tax assets and liabilities as well as the temporary full expensing of certain business assets in our consolidated financial statements for the year ended December 31, 2017. The ultimate impact may differ from these provisional amounts, due to additional analysis, changes in interpretations and assumptions, and additional regulatory guidance that may be issued. The financial statement impact is expected to be complete when the 2017 U.S. corporate income tax return is filed in 2018.

In January 2018, the FASB released guidance on the accounting for tax on the global intangible low-taxed income (“GILTI”) provisions of the Act. The GILTI provisions impose a tax on foreign income in excess of a deemed return on tangible assets of foreign corporations. The guidance indicates that either accounting for deferred taxes related to GILTI inclusions or to treat any taxes on GILTI inclusions as period cost are both acceptable methods subject to an accounting policy election. Effective the first quarter of 2018, we have elected to treat any potential GILTI inclusions as a period charge in the future period in which it is incurred, and therefore this guidance had no impact on our consolidated financial statements for the year ended December 31, 2017.

## **Note 2. Business Combination**

### ***Description of the Transaction***

On June 1, 2016, pursuant to the Share Purchase Agreement, we completed the Acquisition, and acquired all of the outstanding shares of ARIAD Pharmaceuticals (Luxembourg) S.à.r.l., since renamed Incyte Biosciences Luxembourg S.à.r.l., the parent company of ARIAD’s European subsidiaries responsible for the development and commercialization of ICLUSIG (ponatinib) in the European Union (“EU”) and other countries including Switzerland, Norway, Turkey, Israel and Russia (the “Territory”) in exchange for an upfront payment of \$147.5 million, including customary working capital adjustments (the “Upfront Payment”). ICLUSIG is approved in Europe for the treatment of patients with chronic myeloid leukemia and Philadelphia-positive acute lymphoblastic leukemia who are resistant to or intolerant of certain second generation BCR-ABL inhibitors and all patients who have the T3151 mutation. The acquisition of ARIAD Pharmaceuticals (Luxembourg) S.à.r.l. included a fully integrated and established pan-European team including medical, sales and marketing personnel. The existing platform and infrastructure acquired is expected to further our strategic plan and accelerate the establishment of our operations in Europe.

In connection with the closing of the Acquisition, we entered into an Amended and Restated Buy-in License Agreement with ARIAD (the “License Agreement”). Under the terms of the License Agreement, we were granted an exclusive license to develop and commercialize ICLUSIG in the Territory. ARIAD is eligible to receive from us tiered royalties ranging between 32% and 50% on net sales of ICLUSIG in the Territory. The royalties are subject to reduction for certain events related to exclusivity and, if necessary, any third-party patent rights. In addition, ARIAD is eligible to receive up to \$135.0 million in potential future development and regulatory approval milestone payments for ICLUSIG in new oncology indications in the Territory (the “Milestones”), together with additional milestone payments for non-oncology indications, if approved, in the Territory. Under our agreement with ARIAD, we have agreed to fund a portion of the ongoing ICLUSIG clinical studies being conducted by ARIAD, OPTIC and OPTIC-2L, by paying up to \$7.0 million in both 2016 and 2017 (the “Development Costs”). During the quarter ended September 30, 2017, ARIAD discontinued the OPTIC-2L clinical study.

The terms of the License Agreement also included a limited option for a potential future acquirer of ARIAD to purchase the European development and commercialization rights to ICLUSIG from us (the “Buy-Back Provision”). We concluded the Buy-Back Provision was not a derivative as it did not provide for explicit or implicit net settlement, cannot

be readily settled net by a means outside of the contract, and does not provide for delivery of an asset that puts the recipient in a position that is not substantially different from net settlement. We also considered the probability of a potential future buyer exercising the Buy-Back Provision to be near zero and have concluded that any fair value assigned to this provision was de minimis. Takeda Pharmaceutical Company Limited acquired ARIAD in February 2017 but did not exercise the Buy-Back Provision, and the Buy-Back Provision lapsed.

Unless terminated earlier in accordance with its provisions, our obligations to pay full royalties under the License Agreement will continue to be in effect on a country-by-country basis until the latest to occur of (i) the expiration date of the composition patent in the relevant country, (ii) the expiration of any regulatory marketing exclusivity period or other statutory designation that provides similar exclusivity for the commercialization of ICLUSIG in such country and (iii) the seventh anniversary of the first commercial sale of ICLUSIG in such country. We will be obligated to pay royalties at a reduced rate for a specified period of time following such full royalty term. The License Agreement may be terminated in its entirety by us for convenience on 12 months' notice after the third anniversary of the effective date of the License Agreement. The License Agreement may also be terminated by either party under certain other circumstances, including material breach, as set forth in the License Agreement.

#### ***Fair Value of Consideration Transferred***

The fair value of consideration transferred totaled \$440.5 million, which consisted of \$147.5 million in cash pursuant to the Share Purchase Agreement, including net working capital adjustments, and \$293.0 million of contingent consideration related to the License Agreement. Contingent consideration includes the future payments that we may pay to ARIAD for our royalty obligations on future net sales of ICLUSIG, as well as for any future potential milestone payments related to new oncology or non-oncology indications for ICLUSIG.

The fair value of contingent consideration was determined using an income approach based on estimated ICLUSIG revenues in the Territory for both the approved third line treatment, as well as the second line treatment that was under development and was therefore contingent on future clinical results and European Medicines Agency ("EMA") approval. The probability of technical success ("PTS") of the second line indication was estimated at 25% based on the early stage of development and competitive market landscape, and the estimated future cash flows for the second line indication were probability weighted accordingly. The total projected cash flows of the third line and second line indications were estimated over 18 years, and discounted to present value using a discount rate of 10%. In addition, based on the believed limited effectiveness of ICLUSIG beyond the existing oncology indications, the fact that no development is currently ongoing for any new oncology or any non-oncology indications, and the lack of intention by us, ARIAD, or another market participant, to develop ICLUSIG in additional oncology or non-oncology indications, the fair value of any cash flows for any new oncology or non-oncology indication was determined to be nil. The fair value of the contingent consideration was \$293.0 million as of the Acquisition date.

#### ***Assets Acquired and Liabilities Assumed***

The Acquisition has been accounted for as a business combination under the acquisition method of accounting. The following table summarizes the final fair values of the assets acquired and liabilities assumed as of the acquisition date (in thousands).

	<b>Acquisition Fair Values</b>
Current assets	\$ 21,363
Property and equipment	850
Restricted cash	432
Intangible assets <sup>(a)</sup>	283,000
Total identifiable assets	305,645
Current liabilities	(15,538)
Other long term liabilities	(5,226)
Total liabilities assumed	(20,764)
Goodwill <sup>(b)</sup>	155,593
Total fair value of consideration transferred	\$ 440,474

<sup>(a)</sup> As of the effective date of the Acquisition, identifiable intangible assets are required to be measured at fair value. The fair value measurement is based on significant inputs that are unobservable in the market and thus represents a Level 3 measurement. We used an income approach to estimate the fair value of the intangibles which includes licensed intellectual property and IPR&D. The assumptions used to estimate the cash flows of the licensed intellectual property included a discount rate of 15%, estimated gross margins of 98%, income tax rates ranging from 7.8% in periods in which we have established tax holidays to 13.8% thereafter, and operating expenses consisting of direct costs based on the anticipated level of revenues as well as the \$7.0 million of research and development cost sharing payments we owe in 2016 and 2017. The assumptions used to estimate the cash flows of the IPR&D (which related to the potential approval of ICLUSIG as a second line treatment and, as described in Note 8 below, has subsequently been written off) included a PTS of 25%, discount rate of 16%, estimated gross margins of 98%, income tax rates ranging from 7.8% in periods in which we have established tax holidays to 13.8% thereafter, and operating expenses consisting of direct costs based on the anticipated level of revenues as well as probability weighted milestone payments estimated for 2020 related to the clinical results and potential approval of ICLUSIG as a second line treatment. The licensed intellectual property has a weighted-average useful life of approximately 12.5 years and will be amortized using the straight-line method. Amortization expense of the licensed intellectual property is recorded in cost of product revenues on the consolidated statement of operations. The IPR&D was considered an indefinite-lived intangible until the completion or abandonment of the related research and development activities.

<sup>(b)</sup> Goodwill is calculated as the difference between the acquisition date fair value of the consideration transferred and the fair values of the assets acquired and liabilities assumed. The Goodwill is related to the existing platform, infrastructure, and workforce which is expected to generate synergies and further our strategic plan in Europe. Goodwill is not amortized and none of the goodwill is expected to be deductible for tax purposes.

#### ***Acquisition-Related Costs***

We incurred \$1.6 million of transaction costs directly related to the Acquisition, which includes expenditures for advisory, legal, valuation, accounting and other similar services. These costs have been expensed in selling, general and administrative costs on the consolidated statements of operations during the year ended December 31, 2016.

#### ***Revenue and Net Loss of ARIAD Pharmaceuticals (Luxembourg) S.à.r.l.***

The revenues of ARIAD Pharmaceuticals (Luxembourg) S.à.r.l. for the period from the acquisition date to December 31, 2016 were \$29.6 million and net loss was \$48.7 million. The net loss includes the effects of the Acquisition accounting adjustments and acquisition-related costs.

***Pro Forma Impact of Business Combination***

The following unaudited pro forma information presents condensed consolidated results of operations for the years ended December 31, 2016 and 2015, as if the Acquisition had occurred as of January 1, 2015 (in thousands).

	<b>For the Years Ended December 31,</b>			
	<b>2016</b>		<b>2015</b>	
Pro forma revenues	\$	1,148,006	\$	780,758
Pro forma net income (loss)	\$	102,619	\$	(69,892)

The unaudited pro forma condensed consolidated results of operations were prepared using the acquisition method of accounting and are based on the historical financial information of our company and the acquired business which has been adjusted for events that are (i) directly attributable to the Acquisition, (ii) factually supportable, and (iii) expected to have continuing impact on the combined results. The unaudited pro forma information reflects primarily the following adjustments:

- To record amortization expense related to fair value adjustments recorded on the acquired definite lived intangibles;
- To eliminate ARIAD Europe’s interest expense on the intercompany loan in accordance with the terms of the Acquisition;
- To remove balances attributable to the ARIAD Australia entity which are not material. This entity was previously consolidated by ARIAD Europe; however it was not included in the Acquisition; and
- To remove the recognition of revenue relating to distribution agreements in historic periods for those arrangements in which we have no continuing performance obligation and, therefore, the fair value of the assumed deferred revenue balance was zero.

The unaudited pro forma information is not necessarily indicative of the results that would have been obtained if the Acquisition had occurred as of the beginning of the period presented or that may occur in the future, and does not reflect future synergies, integration costs, or other such costs or savings.

**Note 3. Marketable Securities**

The following is a summary of our marketable security portfolio as of December 31, 2017 and 2016, respectively.

	<b>Amortized Cost</b>	<b>Net Unrealized Gains</b>	<b>Net Unrealized Losses</b>	<b>Estimated Fair Value</b>
<b>(in thousands)</b>				
<b>December 31, 2017</b>				
Debt securities (corporate and government)	\$ 271,401	\$ —	\$ (1,265)	\$ 270,136
<b>December 31, 2016</b>				
Debt securities (corporate and government)	\$ 156,330	\$ —	\$ (127)	\$ 156,203

Our debt securities generally have contractual maturity dates of between 12 to 18 months.

***Fair Value Measurements***

FASB accounting guidance defines fair value as the price that would be received to sell an asset or paid to transfer a liability (“the exit price”) in an orderly transaction between market participants at the measurement date. The standard outlines a valuation framework and creates a fair value hierarchy in order to increase the consistency and comparability of fair value measurements and the related disclosures. In determining fair value we use quoted prices and observable inputs.

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Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of us. The fair value hierarchy is broken down into three levels based on the source of inputs as follows:

Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2—Valuations based on observable inputs and quoted prices in active markets for similar assets and liabilities.

Level 3—Valuations based on inputs that are unobservable and models that are significant to the overall fair value measurement.

### ***Recurring Fair Value Measurements***

Our marketable securities consist of investments in corporate debt securities and U.S. government securities that are classified as available-for-sale.

At December 31, 2017 and 2016, our Level 2 corporate debt securities were valued using readily available pricing sources which utilize market observable inputs, including the current interest rate and other characteristics for similar types of investments. Our long term investments classified as Level 1 were valued using the unadjusted closing stock price on The Nasdaq Stock Market.

Our policy is to recognize transfers into and transfers out of fair value hierarchy levels as of the end of the reporting period. During the year ended December 31, 2017, we transferred long term investments from Level 2 to Level 1 due to the lapse of marketability restrictions. The investments are now valued using the unadjusted closing stock price on The Nasdaq Stock Market. There were no transfers out of Level 1 to Level 2 during the period.

The following fair value hierarchy table presents information about each major category of our financial assets measured at fair value on a recurring basis as of December 31, 2017 (in thousands):

	<b>Fair Value Measurement at Reporting Date Using:</b>			<b>Balance as of December 31, 2017</b>
	<b>Quoted Prices in Active Markets for Identical Assets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>	
Cash and cash equivalents	\$ 899,509	\$ —	\$ —	\$ 899,509
Debt securities (corporate and government)	—	270,136	—	270,136
Long term investments (Note 6)	134,356	—	—	134,356
Total assets	\$ 1,033,865	\$ 270,136	\$ —	\$ 1,304,001

The following fair value hierarchy table presents information about each major category of our financial liabilities measured at fair value on a recurring basis as of December 31, 2017 (in thousands):

	<b>Fair Value Measurement at Reporting Date Using:</b>			<b>Balance as of December 31, 2017</b>
	<b>Quoted Prices in Active Markets for Identical Assets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>	
Contingent consideration (Note 2)	\$ —	\$ —	\$ 287,000	\$ 287,000
Total liabilities	\$ —	\$ —	\$ 287,000	\$ 287,000

The following is a roll forward of our Level 3 liabilities (in thousands):

	<b>Level 3</b>
Balance at January 1, 2017	\$ 301,000
Contingent consideration earned during the period but not yet paid	(6,618)
Payments made during the period	(15,086)
Change in fair value of contingent consideration	7,704
Balance at December 31, 2017	<u>\$ 287,000</u>

The fair value of the contingent consideration was determined using an income approach based on estimated ICLUSIG revenues in the Territory for both the approved third line treatment, as well as the second line treatment that was under development until discontinued in the third quarter of 2017. The fair value of the contingent consideration is remeasured each reporting period, with changes in fair value recorded in the consolidated statements of operations. The change in fair value of the contingent consideration during the period ending December 31, 2017 is due primarily to the passage of time and a benefit of \$24.0 million recorded during the third quarter related to the lack of expected future sales royalties payable due to the discontinued OPTIC-2L clinical trial.

We make payments to ARIAD quarterly based on the royalties or any additional milestone payments earned in the previous quarter. As of December 31, 2017, contingent consideration earned but not yet paid was \$6.6 million and included in accrued and other current liabilities.

The following fair value hierarchy table presents information about each major category of our financial assets measured at fair value on a recurring basis as of December 31, 2016 (in thousands):

	<b>Fair Value Measurement at Reporting Date Using:</b>			<b>Balance as of December 31, 2016</b>
	<b>Quoted Prices in Active Markets for Identical Assets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>	
Cash and cash equivalents	\$ 652,343	\$ —	\$ —	\$ 652,343
Debt securities (corporate and government)	—	156,203	—	156,203
Long term investment (Note 6)	31,987	—	—	31,987
Total assets	<u>\$ 684,330</u>	<u>\$ 156,203</u>	<u>\$ —</u>	<u>\$ 840,533</u>

The following fair value hierarchy table presents information about each major category of our financial liabilities measured at fair value on a recurring basis as of December 31, 2016 (in thousands):

	<b>Fair Value Measurement at Reporting Date Using:</b>			<b>Balance as of December 31, 2016</b>
	<b>Quoted Prices in Active Markets for Identical Assets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>	
Contingent consideration (Note 2)	\$ —	\$ —	\$ 301,000	\$ 301,000
Total liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 301,000</u>	<u>\$ 301,000</u>

Net realized loss of \$0.2 million from the sale of marketable securities was included in “Interest and other income, net” on the consolidated statements of operations for the year ended December 31, 2016.

***Non-Recurring Fair Value Measurements***

During the year ended December 31, 2017, there were no measurements required for any assets or liabilities at fair value on a non-recurring basis. During the year ended December 31, 2016, non-recurring fair value measurements related to the fair value of intangible assets and inventory acquired in the Acquisition which are discussed in further detail in Note 2.

**Note 4. Concentrations of Credit Risk**

In December 2009, we entered into a license, development and commercialization agreement with Lilly. In November 2009, we entered into a collaboration and license agreement with Novartis. The concentration of credit risk related to our collaborative partners is as follows:

	Percentage of Total Milestone and Contract Revenues for the Years Ended, December 31,		
	2017	2016	2015
Collaboration Partner A	37 %	40 %	83 %
Collaboration Partner B	63 %	60 %	17 %

Collaboration Partner A and Collaboration Partner B comprised, in the aggregate, 47% and 23% of the accounts receivable balance as of December 31, 2017 and 2016, respectively.

In November 2011, we began commercialization and distribution of JAKAFI to a number of customers. Our product revenues are concentrated in a number of these customers. The concentration of credit risk related to our JAKAFI product revenues is as follows:

	Percentage of Total Net Product Revenues for the Years Ended, December 31,		
	2017	2016	2015
Customer A	24 %	25 %	28 %
Customer B	15 %	17 %	19 %
Customer C	13 %	13 %	13 %
Customer D	8 %	9 %	9 %

We are exposed to risks associated with extending credit to customers related to the sale of products. Customer A, Customer B, Customer C and Customer D comprised, in the aggregate, 25% and 41% of the accounts receivable balance as of December 31, 2017 and 2016, respectively.

The concentration of credit risk relating to ICLUSIG product revenues or accounts receivable is not significant.

**Note 5. Inventory**

Our inventory balance consists of the following:

	December 31,	
	2017	2016
	(in thousands)	
Raw materials	\$ 1,062	\$ 109
Work-in-process	8,615	15,084
Finished goods	4,771	4,106
	14,448	19,299
Inventories-current	6,482	4,106
Inventories-non-current	\$ 7,966	\$ 15,193

Inventories, stated at the lower of cost and net realizable value, consist of raw materials, work-in-process and finished goods. The ICLUSIG inventories acquired on June 1, 2016 totaling \$4.0 million were recorded at fair value less costs to sell, and therefore, resulted in a higher cost of ICLUSIG revenues over a one year period from the acquisition date. At December 31, 2017, \$6.5 million of inventory was classified as current on the consolidated balance sheets as we expect this inventory to be consumed for commercial use within the next twelve months. At December 31, 2017, \$8.0 million of inventory was classified as non-current on the consolidated balance sheets as we did not expect this inventory to be consumed for commercial use within the next twelve months. We obtain some inventory components from a limited

number of suppliers due to technology, availability, price, quality or other considerations. The loss of a supplier, the deterioration of our relationship with a supplier, or any unilateral violation of the contractual terms under which we are supplied components by a supplier could adversely affect our total revenues and gross margins.

JAKAFI raw materials and work-in-process inventory is not subject to expiration and the shelf life for finished goods inventory is 36 months from the start of manufacturing of the finished goods. ICLUSIG raw materials and work-in-process inventory is not subject to expiration and the shelf life for finished goods inventory is 24 months from the start of manufacturing of the finished goods. We evaluate for potential excess inventory by analyzing current and future product demand relative to the remaining product shelf life. We build demand forecasts by considering factors such as, but not limited to, overall market potential, market share, market acceptance and patient usage.

#### **Note 6. License Agreements**

##### *Novartis*

In November 2009, we entered into a Collaboration and License Agreement with Novartis. Under the terms of the agreement, Novartis received exclusive development and commercialization rights outside of the United States to our JAK inhibitor ruxolitinib and certain back-up compounds for hematologic and oncology indications, including all hematological malignancies, solid tumors and myeloproliferative diseases. We retained exclusive development and commercialization rights to JAKAFI (ruxolitinib) in the United States and in certain other indications. Novartis also received worldwide exclusive development and commercialization rights to our MET inhibitor compound capmatinib and certain back-up compounds in all indications. We retained options to co-develop and to co-promote capmatinib in the United States.

Under this agreement, we received an upfront payment and immediate milestone payment totaling \$210.0 million and were initially eligible to receive up to \$1.2 billion in milestone payments across multiple indications upon the achievement of pre-specified events, including up to \$174.0 million for the achievement of development milestones, up to \$495.0 million for the achievement of regulatory milestones and up to \$500.0 million for the achievement of commercialization milestones. In April 2016, we amended this agreement to provide that Novartis has exclusive research, development and commercialization rights outside of the United States to ruxolitinib (excluding topical formulations) in the graft-versus-host-disease (“GVHD”) field. We became eligible to receive up to \$75.0 million of additional potential development and regulatory milestones relating to GVHD. Exclusive of the upfront payment of \$150.0 million received in 2009 and the immediate milestone of \$60.0 million earned in 2010, we have recognized and received in the aggregate \$132.0 million for the achievement of development milestones, \$215.0 million for the achievement of regulatory milestones and \$60.0 million for the achievement of sales milestones through December 31, 2017.

During the year ended December 31, 2017, under this agreement, we recognized a \$40.0 million sales milestone for Novartis achieving annual net sales of a JAK licensed product of \$600.0 million and a \$25.0 million development milestone based on the formal initiation by Novartis of a Phase III clinical trial evaluating ruxolitinib in GVHD. In 2016, we recognized a \$5.0 million payment in exchange for the development and commercialization rights to ruxolitinib in GVHD outside of the United States and a \$40.0 million regulatory milestone for the reimbursement of JAKAVI in Europe for the treatment of patients with polycythemia vera. In 2015, we recognized a \$5.0 million development milestone based on the formal initiation by Novartis of a Phase II clinical trial evaluating capmatinib for a third indication, a \$25.0 million regulatory milestone triggered by the Committee for Medicinal Products for Human Use of the European Medicines Agency adopting a positive opinion for JAKAVI (ruxolitinib) for the treatment of adult patients with polycythemia vera who are resistant to or intolerant of hydroxyurea, a \$15.0 million regulatory milestone for the approval of JAKAVI in Japan for the treatment of patients with polycythemia vera, and a \$20.0 million sales milestone for Novartis achieving annual net sales of a JAK licensed product of \$300.0 million. In 2014, we recognized a \$60.0 million regulatory milestone related to reimbursement of JAKAVI in Europe, a \$25.0 million regulatory milestone for the approval of JAKAVI in Japan for the treatment of patients with myelofibrosis and a \$7.0 million development milestone based on the formal initiation by Novartis of a Phase II clinical trial evaluating capmatinib in non-small cell lung cancer. In 2013, we recognized a \$25.0 million development milestone based on the formal initiation by Novartis of a Phase II clinical trial evaluating capmatinib. In 2012, we recognized a \$40.0 million regulatory milestone payment under this agreement for the achievement of a predefined milestone for the European Union regulatory approval of JAKAVI. In 2011, we recognized a \$15.0 million development milestone for the achievement of a predefined milestone in the Phase I dose-escalation trial

for capmatinib in patients with solid tumors and a \$10.0 million regulatory milestone for the approval of JAKAFI in the United States. In 2010, we recognized \$50.0 million in development milestones for the initiation of the global Phase III trial, RESPONSE, in patients with polycythemia vera. We determined that each of these milestones were substantive as their achievement required substantive efforts by us and was at risk until the milestones were ultimately achieved.

We also are eligible to receive tiered, double-digit royalties ranging from the upper-teens to the mid-twenties on future JAKAFI net sales outside of the United States, and tiered, worldwide royalties on future capmatinib net sales that range from 12% to 14%. Since the achievement of the \$60.0 million regulatory milestone related to reimbursement of JAKAFI in Europe in September 2014, we are obligated to pay to Novartis tiered royalties in the low single-digits on future JAKAFI net sales within the United States. During the years ended December 31, 2017, 2016 and 2015, such royalties payable to Novartis on net sales within the United States totaled \$50.5 million, \$36.8 million and \$24.4 million, respectively, and are reflected in cost of product revenues on the consolidated statements of operations. Each company is responsible for costs relating to the development and commercialization of ruxolitinib in its respective territories, with costs of collaborative studies shared equally. Novartis is also responsible for all costs relating to the development and commercialization of capmatinib.

The Novartis agreement will continue on a program-by-program basis until Novartis has no royalty payment obligations with respect to such program or, if earlier, the termination of the agreement or any program in accordance with the terms of the agreement. Royalties are payable by Novartis on a product-by-product and country-by-country basis until the latest to occur of (i) the expiration of the last valid claim of the licensed patent rights covering the licensed product in the relevant country, (ii) the expiration of regulatory exclusivity for the licensed product in such country and (iii) a specified period from first commercial sale in such country of the licensed product by Novartis or its affiliates or sublicensees. The agreement may be terminated in its entirety or on a program-by-program basis by Novartis for convenience. The agreement may also be terminated by either party under certain other circumstances, including material breach.

We determined that there were two deliverables under the agreement: (i) the ex-U.S. license for ruxolitinib and (ii) our obligations in connection with our participation on the joint development committee for myelofibrosis and polycythemia vera/essential thrombocythemia. We concluded that these deliverables should be accounted for as a single unit of accounting and the \$150.0 million upfront payment received in December 2009 and the immediate \$60.0 million milestone payment received in January 2010 should be recognized on a straight-line basis through December 2013, when we estimated we would complete our obligations in connection with our participation on the joint development committee for myelofibrosis and polycythemia vera, our estimated performance period under the agreement. We completed this substantive performance obligation related to this arrangement in December 2013.

At December 31, 2009, we recorded \$10.9 million of reimbursable costs incurred prior to the effective date of the agreement as deferred revenue on the consolidated balance sheet. These costs were recognized on a straight-line basis through December 2013 consistent with the aforementioned upfront and milestone payments. Future reimbursable costs incurred after the effective date of the agreement with Novartis are recorded net against the related research and development expenses. At December 31, 2017 and 2016, \$1.6 million and \$0.6 million, respectively, of reimbursable costs were included in accounts receivable on the consolidated balance sheets. Research and development expenses for the years ended December 31, 2017, 2016 and 2015 were net of \$3.0 million, \$0.7 million, and \$1.6 million, respectively, of costs reimbursed by Novartis.

Milestone and contract revenue under the Novartis agreement was \$65.0 million, \$45.0 million and \$65.0 million for the years ended December 31, 2017, 2016 and 2015, respectively. In addition, for the years ended December 31, 2017, 2016 and 2015, we recorded \$151.7 million, \$110.7 million and \$74.8 million, respectively, of product royalty revenues related to Novartis net sales of JAKAFI outside the United States. At December 31, 2017 and 2016, \$47.7 million and \$33.3 million, respectively, of product royalties were included in accounts receivable on the consolidated balance sheets.

### ***Lilly - Baricitinib***

In December 2009, we entered into a License, Development and Commercialization Agreement with Lilly. Under the terms of the agreement, Lilly received exclusive worldwide development and commercialization rights to our JAK inhibitor baricitinib, and certain back-up compounds for inflammatory and autoimmune diseases. We received an upfront

payment of \$90.0 million, and were initially eligible to receive up to \$665.0 million in substantive milestone payments across multiple indications upon the achievement of pre-specified events, including up to \$150.0 million for the achievement of development milestones, up to \$365.0 million for the achievement of regulatory milestones and up to \$150.0 million for the achievement of commercialization milestones. Exclusive of the upfront payment of \$90.0 million received in 2009, we have recognized and received, in aggregate, \$129.0 million for the achievement of development milestones and \$135.0 million for the achievement of regulatory milestones through December 31, 2017.

In April 2017, we and Lilly announced that the FDA had issued a complete response letter for the New Drug Application of baricitinib as a once-daily oral medication for the treatment of moderate-to-severe rheumatoid arthritis. The letter indicated that the FDA was unable to approve the application in its current form. Specifically, the FDA indicated that additional clinical data are needed to determine the most appropriate doses. The FDA also stated that additional data are necessary to further characterize safety concerns across treatment arms. In December 2017, Lilly announced that the NDA for baricitinib had been resubmitted and included new safety and efficacy data. The FDA classified the application as a Class II resubmission, which started a new six-month review cycle.

During the year ended December 31, 2017, under this agreement, we recognized a \$30.0 million development milestone for the first patient treated in the atopic dermatitis Phase III program for baricitinib, a \$15.0 million regulatory milestone for the approval of baricitinib for the treatment of rheumatoid arthritis by Japan's Ministry of Health, Labor and Welfare and a \$65.0 million regulatory milestone for the approval of baricitinib for the treatment of moderate-to-severe rheumatoid arthritis in adult patients by the European Commission. In 2016, we recognized a \$35.0 million regulatory milestone for the submission of an NDA to the FDA for the approval of oral once-daily baricitinib for the treatment of moderate-to-severe rheumatoid arthritis and a \$20.0 million regulatory milestone for the submission of a Marketing Authorization Application to the European Medicines Agency for the approval of oral once-daily baricitinib for the treatment of moderate-to-severe rheumatoid arthritis. In 2012, we recognized a \$50.0 million development milestone for the initiation of the rheumatoid arthritis Phase III program for baricitinib. In 2010, we recognized a \$30.0 million development milestone based upon the initial three month data in the Phase IIa clinical trial of baricitinib for the treatment of rheumatoid arthritis and a \$19.0 million development milestone for the Phase IIb clinical trial initiation of baricitinib for the treatment of rheumatoid arthritis. We determined that each of these milestones were substantive as their achievement required substantive efforts by us and was at risk until the milestones were ultimately achieved. In July 2010, we elected to co-develop baricitinib with Lilly in rheumatoid arthritis and we are responsible for funding 30% of the associated future global development costs for this indication from the initiation of the Phase IIb trial through regulatory approval, including post-launch studies required by a regulatory authority. In January 2017, we exercised our co-development options in psoriatic arthritis and atopic dermatitis to fund 30% of future global development costs through regulatory approval, including post-launch studies required by a regulatory authority. We have also exercised our co-development options in systemic lupus erythematosus and axial spondyloarthritis, should Lilly decide to progress into a pivotal program in these indications.

We retained options to co-develop our JAK1/JAK2 inhibitors with Lilly on a compound-by-compound and indication-by-indication basis. Lilly is responsible for all costs relating to the development and commercialization of the compounds unless we elect to co-develop any compounds or indications. If we elect to co-develop any compounds and/or indications, we would be responsible for funding 30% of the associated future global development costs from the initiation of a Phase IIb trial through regulatory approval, including post-launch studies required by a regulatory authority. We would receive an incremental royalty rate increase across all tiers resulting in effective royalty rates ranging up to the high twenties on potential future global net sales for compounds and/or indications that we elect to co-develop. For indications that we elect not to co-develop, we would receive tiered, double-digit royalty payments on future global net sales with rates ranging up to 20% if the product is successfully commercialized. We previously had retained an option to co-promote products in the United States but, in March 2016, we waived our co-promotion option as part of an amendment to the agreement. In February 2017, the European Commission approved baricitinib, which is marketed as OLUMIANT, for the treatment of moderate-to-severe rheumatoid arthritis in adult patients.

Research and development expenses recorded under the Lilly agreement representing 30% of the global development costs for baricitinib for the treatment of rheumatoid arthritis were \$40.8 million, \$27.3 million and \$36.0 million, respectively, for the years ended December 31, 2017, 2016 and 2015. We have retained certain mechanisms to give us cost protection as baricitinib advances in clinical development. We can defer our portion of co-development study costs by indication if they exceed a predetermined level. This deferment would be credited against future milestones or

royalties and we would still be eligible for the full incremental royalties related to the co-development option. In addition, even if we have started co-development funding for any indication, we can at any time opt out and stop future co-development cost sharing. If we elect to do this we would still be eligible for our base royalties plus an incremental, pro-rated royalty commensurate with our contribution to the total co-development cost for those indications for which we co-funded. The Lilly agreement will continue until Lilly no longer has any royalty payment obligations or, if earlier, the termination of the agreement in accordance with its terms. Royalties are payable by Lilly on a product-by-product and country-by-country basis until the latest to occur of (i) the expiration of the last valid claim of the licensed patent rights covering the licensed product in the relevant country, (ii) the expiration of regulatory exclusivity for the licensed product in such country and (iii) a specified period from first commercial sale in such country of the licensed product by Lilly or its affiliates or sublicensees. The agreement may be terminated by Lilly for convenience, and may also be terminated under certain other circumstances, including material breach.

We determined that there were two deliverables under the agreement: (i) the worldwide license and (ii) our obligations in connection with a co-development option. We concluded that these deliverables should be accounted for as a single unit of accounting and the \$90.0 million upfront payment should be recognized on a straight-line basis as revenue through December 2016, our estimated performance period under the agreement. We completed our substantive performance obligation related to this arrangement in December 2016.

Milestone and contract revenue under the Lilly agreement was \$110.0 million, \$67.5 million and \$12.9 million, respectively, for the years ended December 31, 2017, 2016 and 2015. In addition, for the year ended December 31, 2017, we recorded \$9.1 million of product royalty revenues related to Lilly net sales of OLUMIANT outside the United States. At December 31, 2017, \$4.6 million of product royalties were included in accounts receivable on the consolidated balance sheets.

#### ***Lilly – Ruxolitinib***

In March 2016, we entered into an amendment to the agreement with Lilly that amended the non-compete provision of the agreement to allow us to engage in the development and commercialization of ruxolitinib in the GVHD field. We paid Lilly an upfront payment of \$35.0 million and Lilly is eligible to receive up to \$40.0 million in additional regulatory milestone payments relating to ruxolitinib in the GVHD field. During the year ended December 31, 2016, the \$35.0 million upfront payment was recorded in research and development expense in our consolidated statements of operations.

#### ***Pfizer***

In January 2006, we entered into a Collaborative Research and License Agreement with Pfizer for the pursuit of our CCR2 antagonist program. Pfizer gained worldwide development and commercialization rights to our portfolio of CCR2 antagonist compounds. Pfizer's rights extend to the full scope of potential indications, with the exception of multiple sclerosis and autoimmune nephritides, where we retained worldwide rights, along with certain compounds. In the absence of activity on the portfolio, we and Pfizer are currently reviewing strategic options for disposition.

#### ***Agenus***

In January 2015, we entered into a License, Development and Commercialization Agreement with Agenus Inc. and its wholly-owned subsidiary, 4-Antibody AG (now known as Agenus Switzerland Inc.), which we collectively refer to as Agenus. Under this agreement, the parties have agreed to collaborate on the discovery of novel immuno-therapeutics using Agenus' antibody discovery platforms. The agreement became effective on February 18, 2015, upon the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. Upon closing of the agreement, we paid Agenus total consideration of \$60.0 million. Of the \$60.0 million, \$39.8 million was allocated to our stock purchase in Agenus Inc. and was recorded as a long term investment on the consolidated balance sheets and \$20.2 million was allocated to research and development expense on the consolidated statement of operations during the year ended December 31, 2015.

In February 2017, we and Agenus amended this agreement (the "Amended Agreement"). Under the terms of the Amended Agreement, we received exclusive worldwide development and commercialization rights to four checkpoint

modulators directed against GITR, OX40, LAG-3 and TIM-3. In addition to the initial four program targets, we and Agenus have the option to jointly nominate and pursue additional targets within the framework of the collaboration, and in November 2015, three more targets were added. Targets may be designated profit-share programs, where all costs and profits are shared equally by us and Agenus, or royalty-bearing programs, where we are responsible for all costs associated with discovery, preclinical, clinical development and commercialization activities. The programs relating to GITR and OX40 and two of the undisclosed targets were profit-share programs until February 2017, while the other targets currently under collaboration are royalty-bearing programs. The Amended Agreement converted the programs relating to GITR and OX40 to royalty-bearing programs and removed from the collaboration the profit-share programs relating to the two undisclosed targets, with one reverting to us and one reverting to Agenus. Should any of those removed programs be successfully developed by a party, the other party will be eligible to receive the same milestone payments as the royalty-bearing programs and royalties at a 15% rate on global net sales. There are currently no profit-share programs. For each royalty-bearing product other than GITR and OX40, Agenus will be eligible to receive tiered royalties on global net sales ranging from 6% to 12%. For GITR and OX40, Agenus will be eligible to receive 15% royalties on global net sales.

Under the Amended Agreement, we paid Agenus \$20.0 million in accelerated milestones relating to the clinical development of the GITR and OX40 programs, which is recorded in research and development expense on the consolidated statement of operations during the year ended December 31, 2017. Agenus is eligible to receive up to an additional \$510.0 million in future contingent development, regulatory and commercialization milestones across all programs in the collaboration. The agreement may be terminated by us for convenience upon 12 months' notice and may also be terminated under certain other circumstances, including material breach.

In connection with the Amended Agreement, we also agreed to purchase 10.0 million shares of Agenus Inc. common stock for an aggregate purchase price of \$60.0 million in cash, or \$6.00 per share. We completed the purchase of the shares on February 14, 2017, when the closing price on The Nasdaq Stock Market for Agenus Inc. shares was \$4.40 per share. The shares we acquired were not registered under the Securities Act of 1933 on the purchase date and were subject to certain security specific restrictions for a period of time, and accordingly, we estimated a discount for lack of marketability on the shares on the issuance date of \$4.5 million, which resulted in a net fair value of the shares on the issuance date of \$39.5 million. Therefore, of the total consideration paid of \$60.0 million, \$39.5 million was allocated to our stock purchase in Agenus Inc. and was recorded within long term investments on the consolidated balance sheets and \$20.5 million was allocated to research and development expense on the consolidated statement of operations during the year ended December 31, 2017.

We have concluded Agenus Inc. is not a VIE because it has sufficient equity to finance its activities without additional subordinated financial support and its at-risk equity holders have the characteristics of a controlling financial interest. From the date of our initial stock purchase in February 2015 and up to the date of our second stock purchase in February 2017, we owned between 9% and 11% of the outstanding shares of Agenus Inc. common stock. As a result of our February 2017 stock purchase, we owned approximately 18% of the outstanding shares of Agenus Inc. common stock as of December 31, 2017. We concluded that we have the ability to exercise significant influence, but not control, over Agenus Inc. based primarily on our ownership interest, the fact that we have been the largest Agenus stockholder since the date of our initial stock purchase, the level of intra-entity transactions between us and Agenus related to development expenses, as well as other qualitative factors. We have elected the fair value option to account for our long term investment in Agenus Inc. whereby the investment is marked to market through earnings in each reporting period. We believe the fair value option to be the most appropriate accounting method to account for securities in publicly held collaborators for which we have significant influence. For the years ended December 31, 2017, 2016 and 2015, we recorded an unrealized loss of \$13.6 million, \$3.3 million and \$4.6 million, respectively, based on the change in the market price of Agenus Inc.'s common stock from the date of purchase. The fair market value of our long term investment in Agenus Inc. as of December 31, 2017 and 2016 was \$57.9 million and \$32.0 million, respectively.

Research and development expenses for the years ended December 31, 2017, 2016 and 2015, also included \$19.5 million, \$17.5 million and \$14.4 million, respectively, of development costs incurred pursuant to the Agenus arrangement. At December 31, 2017 and 2016, a total of \$3.2 million and \$11.4 million, respectively, of such costs were included in accrued and other liabilities on the consolidated balance sheet.

### ***Hengrui***

In September 2015, we entered into a License and Collaboration Agreement with Jiangsu Hengrui Medicine Co., Ltd. (“Hengrui”). Under the terms of this agreement, we received exclusive development and commercialization rights worldwide, with the exception of Mainland China, Hong Kong, Macau and Taiwan, to INCSHR1210, an investigational PD-1 monoclonal antibody, and certain back-up compounds. Under the terms of this agreement, we paid Hengrui an upfront payment of \$25.0 million in 2015 which was recorded in research and development expense on the consolidated statement of operations. Hengrui was also eligible to receive potential milestone payments of up to \$770.0 million, consisting of \$90.0 million for regulatory approval milestones, \$530.0 million for commercial performance milestones, and \$150.0 million for a clinical superiority milestone. Also, Hengrui was eligible to receive tiered royalties in the high single-digits to mid-double digits based on net sales in our territories. Each company was responsible for costs relating to the development and commercialization of the PD-1 monoclonal antibody in its respective territories. In February 2018, Incyte and Hengrui agreed to terminate the collaboration, pursuant to the terms of the License and Collaboration Agreement.

Research and development expenses for the years ended December 31, 2017, 2016 and 2015, included \$3.2 million, \$9.8 million and \$0.5 million, respectively, of development costs incurred pursuant to the Hengrui agreement.

### ***Merus***

In December 2016, we entered into a Collaboration and License Agreement with Merus N.V. Under this agreement, which became effective in January 2017, the parties have agreed to collaborate with respect to the research, discovery and development of bispecific antibodies utilizing Merus’ technology platform. The collaboration encompasses up to eleven independent programs, including two of Merus’ current preclinical immuno-oncology discovery programs. We received exclusive development and commercialization rights outside of the United States to products and product candidates resulting from one of Merus’ current preclinical discovery programs, referred to as “Program 1.” We also received worldwide exclusive development and commercialization rights to products and product candidates resulting from the other current Merus preclinical discovery program that is subject to the collaboration and to up to nine additional programs. Merus retained exclusive development and commercialization rights in the United States to products and product candidates resulting from Program 1 and options, subject to certain conditions, to co-fund development of products resulting from two other programs in exchange for a share of profits in the United States. Should Program 1 fail to successfully complete IND-enabling toxicology studies, Merus would be granted an additional option to co-fund development of a program in exchange for a share of profits in the United States. All costs related to the collaboration are subject to joint research and development plans. Each party will share equally the costs of mutually agreed global development activities for Program 1, and fund itself any independent development activities in its territory. We will be responsible for all research, development and commercialization costs relating to all other programs, subject to Merus’ election to co-fund development and co-detail described above. If Merus exercises its co-funding option for a program, Merus would be responsible for funding 35% of the associated future global development costs and, for certain of such programs, would be responsible for reimbursing us for certain development costs incurred prior to the option exercise.

In February 2017, we paid Merus an upfront non-refundable payment of \$120.0 million, which is recorded in research and development expense on the consolidated statement of operations. For each program as to which Merus does not have commercialization or co-development rights, Merus will be eligible to receive up to \$100.0 million in future contingent development and regulatory milestones and up to \$250.0 million in commercialization milestones as well as tiered royalties ranging from 6% to 10% of global net sales. For each program as to which Merus exercises its option to co-fund development, Merus will be eligible to receive a 50% share of profits (or sustain 50% of any losses) in the United States and be eligible to receive tiered royalties ranging from 6% to 10% of net sales of products outside of the United States. If Merus opts to cease co-funding a program as to which it exercised its co-development option, then Merus will no longer receive a share of profits in the United States but will be eligible to receive the same milestones from the co-funding termination date and the same tiered royalties described above with respect to non-co-developed programs and, depending on the stage at which Merus chose to cease co-funding development costs, additional royalties ranging up to 4% of net sales in the United States. For Program 1, we and Merus will each be eligible to receive tiered royalties on net sales in the other party’s territory at rates ranging from 6% to 10%.

The Merus agreement will continue on a program-by-program basis until we have no royalty payment obligations

with respect to such program or, if earlier, the termination of the agreement or any program in accordance with the terms of the agreement. The agreement may be terminated in its entirety or on a program-by-program basis by us for convenience. The agreement may also be terminated by either party under certain other circumstances, including material breach, as set forth in the agreement. If the agreement is terminated with respect to one or more programs, all rights in the terminated programs revert to Merus, subject to payment to us of a reverse royalty of up to 4% on sales of future products, if Merus elects to pursue development and commercialization of products arising from the terminated programs.

In addition, in December 2016, we entered into a Share Subscription Agreement with Merus, pursuant to which we agreed to purchase 3.2 million common shares of Merus for an aggregate purchase price of \$80.0 million in cash, or \$25.00 per share.

We agreed to certain standstill provisions whereby we are obligated to refrain from taking certain actions with respect to Merus or Merus' common shares during a period ending on the earliest of (a) three years from the closing date of our share purchase, (b) the date Merus publicly announces any merger or similar business combination or another party announces an intention to acquire a substantial portion of Merus' securities, and (c) the termination of the Collaboration and License Agreement. The standstill provisions are subject to certain exceptions, including an exception that allows us to maintain our percentage ownership following equity financings by Merus. We also agreed, subject to limited exceptions, not to sell or otherwise transfer any of our Merus shares for a period, referred to as the Lock-Up Period, ending on the earlier of 18 months after the closing date of the sale of the Shares or the end of the standstill period. In addition, if the standstill period has not been terminated earlier upon the occurrence of certain events, for a period of three years after the Lock-Up Period, we will be restricted from selling or otherwise transferring more than one-third of our Merus shares during any 12-month period or 10% of our Merus shares during any three-month period, unless Merus consents otherwise. We have further agreed that during the standstill period, we will vote all of our Merus shares in accordance with the recommendation of a majority of Merus' supervisory board. However, we may vote our Merus shares at our own discretion for certain extraordinary matters, including a change in control of Merus. Merus has agreed to customary resale registration rights with respect to our Merus shares; however, any such resales will be subject to the Lock-Up Period and volume limitations on sale and transfer described above.

We completed the purchase of the shares on January 23, 2017 when the closing price on The Nasdaq Stock Market for Merus shares was \$24.50 per share. The shares we acquired were not registered under the Securities Act of 1933 on the purchase date and were subject to certain security specific restrictions for a period of time, and accordingly, we estimated a discount for lack of marketability on the shares on the issuance date of \$5.6 million, which resulted in a net fair value of the shares on the issuance date of \$72.8 million. Of the total consideration paid of \$80.0 million, \$72.8 million was allocated to our stock purchase in Merus and was recorded as a long term investment on the consolidated balance sheets and \$7.2 million was allocated to research and development expense on the consolidated statement of operations during the year ended December 31, 2017. The fair market value of our total long term investment in Merus as of December 31, 2017 was \$62.1 million.

We have concluded Merus is not a VIE because it has sufficient equity to finance its activities without additional subordinated financial support and its at-risk equity holders have the characteristics of a controlling financial interest. As of December 31, 2017, we owned approximately 17% of the outstanding shares of Merus common stock and conclude that we have the ability to exercise significant influence, but not control, over Merus based primarily on our ownership interest, the level of intra-entity transactions between us and Merus related to development expenses, as well as other qualitative factors. We have elected the fair value option to account for our long term investment in Merus whereby the investment is marked to market through earnings in each reporting period. We believe the fair value option to be the most appropriate accounting method to account for securities in publicly held collaborators for which we have significant influence. For the year ended December 31, 2017, we recorded an unrealized loss of \$10.7 million, based on the change in fair value of Merus' common stock from the date of purchase.

Research and development expenses for the year ended December 31, 2017 included \$6.5 million of additional development costs incurred pursuant to the Merus agreement. At December 31, 2017, a total of \$2.1 million of such costs were included in accrued and other liabilities on the consolidated balance sheet.

## ***Calithera***

In January 2017, we entered into a Collaboration and License Agreement with Calithera Biosciences, Inc. Under this agreement, we received an exclusive, worldwide license to develop and commercialize small molecule arginase inhibitors, including CB-1158, which is currently in Phase I clinical trials, for hematology and oncology indications. We have agreed to co-fund 70% of the global development costs for the development of the licensed products for hematology and oncology indications. Calithera will have the right to conduct certain clinical development under the collaboration, including combination studies of a licensed product with a proprietary compound of Calithera. We will be entitled to 60% of the profits and losses from net sales of licensed product in the United States, and Calithera will have the right to co-detail licensed products in the United States, and we have agreed to pay Calithera tiered royalties ranging from the low to mid-double digits on net sales of licensed products outside the United States. Calithera may opt out of its co-funding obligation, in which case the U.S. profit sharing will no longer be in effect, and we have agreed to pay Calithera tiered royalties ranging from the low to mid-double digits on net sales of licensed products both in the United States and outside the United States, and additional royalties to reimburse Calithera for previously incurred development costs.

In January 2017, we paid Calithera an upfront license fee of \$45.0 million and have agreed to pay potential development, regulatory and sales milestone payments of over \$430.0 million if the profit share is in effect, or \$750.0 million if the profit share terminates.

The Calithera agreement will continue on a product-by-product and country-by-country basis for so long as we are developing or commercializing products in the United States (if the parties are sharing profits in the United States) and until we have no further royalty payment obligations, unless earlier terminated according to the terms of the agreement. The agreement may be terminated in its entirety or on a product-by-product and/or a country-by-country basis by us for convenience. The agreement may also be terminated by us for Calithera's uncured material breach, by Calithera for our uncured material breach and by either party for bankruptcy or patent challenge. If the agreement is terminated early with respect to one or more products or countries, all rights in the terminated products and countries revert to Calithera.

In addition, in January 2017, we entered into a Stock Purchase Agreement with Calithera for the purchase of 1,720,430 common shares of Calithera for an aggregate purchase price of \$8.0 million in cash, or \$4.65 per share. We completed the purchase of the shares on January 30, 2017 when the closing price on The Nasdaq Stock Market was \$6.75 per share. The shares we acquired were registered under the Securities Act of 1933 on the purchase date and there were no security specific restrictions for these shares, and therefore the value of the 1.7 million shares acquired by us was \$11.6 million. We paid total consideration of \$53.0 million to Calithera, composed of the \$45.0 million upfront license fee and the \$8.0 million stock purchase price. Of the \$53.0 million, \$11.6 million was allocated to our stock purchase in Calithera and was recorded within long term investments on the consolidated balance sheets and \$41.4 million was allocated to research and development expense on the consolidated statement of operations during the year ended December 31, 2017. The fair market value of our long term investment in Calithera as of December 31, 2017 was \$14.4 million.

We have concluded Calithera is not a VIE because it has sufficient equity to finance its activities without additional subordinated financial support and its at-risk equity holders have the characteristics of a controlling financial interest. As of December 31, 2017, we owned approximately 5% of the outstanding shares of Calithera common stock and there are several other stockholders who hold larger positions of Calithera. As we do not hold a significant position of the voting shares of Calithera and lack the qualitative characteristics associated with the ability to exercise significant influence, our ownership interest does not meet the criteria to be accounted for as an equity method investment. We intend to hold the investment in Calithera for the foreseeable future and therefore, we are accounting for our shares held in Calithera as an available-for-sale investment, whereby the investment is marked to market each period with unrealized gains and losses recorded in accumulated other comprehensive income (loss). Given our intent to hold the investment for the foreseeable future, we have classified the investment within long term investments on the accompanying balance sheet. For the year ended December 31, 2017, we recorded an unrealized gain of \$2.8 million within other comprehensive income (loss) based on the change in fair value of Calithera's common stock from the date of purchase.

In March 2017, Calithera earned a \$12.0 million milestone payment from us for the achievement of pharmacokinetic and pharmacodynamics goals for CB-1158 which is recorded in research and development expense on our consolidated statement of operations during the year ended December 31, 2017. Research and development expenses for the year ended December 31, 2017 also included \$23.4 million of additional development costs incurred pursuant to

the Calithera agreement. At December 31, 2017, a total of \$0.9 million of such costs were included in accrued and other liabilities on the consolidated balance sheet.

### **MacroGenics**

In October 2017, we entered into a Global Collaboration and License Agreement with MacroGenics, Inc. Under this agreement, we received exclusive development and commercialization rights worldwide to MacroGenics' MGA012, an investigational monoclonal antibody that inhibits PD-1. Except as set forth in the succeeding sentence, we will have sole authority over and bear all costs and expenses in connection with the development and commercialization of MGA012 in all indications, whether as a monotherapy or as part of a combination regimen. MacroGenics has retained the right to develop and commercialize, at its cost and expense, its pipeline assets in combination with MGA012. In addition, MacroGenics has the right to manufacture a portion of both companies' global clinical and commercial supply needs of MGA012. In December 2017, we paid MacroGenics an upfront payment of \$150.0 million which is recorded in research and development expense on our consolidated statement of operations. MacroGenics will be eligible to receive up to \$420.0 million in future contingent development and regulatory milestones, and up to \$330.0 million in commercial milestones as well as tiered royalties ranging from 15% to 24% of global net sales.

The MacroGenics agreement will continue until we are no longer commercializing, developing or manufacturing MGA012 or, if earlier, the termination of the agreement in accordance with its terms. The agreement may be terminated in its entirety or on a licensed product by licensed product basis by us for convenience. The agreement may also be terminated by either party under certain other circumstances, including material breach, as set forth in the agreement.

### **Note 7. Property and Equipment**

Property and equipment consists of the following:

	<b>December 31,</b>	
	<b>2017</b>	<b>2016</b>
	<b>(in thousands)</b>	
Office equipment	\$ 14,674	\$ 9,243
Laboratory equipment	48,807	37,203
Computer equipment	51,351	38,184
Land	5,350	4,125
Building and leasehold improvements	214,245	130,734
	334,427	219,489
Less accumulated depreciation and amortization	(74,664)	(51,810)
Property and equipment, net	<u>\$ 259,763</u>	<u>\$ 167,679</u>

Depreciation expense, including amortization expense of leasehold improvements, was \$24.6 million, \$14.2 million and \$11.3 million for the years ended December 31, 2017, 2016 and 2015, respectively.

In April 2016, we completed our purchase of the previously leased land and building comprising approximately 190,000 square feet of laboratory and office space located in Wilmington, Delaware. We previously accounted for the lease as a direct financing arrangement. In total, upon completion of the purchase, we paid \$81.3 million, including closing costs, for the purchase of the land and building and our direct financing obligation related to the lease was relieved. We recorded the difference between the amount paid for the purchase of the land and building (\$81.3 million) and the remaining direct financing obligation on the purchase date (\$45.9 million) as property and equipment. A total of \$3.8 million was allocated to land and the remaining \$31.6 million was allocated to buildings and leasehold improvements, which we estimated using the assistance of a third-party valuation specialist. The land is not being amortized and we are depreciating the building over its estimated useful life of 40 years. In addition, the restricted investments related to the direct financing lease were released upon closing of the agreement of sale.

In September 2016, we entered into two agreements to purchase two buildings at 1701 Augustine Cut-off in Wilmington, Delaware. The purchase closed in March 2017 for a total purchase price of approximately \$8.1 million, consisting of \$1.2 million of land and \$6.9 million of buildings and leasehold improvements, which we estimated using

the assistance of a third-party valuation specialist.

In October 2017, we completed the construction of a 154,000 square foot office building located in Wilmington, Delaware totaling approximately \$91.3 million and are depreciating the building over its estimated useful life of 40 years.

**Note 8. Intangible Assets and Goodwill**

***Intangible Assets, Net***

The components of intangible assets were as follows (in thousands, except for useful life):

	Weighted-Average Useful Lives (Years)	Balance at December 31, 2017			Balance at December 31, 2016		
		Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
<b>Finite-lived intangible assets:</b>							
Licensed IP <sup>(1)</sup>	12.5	\$ 271,000	\$ 34,099	\$ 236,901	\$ 271,000	\$ 12,563	\$ 258,437
<b>Indefinite-lived intangible assets:</b>							
Acquired IPR&D <sup>(1)</sup>	N/A	—	—	—	12,000	—	12,000
		<u>\$ 271,000</u>	<u>\$ 34,099</u>	<u>\$ 236,901</u>	<u>\$ 283,000</u>	<u>\$ 12,563</u>	<u>\$ 270,437</u>

<sup>(1)</sup>We acquired certain intangible assets as part of the Acquisition, as described further in Note 2. During the third quarter of 2017, we wrote-off the acquired IPR&D asset of \$12.0 million due to the discontinuation of the OPTIC-2L study. The write-off of the IPR&D asset was recorded in research and development expense on the consolidated statements of operations.

Amortization expense was \$21.5 million and \$12.6 million for the years ended December 31, 2017 and 2016, respectively, and is recorded in cost of product revenues on the consolidated statement of operations. Estimated aggregate amortization expense based on the current carrying value of amortizable intangible assets will be as follows for the years ending December 31 (in thousands):

	2018	2019	2020	2021	2022	Thereafter
Amortization expense	\$ 21,536	\$ 21,536	\$ 21,536	\$ 21,536	\$ 21,536	\$ 129,221

***Goodwill***

The changes to the carrying amount of goodwill for years ended December 31, 2017 and 2016 were as follows (in thousands):

	Goodwill
Balance, January 1, 2016	\$ —
Additions (Note 2)	155,725
Adjustments	(132)
Balance, December 31, 2016	<u>\$ 155,593</u>
Additions	—
Adjustments	—
Balance, December 31, 2017	<u>\$ 155,593</u>

**Note 9. Convertible Notes**

The components of the convertible notes were as follows (in thousands):

Debt	Interest Rates		Carrying Amount	
	December 31, 2017	Maturities	2017	2016
0.375% Convertible Senior Notes due 2018	0.375 %	2018	\$ 7,393	\$ 340,916
1.25% Convertible Senior Notes due 2020	1.25 %	2020	16,608	310,565
			24,001	651,481
Less current portion			7,393	—
			<u>\$ 16,608</u>	<u>\$ 651,481</u>

Annual maturities of all convertible notes are as follows (in millions):

2018	\$	7.7
2019		—
2020		19.1
2021		—
Thereafter		—
	<u>\$</u>	<u>26.8</u>

The carrying amount and fair value of our convertible notes were as follows (in thousands):

	December 31,			
	2017		2016	
	Carrying Amount	Fair Value	Carrying Amount	Fair Value
0.375% Convertible Senior Notes due 2018	\$ 7,393	\$ 14,129	\$ 340,916	\$ 749,988
1.25% Convertible Senior Notes due 2020	16,608	35,431	310,565	761,300
	<u>\$ 24,001</u>	<u>\$ 49,560</u>	<u>\$ 651,481</u>	<u>\$ 1,511,288</u>

The fair values of the 0.375% Convertible Senior Notes due 2018 (the “2018 Notes”) and the 1.25% Convertible Senior Notes due 2020 (the “2020 Notes”) are based on data from readily available pricing sources which utilize market observable inputs and other characteristics for similar types of instruments, and, therefore, these convertible senior notes are classified within Level 2 in the fair value hierarchy.

On November 14, 2013, we issued, in a private placement, \$375.0 million aggregate principal amount of the 2018 Notes and \$375.0 million aggregate principal amount of the 2020 Notes. Entities affiliated with Julian C. Baker, one of our directors and principal stockholders (the “Baker Entities”), purchased \$250.0 million aggregate principal amount of the 2018 Notes and \$250.0 million aggregate principal amount of the 2020 Notes in this private placement. As of December 31, 2016, the Baker Entities owned \$259.0 million and \$274.5 million aggregate principal amounts of the 2018 and 2020 Notes, respectively, which were exchanged in 2017 for shares of common stock as described below. The 2018 Notes bear interest at a rate of 0.375% per annum and the 2020 Notes bear interest at a rate of 1.25% per annum, in each case payable semi-annually in arrears in cash on May 15 and November 15, beginning on May 15, 2014. The 2018 Notes will mature on November 15, 2018 and the 2020 Notes will mature on November 15, 2020, in each case unless earlier purchased or converted. We may not redeem the Notes prior to their relevant scheduled maturity dates.

Prior to May 14, 2014, the 2018 and 2020 Notes were not convertible except in connection with a make-whole fundamental change, as defined in the respective indentures. Beginning on, and including, May 15, 2014, the 2018 and 2020 Notes are convertible prior to the close of business on the business day immediately preceding May 15, 2018, in the case of the 2018 Notes, and May 15, 2020, in the case of the 2020 Notes, only under the following circumstances: (1) during any calendar quarter commencing after the calendar quarter ending on March 31, 2014 (and only during such calendar quarter), if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price for the 2018 Notes or 2020 Notes, as applicable, on each applicable trading day; (2) during the five business day period after any five consecutive trading day period (the

“measurement period”) in which the trading price per \$1,000 principal amount of 2018 Notes or 2020 Notes, as applicable, for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate for the 2018 Notes or 2020 Notes, as applicable, on each such trading day; or (3) upon the occurrence of specified corporate events. On or after May 15, 2018, in the case of the 2018 Notes, and May 15, 2020, in the case of the 2020 Notes, until the close of business on the second scheduled trading day immediately preceding the relevant maturity date, the Notes are convertible at any time, regardless of the foregoing circumstances. Upon conversion we will pay or deliver, as the case may be, cash, shares of common stock or a combination of cash and shares of common stock, at our election.

On January 1, 2018, the 2018 and 2020 Notes became convertible through at least March 31, 2018, based on the meeting the conversion criteria related to the sale price of our common stock during the calendar quarter ended December 31, 2017 as described in (1) above. The 2018 Notes will mature in November 2018, and accordingly, are classified in short term liabilities on the consolidated balance sheet at December 31, 2017. The 2020 Notes are reflected in long term liabilities on the consolidated balance sheet at December 31, 2017 as management’s intent is to settle any conversions of the 2020 Notes during this period in shares of our common stock.

The initial conversion rate for the 2018 Notes is 19.3207 shares of common stock per \$1,000 principal amount, equivalent to an initial conversion price of approximately \$51.76 per share. The initial conversion rate for the 2020 Notes is 19.3207 shares of common stock per \$1,000 principal amount, equivalent to an initial conversion price of approximately \$51.76 per share. The conversion rate for each series of the 2018 and 2020 Notes will be subject to adjustment for certain events but will not be adjusted for any accrued and unpaid interest. Upon the occurrence of certain fundamental changes, the holders of the 2018 and 2020 Notes may require us to purchase all or a portion of their 2018 and 2020 Notes for cash at a price equal to 100% of the principal amount of the 2018 and 2020 Notes, plus accrued and unpaid interest, including additional interest, if any, to, but excluding, the fundamental change purchase date. In addition, if, and to the extent, a holder elects to convert any 2018 or 2020 Note in connection with a make-whole fundamental change transaction, as defined in the indenture, we will, under certain circumstances, increase the applicable conversion rate by a number of additional shares of our common stock.

Since the 2018 and 2020 Notes can be settled in cash or common shares or a combination of cash and common shares at our option, we determined the embedded conversion options in the 2018 and 2020 Notes are not required to be separately accounted for as a derivative. However, since the 2018 and 2020 Notes are within the scope of the accounting guidance for cash convertible instruments, we are required to separate the 2018 and 2020 Notes into a liability and equity component. The carrying amount of the liability component is calculated by measuring the fair value of a similar liability that does not have an associated equity component. The carrying amount of the equity component representing the embedded conversion option is determined by deducting the fair value of the liability component from the initial proceeds. The excess of the principal amount of the liability component over its carrying amount is amortized to interest expense over the expected life of a similar liability that does not have an associated equity component using the effective interest method. The equity component is not re-measured as long as it continues to meet the conditions for equity classification in the accounting guidance for contracts in an entity’s own equity.

The liability component of the 2018 Notes on the date of issuance was estimated at \$299.4 million, and accordingly, the equity component on the date of issuance was \$75.6 million. The discount on the 2018 Notes is being amortized to interest expense over the term of the 2018 Notes, using the effective interest method. The carrying value of the 2018 Notes was \$7.4 million and \$340.9 million, respectively, (net of \$0.3 million and \$34.1 million of debt discount and issuance costs, respectively) at December 31, 2017 and December 31, 2016.

The liability component of the 2020 Notes on the date of issuance was estimated at \$274.8 million, and accordingly, the equity component on the date of issuance was \$100.2 million. The discount on the 2020 Notes is being amortized to interest expense over the term of the 2020 Notes, using the effective interest method. The carrying value of the 2020 Notes was \$16.6 million and \$310.6 million, respectively, (net of \$2.5 million and \$64.2 million debt discount and issuance costs, respectively) at December 31, 2017 and December 31, 2016.

During the year ended December 31, 2017, we entered into separately negotiated agreements with certain holders of the 2018 Notes pursuant to which such holders agreed to exchange a total of \$367.2 million in aggregate principal amount of the 2018 Notes for the shares of our common stock into which the 2018 Notes were originally convertible,

aggregating 7.1 million shares, an additional 0.1 million of premium shares (equivalent to \$12.6 million in value) and \$2.0 million in cash. Similarly we entered into separately negotiated agreements with certain holders of the 2020 Notes pursuant to which such holders agreed to exchange a total of \$355.6 million in aggregate principal amount of the 2020 Notes for the shares of our common stock into which the 2020 Notes were originally convertible, aggregating 6.9 million shares, an additional 0.2 million of premium shares (equivalent to \$26.8 million in value) and \$7.0 million in cash. Included in the agreements were those with the Baker Entities, which agreed to exchange \$259.0 million in aggregate principal amount of the 2018 Notes and \$274.5 million in aggregate principal amount of the 2020 Notes for an aggregate of 10.6 million shares.

Pursuant to the guidance within the ASC 470-20-40-20, we measured the difference between the fair value and carrying value of the liability portion of the 2018 and 2020 Notes which resulted in recording expense related to senior note conversions of \$1.4 million related to the 2018 Notes and \$5.1 million related to the 2020 Notes. The estimated fair value of the debt component was determined using a valuation model which is subject to judgement. Assumptions used within the valuation model include an estimated credit rating and an estimated market-based cost of debt. These assumptions were used to perform a discounted cash flow analysis on the future interest and principal payments to determine the estimated fair value of the debt at inducement.

In addition, the fair value of the premium shares issued pursuant to these agreements as well as the cash paid in connection with the agreements totaled \$48.4 million and is also included within expense related to senior note conversions on the consolidated statement of operations during the year ended December 31, 2017.

#### **Note 10. Stockholders' Deficit**

*Preferred Stock.* We are authorized to issue 5,000,000 shares of preferred stock, none of which was outstanding as of December 31, 2017 and 2016. The Board of Directors may determine the rights, preferences and privileges of any preferred stock issued in the future.

*Common Stock.* We are authorized to issue 400,000,000 shares of common stock.

On September 7, 2017, we completed a public offering of 4,945,000 shares of our authorized but unissued common stock pursuant to an effective shelf registration statement. The underwriter had an option for a period of 30 days to purchase a maximum of 741,750 additional shares of our common stock, which expired unexercised. We sold the shares of common stock to the underwriter at a price of \$131.46 per share, resulting in net proceeds, after deducting expenses related to the offering, of approximately \$649.4 million.

*Stock Compensation Plans.* As of December 31, 2017, we had reserved a total of 13,512,446 shares of our common stock for future issuance related to our stock plans as described below.

*2010 Stock Incentive Plan.* In May 2010 the Board of Directors adopted the 2010 Stock Incentive Plan, which was amended and restated in April 2013 (the "2010 Plan") for issuance of common stock to employees, non-employee directors, consultants, and scientific advisors. Options are granted to employees, consultants, and scientific advisors under the 2010 Plan, pursuant to a formula determined by our Board of Directors. All options are exercisable at the fair market value of the stock on the date of grant. Non-employee director options expire after ten years.

In May 2012, our stockholders approved an increase in the number of shares of common stock reserved for issuance under the 2010 Plan from 12,553,475 to 16,553,475. In May 2013, our stockholders approved an increase in the number of shares of common stock reserved for issuance under the 2010 Plan from 16,553,475 to 21,753,475. In May 2014, our stockholders approved an increase in the number of shares of common stock reserved for issuance under the 2010 Plan from 21,753,475 to 24,753,475. In May 2016, our stockholders approved an increase in the number of shares of common stock reserved for issuance under the 2010 Plan from 24,753,475 to 30,753,475.

Option activity under the 2010 Stock Plan was as follows:

	Shares Available for Grant	Shares Subject to Outstanding Options	
		Shares	Weighted Average Exercise Price
Balance at December 31, 2016	6,327,138	11,504,572	\$ 48.40
Options granted	(2,562,773)	2,562,773	\$ 119.48
Options exercised	—	(2,715,456)	\$ 30.50
Options cancelled	145,336	(145,336)	\$ 97.30
Balance at December 31, 2017	3,909,701	11,206,553	\$ 68.36

In July 2016, we revised the terms of our annual stock option grants to provide that new option grants would generally have a 10-year term and vest over four years, with 25% vesting after one year and the remainder vesting in 36 equal monthly installments. Previously, our option grants generally had 7-year terms and vested over three years, with 33% vesting after one year and the remainder vesting in 24 equal monthly installments.

Options to purchase a total of 7,250,283, 7,995,735 and 8,239,929 shares as of December 31, 2017, 2016 and 2015, respectively, were exercisable and vested. The aggregate intrinsic value of options exercised for the years ended December 31, 2017, 2016 and 2015 were \$264.2 million, \$137.0 million and \$416.3 million, respectively. At December 31, 2017 the aggregate intrinsic value of options outstanding and vested options are \$362.8 million and \$362.0 million, respectively.

The following table summarizes information about stock options outstanding as of December 31, 2017 for the 2010 Plan:

Range of Exercise Prices	Options Outstanding			Options Exercisable		
	Number Outstanding	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price	
\$2.80 - \$17.79	1,460,251	0.94	\$ 16.13	1,460,251	\$ 16.13	
\$17.89 - \$18.30	105,542	1.50	18.12	105,542	18.12	
\$18.32 - \$18.32	1,634,218	2.09	18.32	1,634,218	18.32	
\$18.97 - \$64.55	1,605,405	3.16	47.54	1,605,405	47.54	
\$67.06 - \$73.21	1,168,504	4.80	73.09	828,825	73.06	
\$73.29 - \$85.49	1,137,905	8.02	82.88	508,487	82.45	
\$88.46 - \$95.54	198,735	7.72	91.49	81,033	90.38	
\$95.76 - \$95.76	1,161,545	5.75	95.76	539,083	95.76	
\$101.00 - \$109.68	262,613	7.42	106.54	154,362	107.32	
\$113.64 - \$138.52	2,471,835	9.13	120.26	333,077	115.11	
	11,206,553			7,250,283		

*Restricted Stock Units and Performance Stock Units .*

In January 2014, we began granting RSUs and PSUs to our employees at the share price on the date of grant. Each RSU represents the right to acquire one share of our common stock. Each RSU granted prior to July 2016 was subject to cliff vesting after three years. In July 2016, we revised the terms of our RSU grants to provide that the awards will vest 25% annually over four years.

Also, in January 2014, Hervé Hoppenot, our President and Chief Executive Officer, was granted a one-time grant of 400,000 RSUs outside of our 2010 Stock Incentive Plan. Vesting of the RSUs will be subject to Mr. Hoppenot's continued employment on the applicable vesting dates, with one-sixth of the RSUs vesting at the end of each of the calendar years 2014 through 2019, subject to earlier acceleration of vesting upon the occurrence of certain events in accordance with the terms of his employment agreement. As of December 31, 2017, a total of 200,000 RSUs granted to Mr. Hoppenot vested, leaving 200,000 RSUs outstanding.

We did not grant any PSUs during the years ended December 31, 2015, 2016 or 2017. We granted a total of 55,326 PSUs during the year ended December 31, 2014. At December 31, 2016, we recognized stock compensation expense for these awards if the performance conditions were deemed probable of achievement at that date. For PSUs, containing performance conditions which were not deemed probable of achievement at December 31, 2016, no stock compensation expense was recognized for these awards. The actual number of shares of our common stock into which each PSU converted was at a multiplier of 100% based on the performance conditions achieved as of December 31, 2016. As of December 31, 2017, all PSUs had vested and were released.

Based on our historical experience of employee turnover, we have assumed an annualized forfeiture rate of 5% for our options, PSUs and RSUs. Under the true-up provisions of the stock compensation guidance, we will record additional expense as the awards vest if the actual forfeiture rate is lower than we estimated, and will record a recovery of prior expense if the actual forfeiture is higher than we estimated.

RSU and PSU award activity under the 2010 Stock Plan was as follows:

	Shares Available for Grant	Shares Subject to Outstanding Awards	
		Shares	Grant Date Value
Balance at December 31, 2016	1,146,152	1,246,570	\$ 82.05
RSUs granted	(427,668)	427,668	\$ 124.87
RSUs cancelled	50,718	(50,718)	\$ 90.21
RSUs released	—	(401,484)	\$ 125.83
PSUs released	—	(43,376)	\$ 122.16
Balance at December 31, 2017	769,202	1,178,660	\$ 98.88

*Employee Stock Purchase Plan.* On May 21, 1997, our stockholders adopted the 1997 Employee Stock Purchase Plan (the “ESPP”). Each regular full-time and part-time employee working 20 hours or more per week is eligible to participate after one month of employment. We issued 157,277, 126,648 and 194,453 shares under the ESPP in 2017, 2016 and 2015, respectively. For the years ended December 31, 2017, 2016 and 2015, we recorded stock compensation expense of \$3.2 million, \$2.4 million and \$2.4 million, respectively, as the ESPP is considered compensatory under the FASB stock compensation rules. As of December 31, 2017, 927,233 shares remain available for issuance under the ESPP.

#### Note 11. Stock Compensation

We recorded \$133.1 million, \$96.2 million and \$69.9 million, respectively, of stock compensation expense for the years ended December 31, 2017, 2016 and 2015. We utilized the Black-Scholes valuation model for estimating the fair value of the stock options granted, with the following weighted-average assumptions:

	Employee Stock Options For the Year Ended			Employee Stock Purchase Plan For the Year Ended		
	December 31,			December 31,		
	2017	2016	2015	2017	2016	2015
Average risk-free interest rates	1.80 %	1.30 %	1.35 %	1.53 %	0.90 %	0.81 %
Average expected life (in years)	5.25	4.99	5.03	0.50	0.50	0.50
Volatility	49 %	50 %	49 %	38 %	48 %	55 %
Weighted-average fair value (in dollars)	53.41	39.35	34.55	19.42	18.82	16.26

The risk-free interest rate is derived from the U.S. Federal Reserve rate in effect at the time of grant. The expected life calculation is based on the observed and expected time to the exercise of options by our employees based on historical exercise patterns for similar type options. Expected volatility is based on the historical volatility of our common stock over the period commensurate with the expected life of the options. A dividend yield of zero is assumed based on the fact that we have never paid cash dividends and have no present intention to pay cash dividends.

Total compensation cost of options granted but not yet vested, as of December 31, 2017, was \$95.2 million, which is expected to be recognized over the weighted average period of 1.6 years. Total compensation cost of RSUs granted but

not yet vested, as of December 31, 2017, was \$55.9 million, which is expected to be recognized over the weighted average period of 1.4 years.

**Note 12. Income Taxes**

We are subject to U.S. federal, state and foreign corporate income taxes. The provision for income taxes is based on income (loss) before provision for income taxes as follows (in thousands):

	Year Ended December 31,		
	2017	2016	2015
U.S.	\$ 36,493	\$ 272,574	\$ 110,560
Non-U.S.	(348,783)	(165,170)	(103,004)
Income (loss) before income taxes	<u>\$ (312,290)</u>	<u>\$ 107,404</u>	<u>\$ 7,556</u>

Our provision for income taxes consists of the following (in thousands):

	Year Ended December 31,		
	2017	2016	2015
Current:			
State	\$ 486	\$ 2,700	\$ 1,025
Foreign	1,171	482	—
	<u>1,657</u>	<u>3,182</u>	<u>1,025</u>
Deferred:			
State	(805)	—	—
Foreign	—	—	—
	<u>(805)</u>	<u>—</u>	<u>—</u>
Total provision for income taxes	<u>\$ 852</u>	<u>\$ 3,182</u>	<u>\$ 1,025</u>

A reconciliation of income taxes at the U.S. federal statutory rate to the provision for income taxes is as follows (in thousands):

	Year Ended December 31,		
	2017	2016	2015
Provision (benefit) at U.S. federal statutory rate	\$ (109,302)	\$ 37,591	\$ 2,645
Unbenefited net operating losses and tax credits	(99,254)	(47,410)	(29,424)
Non-deductible amortization of debt discount	—	—	1,087
Excess tax benefits related to share-based compensation	(81,021)	(29,541)	—
Deferred tax impact of Tax Cuts and Jobs Act of 2017	196,751	—	—
Foreign tax rate differential	86,777	39,975	21,443
Non-deductible officer compensation	6,351	2,061	4,696
Other	550	506	578
Provision for income taxes	<u>\$ 852</u>	<u>\$ 3,182</u>	<u>\$ 1,025</u>

The foreign tax rate differential in the table above reflects the impact of operations in jurisdictions with tax rates that differ from the U.S. federal statutory rate.

Significant components of our deferred tax assets and liabilities are as follows (in thousands):

	<b>December 31,</b>	
	<b>2017</b>	<b>2016</b>
<b>Deferred tax assets:</b>		
Net operating loss carry forwards	\$ 259,189	\$ 481,155
Federal and state research credits	333,311	250,324
Capitalized research and development	37,044	18,618
Deferred revenue and accruals	11,721	9,882
Non-cash compensation	44,647	56,370
Contingent consideration	41,831	32,500
Intangibles, net	94,249	—
Other	25,724	19,533
Total gross deferred tax assets	847,716	868,382
Less valuation allowance for deferred tax assets	(834,783)	(820,233)
Net deferred tax assets	<u>\$ 12,933</u>	<u>\$ 48,149</u>
<b>Deferred tax liabilities:</b>		
Property and equipment	\$ (11,463)	\$ (7,761)
Intangibles, net	—	(5,337)
Equity component of 2018 Notes and 2020 Notes	(665)	(35,051)
Total gross deferred tax liabilities	(12,128)	(48,149)
Net deferred income taxes	<u>\$ 805</u>	<u>\$ —</u>

As of December 31, 2017, the Company has NOL carryforwards, research and development credit carryforwards and orphan drug tax credit carryforwards as follows (in thousands):

	<u>Amount</u>	<u>Expiring if not utilized</u>
<b>Net operating loss carryforwards</b>		
Federal	\$ 862,876	2024 through 2037
State	504,535	2024 through 2037
Foreign	420,725	2020 through 2024
<b>Research and development credit carryforwards</b>		
Federal	154,135	2018 through 2037
State	21,577	Indefinite
Orphan drug tax credit carryforwards	181,480	2029 through 2037

Our ability to utilize our federal and state NOLs may be limited under Internal Revenue Code Section 382 (“Section 382”). Section 382 imposes annual limitations on the utilization of NOL carryforwards and other tax attributes upon an ownership change. In general terms, an ownership change may result from transactions that increase the aggregate ownership of certain stockholders in our stock by more than 50 percentage points over a testing period (generally three years). We have completed a Section 382 analysis through the year ended December 31, 2017. Based on this analysis, our NOLs and other tax attributes accumulated through 2017 should not be limited under Section 382.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 was signed into law making significant changes to the Internal Revenue Code. The Act contains numerous provisions impacting corporate taxpayers. Changes include a federal corporate tax rate decrease from 35% to 21% effective for tax years beginning after December 31, 2017, the transition of U.S. international taxation from a worldwide tax system to a territorial system and temporary full expensing of certain business assets. We have recorded provisional tax impacts related to the revaluation of deferred tax assets and liabilities as well as the temporary full expensing of certain business assets in our consolidated financial statements for the year ended December 31, 2017. The ultimate impact may differ from these provisional amounts, due to additional analysis, changes in interpretations and assumptions, and additional regulatory guidance that may be issued. The financial statement impact is expected to be complete when the 2017 U.S. corporate income tax return is filed in 2018.

The valuation allowance for deferred tax assets increased by approximately \$14.6 million during the year ended December 31, 2017, increased by approximately \$277.3 million during the year ended December 31, 2016 and decreased by approximately \$126.2 million during the year ended December 31, 2015. Upon enactment of the Act, the Company remeasured its U.S. deferred tax assets and liabilities at the applicable tax rate of 21%. The remeasurement resulted in a total decrease in these net assets of \$197.0 million, which was fully offset by a corresponding valuation allowance reduction.

Valuation allowances require an assessment of both positive and negative evidence when determining whether it is more likely than not that deferred tax assets are recoverable. Such assessment is required on a jurisdiction-by-jurisdiction basis. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible.

Based upon the Company's analysis of its historical operating results, as well as projections of the Company's future taxable income (losses) during the periods in which the temporary differences will be recoverable, management believes the uncertainty regarding the realization of its U.S. and Swiss net deferred tax assets requires a full valuation allowance against such net assets as of December 31, 2017. When performing our assessment on projections of future taxable income (losses), we consider factors such as the likelihood of regulatory approval and commercial success of products currently under development, among other factors.

The financial statement recognition of the benefit for a tax position is dependent upon the benefit being more likely than not to be sustainable upon audit by the applicable taxing authority. If this threshold is met, the tax benefit is then measured and recognized at the largest amount that is greater than 50% likely of being realized upon ultimate settlement. If such unrecognized tax benefits were realized and not subject to valuation allowances, we would recognize a tax benefit of \$18.0 million. The following table summarizes the gross amounts of unrecognized tax benefits (in thousands):

	<u>Year Ended December 31,</u>	
	<u>2017</u>	<u>2016</u>
Balance at beginning of year	\$ 10,798	\$ 836
Additions related to prior periods tax positions	2,571	6,740
Reductions related to prior periods tax positions	(821)	—
Additions related to current period tax positions	5,555	2,652
Acquisitions	—	570
Reductions due to lapse of applicable statute of limitations	(81)	—
Balance at end of year	<u>\$ 18,022</u>	<u>\$ 10,798</u>

Our policy is to recognize interest and penalties related to uncertain tax positions, if any, as a component of income tax expense. As of December 31, 2017 and 2016, we accrued interest and penalties of \$0.3 million. Due to NOL and tax credit carry forwards that remain unutilized, U.S. federal and state income tax returns remain subject to examination for three years after utilization of that year's NOL carryforward. The earliest year which generated an NOL included in our current NOL carryforward is 2004 for U.S. federal tax purposes. All tax years for our foreign subsidiaries are open to audit in their respective jurisdictions.

### **Note 13. Net Income (Loss) Per Share**

Our basic net income (loss) per share is computed by dividing the net income (loss) by the number of weighted average common shares outstanding during the period. Our diluted net income (loss) per share is computed by dividing net income (loss) by the weighted average common shares outstanding during the period assuming potentially dilutive common shares of stock options, RSUs and common shares issuable upon conversion of the 2018 Notes and 2020 Notes using the if-converted method. Common shares issuable upon conversion of the 2018 Notes and 2020 Notes were excluded from the diluted net income (loss) per share computation for all periods presented as their share effect was anti-dilutive.

Net income (loss) per share was calculated as follows for the periods indicated below:

(in thousands, except per share data)	Year Ended December 31,		
	2017	2016	2015
<b>Basic Net Income (Loss) Per Share</b>			
Basic net income (loss)	\$ (313,142)	\$ 104,222	\$ 6,531
Weighted average common shares outstanding	204,580	187,873	179,601
Basic net income (loss) per share	\$ (1.53)	\$ 0.55	\$ 0.04
<b>Diluted Net Income (Loss) Per Share</b>			
Diluted net income (loss)	\$ (313,142)	\$ 104,222	\$ 6,531
Weighted average common shares outstanding	204,580	187,873	179,601
Dilutive stock options and RSUs	—	6,252	7,701
Weighted average shares used to compute diluted net income (loss) per share	204,580	194,125	187,302
Diluted net income (loss) per share	\$ (1.53)	\$ 0.54	\$ 0.03

The potential common shares that were excluded from the diluted net income (loss) per share computation are as follows:

	2017	2016	2015
Outstanding stock options and awards	12,585,213	2,792,424	494,468
Common shares issuable upon conversion of the 2018 Notes	149,375	7,245,149	7,245,263
Common shares issuable upon conversion of the 2020 Notes	368,939	7,241,284	7,241,361
Total potential common shares excluded from diluted net income (loss) per share computation	13,103,527	17,278,857	14,981,092

#### Note 14. Employee Benefit Plans

##### *Defined Contribution Plans*

We have a defined contribution plan qualified under Section 401(k) of the Internal Revenue Code covering all domestic employees and defined contribution plans for other Incyte employees in Europe. Employees may contribute a portion of their compensation, which is then matched by us, subject to certain limitations. Defined contribution expense was \$8.9 million, \$6.6 million and \$2.9 million for the years ended December 31, 2017, 2016 and 2015, respectively. Included in the 2017 and 2016 defined contribution expense is \$1.0 million and \$0.3 million, respectively, of expense related to matching contributions under the European defined contribution plans.

##### *Defined Benefit Pension Plans*

In connection with the Acquisition, we assumed a defined benefit pension plan for the former ARIAD employees. In addition, we established another defined benefit pension plan for other Incyte employees in Europe. The pension plans provide benefits to employees upon retirement, death or disability. The assets of the pension plans are held in collective investment accounts represented by the cash surrender value of an insurance policy and are classified as Level 2 within the fair value hierarchy.

The pension plans assumptions reflect the expected investment return and discount rate on plan assets and disability rate probabilities. The benefit obligation at December 31, 2017 for the plans was determined using a discount rate of 0.75%, rate of compensation increase of 2.00% and long-term expected return on plan assets of 0.75%. The 2017

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net periodic benefit cost for the plans was determined using a discount rate of 0.75%, rate of compensation increase of 1.50% and long-term expected return on plan assets of 0.75%. The benefit obligation at December 31, 2016 for the plans was determined using a discount rate of 0.75%, rate of compensation increase of 1.50% and long-term expected return on plan assets of 0.75%. The 2016 net periodic benefit cost for the plans was determined using a discount rate of 0.75%, rate of compensation increase of 1.50% and long-term expected return on plan assets of 0.75%.

Summarized information regarding changes in the obligations and plan assets, the funded status and the amounts recorded as of December 31, 2017 and 2016 were as follows (in thousands):

	2017	2016
Benefit obligation, beginning of year	\$ 23,787	\$ —
Benefit obligations acquired / established	—	17,591
Employer service cost	2,836	1,225
Interest cost	190	76
Plan participants' contributions	1,101	536
Actuarial loss	4,514	2,249
Plan change	1,430	—
Benefit payments from fund	2,853	2,548
Expenses paid from assets	(36)	(20)
Translation (gain) loss	909	(418)
Benefit obligation, end of year	<u>37,584</u>	<u>23,787</u>
Fair value of plan assets, beginning of year	16,699	—
Fair value of plan assets acquired / established	—	12,598
Actual return on plan assets	88	100
Employer contributions	2,891	1,323
Plan participants' contributions	1,101	536
Benefit payments from fund	2,853	2,548
Expenses paid from assets	(36)	(20)
Translation (gain) loss	595	(386)
Fair value of plan assets, end of year	<u>24,191</u>	<u>16,699</u>
Unfunded liability, end of year	<u>\$ 13,393</u>	<u>\$ 7,088</u>

The accumulated benefit obligation is \$33.1 million and \$22.6 million as of December 31, 2017 and 2016, respectively. The unfunded liability is reported in other liabilities on the consolidated balance sheet as of December 31, 2017 and 2016.

The net periodic benefit cost for the year ended December 31, 2017 and 2016 was as follows (in thousands):

	2017	2016
Service cost	\$ 2,836	\$ 1,225
Interest cost	190	76
Expected return on plan assets	(138)	(59)
Amortization of prior service cost	154	—
Amortization of actuarial losses	141	—
Net periodic benefit cost	<u>\$ 3,183</u>	<u>\$ 1,242</u>

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Other changes in the plans assets and the benefit obligation that is recognized in accumulated other comprehensive loss for the year ended December 31, 2017 and 2016 were as follows, net of tax (in thousands):

	2017	2016
Pension liability in other comprehensive loss, beginning of year	\$ 2,750	\$ —
Plan change	1,276	506
Net prior service costs	(140)	—
Net loss	4,564	2,244
Pension liability in other comprehensive loss, end of year	<u>\$ 8,450</u>	<u>\$ 2,750</u>

The prior service cost for the pension plans that will be amortized from accumulated other comprehensive loss into net periodic benefit cost over the next fiscal year is \$0.2 million. The actuarial loss for the pension plans that will be amortized from accumulated other comprehensive loss into net periodic benefit cost over the next fiscal year is \$0.3 million.

We expect to contribute a total of \$3.2 million to the pension plans in 2018. The following benefit payments, which reflect expected future service, as appropriate, are expected to be paid (in thousands):

2018	\$ 1,312
2019	1,418
2020	1,496
2021	1,727
2022	1,801
2023-2027	10,435
Total	<u>\$ 18,189</u>

**Note 15. Commitments and Contingencies**

Rent expense for all leases for the years ended December 31, 2017, 2016 and 2015, was approximately \$8.2 million, \$5.4 million and \$1.3 million, respectively.

As of December 31, 2017, future non-cancelable minimum payments under operating, direct financing and capital leases were as follows:

Year Ended December 31,	Operating Leases (in millions)	Capital Lease (in millions)
2018	\$ 11.5	\$ 0.5
2019	6.2	0.1
2020	2.3	—
2021	0.7	—
2022	0.3	—
Thereafter	0.1	—
Total minimum lease payments	<u>\$ 21.1</u>	<u>\$ 0.6</u>

We lease approximately 160,000 square feet of office space in Chadds Ford, Pennsylvania, approximately 100,000 square feet of laboratory and office space in Wilmington, Delaware and approximately 63,000 square feet of office space in Europe and Japan.

We have entered into and may in the future seek to license additional rights relating to technologies or drug development candidates in connection with our drug discovery and development programs. Under these licenses, we may be required to pay upfront fees, milestone payments, and royalties on sales of future products, which are not reflected in the table above.

**Note 16. Segment Information**

We currently operate in one operating business segment focused on the discovery, development and commercialization of proprietary therapeutics. Our chief operating decision-maker manages the operations of our company as a single operating segment. We do not operate in any material separate lines of business or separate business entities with respect to our products or product development.

During the year ended December 31, 2017, total revenues generated by subsidiaries in the United States was \$1.5 billion and total revenues generated from subsidiaries in Europe was \$66.9 million. During the year ended December 31, 2016, total revenues generated by subsidiaries in the United States was \$1.1 billion and total revenues generated from subsidiaries in Europe was \$29.6 million. For the year ended December 31, 2017, product revenues, net consisted of \$1.1 billion of JAKAFI product revenues, net and \$66.9 million of ICLUSIG product revenues, net. For the year ended December 31, 2016, product revenues, net consisted of \$852.8 million of JAKAFI product revenues, net and \$29.6 million of ICLUSIG product revenues, net. For the year ended December 31, 2015, all revenues were generated in the United States and all product revenues, net were from JAKAFI sales. As of December 31, 2017, property and equipment, net was approximately \$252.4 million in the United States and approximately \$7.4 million in Europe. As of December 31, 2016, property and equipment, net was approximately \$165.0 million in the United States and approximately \$2.7 million in Europe.

**Note 17. Interim Consolidated Financial Information (Unaudited)**

(in thousands, except per share data)	Fiscal 2017 Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
Revenues <sup>(1)</sup>	\$ 384,082	\$ 326,444	\$ 381,534	\$ 444,156
Net income (loss)	\$ (187,083)	\$ (12,484)	\$ 36,054	\$ (149,629)
Basic net income (loss) per share	\$ (0.96)	\$ (0.06)	\$ 0.17	\$ (0.71)
Diluted net income (loss) per share	\$ (0.96)	\$ (0.06)	\$ 0.17	\$ (0.71)
Shares used in computation of basic net income (loss) per share	195,260	205,141	206,796	211,125
Shares used in computation of diluted net income (loss) per share	195,260	205,141	212,610	211,125

(in thousands, except per share data)	Fiscal 2016 Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
Revenues <sup>(2)</sup>	\$ 263,464	\$ 246,288	\$ 269,469	\$ 326,498
Net income	\$ 24,047	\$ 34,425	\$ 36,877	\$ 8,873
Basic net income per share	\$ 0.13	\$ 0.18	\$ 0.20	\$ 0.05
Diluted net income per share	\$ 0.12	\$ 0.18	\$ 0.19	\$ 0.05
Shares used in computation of basic net income per share	187,184	187,682	188,029	188,598
Shares used in computation of diluted net income per share	192,625	193,015	194,265	195,187

(1) The quarters ended March 31, 2017, June 30, 2017, September 30, 2017 and December 31, 2017 include \$264.8 million, \$291.7 million, \$322.0 million, and \$321.8 million, respectively, of product revenues, net, relating to JAKAFI and ICLUSIG. The quarters ended March 31, 2017, June 30, 2017, September 30, 2017 and December 31, 2017 include \$29.2 million, \$34.8 million, \$44.5 million and \$52.3 million, respectively, of product royalty revenues related to the sale of JAKAFI and OLUMIANT outside the United States. In November 2009 and December 2009, we entered into collaborative research and license agreements with Novartis and Lilly, respectively. The quarters ended March 31, 2017, June 30, 2017, September 30, 2017 and December 31, 2017 include \$90.0 million, \$0.0 million, \$15.0 million and \$70.0 million, respectively, of milestone and contract revenues relating to these agreements.

(2) The quarter ended March 31, 2016 includes \$183.3 million of product revenues, net, relating to JAKAFI. The quarters ended June 30, 2016, September 30, 2016 and December 31, 2016 include \$212.1 million, \$236.6 million and \$250.4 million, respectively, of product revenues, net, relating to JAKAFI and ICLUSIG. The quarters ended March 31, 2016, June 30, 2016, September 30, 2016 and December 31, 2016 include \$21.9 million, \$26.0 million, \$29.6 million and \$33.2 million, respectively, of product royalty revenues related to the sale of JAKAFI outside the

United States. In November 2009 and December 2009, we entered into collaborative research and license agreements with Novartis and Lilly, respectively. The quarters ended March 31, 2016, June 30, 2016, September 30, 2016 and December 31, 2016 include \$58.2 million, \$8.2 million, \$3.2 million and \$42.9 million, respectively, of milestone and contract revenues relating to these agreements.

**Note 18. Subsequent Events**

In January 2018, we entered into a target discovery, research collaboration and option agreement with Syros Pharmaceuticals, Inc. Under this agreement, Syros will use its proprietary gene control platform to identify novel therapeutic targets with a focus in myeloproliferative neoplasms and we have received options to obtain exclusive worldwide rights to intellectual property resulting from the collaboration for up to seven validated targets. We will have exclusive worldwide rights to develop and commercialize any therapies under the collaboration that modulate those validated targets. We have agreed to pay Syros up to \$54.0 million in target selection and option exercise fees should we decide to exercise all of our options under the agreement. For products resulting from the collaboration against each of the seven selected and validated targets, we have agreed to pay up to \$50.0 million in potential development and regulatory milestones and up to \$65.0 million in potential commercial milestones. Syros is also eligible to receive low single-digit royalties on net sales of products resulting from the collaboration. We also entered into a related stock purchase agreement with Syros.

We paid Syros \$2.5 million in cash for access to proprietary technology and \$7.5 million in cash for research and development services which will be recorded in research and development expense, and \$10.0 million for the purchase of common stock at \$12.61 per share which will be recorded as a long term investment.

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

Not applicable.

**Item 9A. Controls and Procedures**

*Evaluation of disclosure controls and procedures.* We maintain “disclosure controls and procedures,” as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934 (the “Exchange Act”), that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Our disclosure controls and procedures have been designed to meet reasonable assurance standards. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Based on their evaluation as of the end of the period covered by this Annual Report on Form 10-K, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

*Changes in internal control over financial reporting.* There were no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) for the quarter ended December 31, 2017, that materially affected or are reasonably likely to materially affect our internal control over financial reporting.

*Management’s annual report on internal control over financial reporting.* Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Because of its inherent limitations, internal control over financial reporting may not prevent or detect

misstatements. Projections of any evaluation of the effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on our evaluation under the framework in *Internal Control—Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2017. The effectiveness of our internal control over financial reporting as of December 31, 2017 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included herein.

## **Report of Independent Registered Public Accounting Firm**

To the Stockholders and the Board of Directors of Incyte Corporation

### **Opinion on Internal Control over Financial Reporting**

We have audited Incyte Corporation's internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Incyte Corporation (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of Incyte Corporation as of December 31, 2017 and 2016, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2017, and the related notes and our report dated February 15, 2018 expressed an unqualified opinion thereon.

### **Basis for Opinion**

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

### **Definition and Limitations of Internal Control Over Financial Reporting**

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania  
February 15, 2018

**Item 9B. Other Information**

None.

**PART III**

**Item 10. Directors, Executive Officers and Corporate Governance**

The information required by this item (with respect to Directors) is incorporated by reference from the information under the caption “Election of Directors” contained in our Proxy Statement to be filed with the Securities and Exchange Commission in connection with the solicitation of proxies for our 2018 Annual Meeting of Stockholders to be held on May 1, 2018 (the “Proxy Statement”). Certain information required by this item concerning executive officers is set forth in Part I of this Report under the caption “Executive Officers of the Registrant” and is incorporated herein by reference.

Item 405 of Regulation S-K calls for disclosure of any known late filing or failure by an insider to file a report required by Section 16(a) of the Exchange Act. This disclosure is contained in the section entitled “Section 16(a) Beneficial Ownership Reporting Compliance” in the Proxy Statement and is incorporated herein by reference.

We have adopted a Code of Business Conduct and Ethics that applies to all of our officers and employees, including our Chief Executive Officer, Chief Financial Officer, Corporate Controller and other employees who perform financial or accounting functions. The Code of Business Conduct and Ethics sets forth the basic principles that guide the business conduct of our employees. We have also adopted a Senior Financial Officers’ Code of Ethics that specifically applies to our Chief Executive Officer, Chief Financial Officer, Corporate Controller, and others providing similar functions. Stockholders may request a free copy of our Code of Business Conduct and Ethics and our Senior Financial Officers’ Code of Ethics by contacting Incyte Corporation, Attention: Investor Relations, 1801 Augustine Cut-Off, Wilmington, DE 19803.

To date, there have been no waivers under our Code of Business Conduct and Ethics or Senior Financial Officers’ Code of Ethics. We intend to disclose future amendments to certain provisions of our Code of Business Conduct and Ethics or Senior Financial Officers’ Code of Ethics or any waivers, if and when granted, of our Code of Business Conduct and Ethics or Senior Financial Officers’ Code of Ethics on our website at <http://www.incyte.com> within four business days following the date of such amendment or waiver.

Our Board of Directors has appointed an Audit Committee of three directors, currently comprised of Mr. Paul J. Clancy, as Chairman, Mr. Paul A. Brooke, and Ms. Wendy Dixon. The Board of Directors has also determined that Mr. Clancy and Mr. Brooke are each qualified as an Audit Committee Financial Expert under the definition outlined by the Securities and Exchange Commission. In addition, each of the members of the Audit Committee qualifies as an “independent director” under the applicable standards of The Nasdaq Stock Market.

**Item 11. Executive Compensation**

The information required by this item is incorporated by reference from the information under the captions “Compensation of Directors” and “Executive Compensation” contained in the Proxy Statement.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

The information required by this item is incorporated by reference from the information under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” contained in the Proxy Statement.

**Item 13. Certain Relationships and Related Transactions, and Director Independence**

The information required by this item is incorporated by reference from the information under the captions “Corporate Governance—Certain Relationships and Related Transactions” and “Corporate Governance—Director Independence” contained in the Proxy Statement.

**Item 14. Principal Accountant Fees and Services**

The information required by this item is incorporated by reference from the information under the caption “Ratification of Independent Registered Public Accounting Firm—Principal Accountant Fees and Services” contained in the Proxy Statement.

**PART IV**

**Item 15. Exhibits, Financial Statement Schedules**

**(a) Documents filed as part of this report:**

- (1) Financial Statements

Reference is made to the Index to Consolidated Financial Statements of Incyte Corporation under Item 8 of Part II hereof.

- (2) Financial Statement Schedules

All financial statement schedules have been omitted because they are not applicable or not required or because the information is included elsewhere in the Consolidated Financial Statements or the Notes thereto.

- (3) Exhibits

See Item 15(b) below. Each management contract or compensatory plan or arrangement required to be filed has been identified.

**(b) Exhibits**

<b>Exhibit Number</b>	<b>Description of Document</b>
3(i)	<a href="#">Integrated copy of the Restated Certificate of Incorporation, as amended, of the Company (incorporated by reference to Exhibit 3(i) to the Company’s Annual Report on Form 10-K for the year ended December 31, 2009).</a>
3(ii)	<a href="#">Bylaws of the Company, as amended as of November 15, 2017 (incorporated by reference to Exhibit 3.1 to the Company’s Current Report on Form 8-K filed November 17, 2017).</a>
4.1	<a href="#">Form of Common Stock Certificate (incorporated by reference to the exhibit of the same number to the Company’s Annual Report on Form 10-K for the year ended December 31, 2002).</a>
4.2	<a href="#">Indenture, dated as of November 14, 2013, between the Company and U.S. Bank National Association, as trustee (incorporated by reference to Exhibit 4.1 to the Company’s Current Report on Form 8-K filed November 14, 2013).</a>
4.3	<a href="#">Indenture, dated as of November 14, 2013, between the Company and U.S. Bank National Association, as trustee (incorporated by reference to Exhibit 4.2 to the Company’s Current Report on Form 8-K filed November 14, 2013).</a>
10.1#	<a href="#">1993 Directors’ Stock Option Plan of Incyte Corporation, as amended (incorporated by reference to Exhibit 10.2 to the Company’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2009).</a>
10.2#	<a href="#">Incyte Corporation Amended and Restated 2010 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed May 27, 2016).</a>
10.3#	<a href="#">Form of Stock Option Agreement for Executive Officers under the Incyte Corporation Amended and Restated 2010 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 10.7 to the Company’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2016).</a>

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<b>Exhibit Number</b>	<b>Description of Document</b>
10.4#	<a href="#">Form of Nonstatutory Stock Option Agreement under the 2010 Stock Incentive Plan (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2014).</a>
10.5#	<a href="#">Form of Incentive Stock Option Agreement under the 2010 Stock Incentive Plan (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2014).</a>
10.6#	<a href="#">Form of Nonstatutory Stock Option Agreement for Outside Directors under the 2010 Stock Incentive Plan (incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K for the year ended December 31, 2013).</a>
10.7#	<a href="#">Form of Restricted Stock Unit Award Agreement under the 2010 Stock Incentive Plan (incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2014).</a>
10.8#	<a href="#">Form of Performance Share Award Agreement under the 2010 Stock Incentive Plan (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2014).</a>
10.9#	Form of Indemnity Agreement between the Company and its directors and officers (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 (File No. 33 68138)).
10.10#	<a href="#">1997 Employee Stock Purchase Plan of Incyte Corporation, as amended (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed May 27, 2016).</a>
10.11#	<a href="#">Form of Employment Agreement between the Company and Barry P. Flannelly (effective as of August 11, 2014), David W. Gryska (effective as of October 31, 2014), Steven H. Stein (effective as of March 2, 2015), and Vijay K. Iyengar (effective as of May 9, 2016) (incorporated by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-K for the year ended December 31, 2012).</a>
10.12#	<a href="#">Form of Amended and Restated Employment Agreement, effective as of April 18, 2012, between the Company and Reid M. Huber, Paula J. Swain and Wenqing Yao (incorporated by reference to Exhibit 10.14 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2012).</a>
10.13#	<a href="#">Offer of Employment Letter, dated as of January 3, 2014, from the Company to Hervé Hoppenot (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed January 13, 2014).</a>
10.13.1#	<a href="#">Employment Agreement between the Company and Hervé Hoppenot dated as of January 11, 2014 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed January 13, 2014).</a>
10.13.2#	<a href="#">Amendment, dated as of April 13, 2015, to Employment Agreement between the Company and Hervé Hoppenot, dated as of January 11, 2014 (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015).</a>
10.14#	<a href="#">Restricted Stock Unit Award Agreement between the Company and Hervé Hoppenot dated January 13, 2014 (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed January 13, 2014).</a>
10.15†	<a href="#">Collaboration and License Agreement entered into as of November 24, 2009, by and between the Company and Novartis International Pharmaceutical Ltd. (incorporated by reference to Exhibit 10.21 to the Company's Annual Report on Form 10-K for the year ended December 31, 2009).</a>
10.15.1†	<a href="#">Amendment, dated as of April 5, 2016, to Collaboration and License Agreement entered into as of November 24, 2009, by and between the Company and Novartis International Pharmaceutical Ltd. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016).</a>
10.16†	<a href="#">License, Development and Commercialization Agreement, entered into as of December 18, 2009, by and between the Company and Eli Lilly and Company (incorporated by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K for the year ended December 31, 2009).</a>
10.16.1†	<a href="#">Amendment, dated June 22, 2010, to License, Development and Commercialization Agreement entered into as of December 18, 2009, by and between the Company and Eli Lilly and Company (incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2010).</a>

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<b>Exhibit Number</b>	<b>Description of Document</b>
10.16.2†	<a href="#">Third Amendment, entered into effective March 31, 2016, to License, Development and Commercialization Agreement entered into as of December 18, 2009, by and between the Company and Eli Lilly and Company (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016).</a>
10.16.3†	<a href="#">Fourth Amendment, entered into effective December 13, 2016, to License, Development and Commercialization Agreement entered into as of December 18, 2009, by and between the Company and Eli Lilly and Company (incorporated by reference to Exhibit 10.21.4 to Amendment No. 2 on Form 10-K/A to the Company's Annual Report on Form 10-K for the year ended December 31, 2016).</a>
10.17†	<a href="#">License, Development and Commercialization Agreement, dated as of January 9, 2015, by and among the Company, Incyte Europe S.à.r.l. (a wholly owned subsidiary of the Company), Agenus Inc. and 4-Antibody AG (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015).</a>
10.17.1†	<a href="#">First Amendment, dated as of February 14, 2017, to License, Development and Commercialization Agreement entered into as of January 9, 2015, by and among the Company, Incyte Europe S.à.r.l. (a wholly owned subsidiary of the Company), Agenus Inc. and Agenus Switzerland Inc. (f/k/a 4-Antibody AG) (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2017).</a>
10.18†	<a href="#">Stock Purchase Agreement, dated as of February 14, 2017, between the Company and Agenus Inc. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2017).</a>
10.19†	<a href="#">Share Purchase Agreement, dated as of May 9, 2016, by and among Incyte Europe S.à.r.l., ARIAD Pharmaceuticals (Cayman) L.P., ARIAD Pharmaceuticals, Inc., as guarantor, and the Company, as guarantor (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016).</a>
10.20†	<a href="#">Amended and Restated Buy-In License Agreement, dated as of June 1, 2016, between ARIAD Pharmaceuticals, Inc., ARIAD Pharmaceuticals (Europe) S.à.r.l. and the Company, as guarantor (incorporated by reference to Exhibit 10.3 to Amendment No. 1 on Form 10-Q/A to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016).</a>
10.21†	<a href="#">Collaboration and License Agreement, dated December 20, 2016, by and between the Company and Merus N.V. (incorporated by reference to Exhibit 10.27 to Amendment No. 2 on Form 10-K/A to the Company's Annual Report on Form 10-K for the year ended December 31, 2016).</a>
10.22†	<a href="#">Share Subscription Agreement, dated December 20, 2016, by and between the Company and Merus N.V. (incorporated by reference to Exhibit 10.28 to Amendment No. 2 on Form 10-K/A to the Company's Annual Report on Form 10-K for the year ended December 31, 2016).</a>
10.23†*	<a href="#">Global Collaboration and License Agreement, dated October 24, 2017, by and between the Company and MacroGenics, Inc.</a>
10.24	<a href="#">Registration Rights Agreement, dated as of February 12, 2016, between the Company and 667, L.P., Baker Brothers Life Sciences, L.P. and 14159, L.P. (incorporated by reference to Exhibit 10.28 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015).</a>
12.1*	<a href="#">Computation of Ratios of Earnings to Fixed Charges.</a>
21.1*	<a href="#">Subsidiaries of the Company.</a>
23.1*	<a href="#">Consent of Ernst &amp; Young LLP, Independent Registered Public Accounting Firm.</a>
24.1*	Power of Attorney (see page 130 of this Form 10-K).
31.1*	<a href="#">Rule 13a 14(a) Certification of the Chief Executive Officer.</a>
31.2*	<a href="#">Rule 13a 14(a) Certification of the Chief Financial Officer.</a>
32.1**	<a href="#">Statement of the Chief Executive Officer under Section 906 of the Sarbanes Oxley Act of 2002 (18 U.S.C Section 1350).</a>
32.2**	<a href="#">Statement of the Chief Financial Officer under Section 906 of the Sarbanes Oxley Act of 2002 (18 U.S.C Section 1350).</a>
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Presentation Linkbase Document

<b>Exhibit Number</b>	<b>Description of Document</b>
101.DEF*	XBRL Taxonomy Definition Linkbase Document

\* Filed herewith.

\*\* In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release Nos. 33-8238 and 34-47986, Final Rule: Management's Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-K and will not be deemed "filed" for purpose of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.

† Confidential treatment has been requested with respect to certain portions of these agreements.

# Indicates management contract or compensatory plan or arrangement.

Copies of above exhibits not contained herein are available to any stockholder upon written request to: Investor Relations, Incyte Corporation, 1801 Augustine Cut-Off, Wilmington, DE 19803.

**(c) Financial Statements and Schedules**

Reference is made to Item 15(a)(2) above.

**Item 16. Form 10-K Summary .**

Not applicable.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

INCYTE CORPORATION

By: /s/Hervé Hoppenot

Hervé Hoppenot

*Chairman, President, and Chief Executive Officer*

Date: February 15, 2018

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Hervé Hoppenot, David W. Gryska, and Eric H. Siegel, and each of them, his true and lawful attorneys-in-fact, each with full power of substitution, for him or her in any and all capacities, to sign any amendments to this report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact or their substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Hervé Hoppenot</u> Hervé Hoppenot	Chairman, President, and Chief Executive Officer (Principal Executive Officer) and Director	February 15, 2018
<u>/s/ David W. Gryska</u> David W. Gryska	Chief Financial Officer (Principal Financial Officer)	February 15, 2018
<u>/s/ Paul Trower</u> Paul Trower	VP, Finance (Principal Accounting Officer)	February 15, 2018
<u>/s/ Julian C. Baker</u> Julian C. Baker	Director	February 15, 2018
<u>/s/ Jean-Jacques Bienaimé</u> Jean-Jacques Bienaimé	Director	February 15, 2018
<u>/s/ Paul A. Brooke</u> Paul A. Brooke	Director	February 15, 2018
<u>/s/ Paul J. Clancy</u> Paul J. Clancy	Director	February 15, 2018
<u>/s/ Wendy L. Dixon</u> Wendy L. Dixon	Director	February 15, 2018
<u>/s/ Jacquelyn A. Fouse</u> Jacquelyn A. Fouse	Director	February 15, 2018
<u>/s/ Paul A. Friedman</u> Paul A. Friedman	Director	February 15, 2018

**CONFIDENTIAL TREATMENT MATERIAL**

**CONFIDENTIAL TREATMENT REQUESTED:** *Information for which confidential treatment has been requested is omitted and is noted with asterisks. An unredacted version of this document has been filed separately with the Securities and Exchange Commission (the “Commission”).*

**GLOBAL COLLABORATION AND LICENSE AGREEMENT**

**BY AND BETWEEN**

**MACROGENICS, INC.**

**AND**

**INCYTE CORPORATION**

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**CONFIDENTIAL TREATMENT REQUESTED**

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**[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.**

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**LIST OF EXHIBITS**

- Exhibit A – Licensed Patents
- Exhibit B-1 – Incyte Global Development Plan
- Exhibit B-2 – MacroGenics Global Development Plan
- Exhibit C – Existing Third Party Licenses
- Exhibit D – Form of Press Release
- Exhibit E – Ongoing Clinical Study Activities
- Exhibit F – Shared Prosecution Expense Countries
- Exhibit G – [\*\*]
- Exhibit H – [\*\*]

v

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

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**GLOBAL COLLABORATION AND LICENSE AGREEMENT**

This **GLOBAL COLLABORATION AND LICENSE AGREEMENT** (“**Agreement**”) is entered into as of October 24, 2017 (the “**Execution Date**”), by and between **INCYTE CORPORATION**, a Delaware corporation, having its principal place of business at 1801 Augustine Cut-Off, Wilmington, DE 19803 (hereinafter “**Incyte**”), and **MACROGENICS, INC.**, a Delaware corporation, having its principal place of business at 9704 Medical Center Drive, Rockville, MD 20850 (“**MacroGenics**”). Incyte and MacroGenics are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**”.

**WHEREAS**, MacroGenics has discovered and is developing the Licensed Compound (as defined below), coded by MacroGenics as “MGA012”, for various human therapeutic uses;

**WHEREAS**, Incyte desires to obtain certain rights to Develop, Manufacture, and Commercialize the Licensed Compound and products and treatment regimens incorporating the Licensed Compound, all in accordance with the terms and conditions of this Agreement; and

**WHEREAS**, MacroGenics is willing to grant such rights, retaining certain rights for itself, all in accordance with the terms and conditions of this Agreement.

**NOW, THEREFORE**, in consideration of the foregoing and the premises and conditions set forth herein, the Parties agree as follows:

**ARTICLE 1  
DEFINITIONS**

**1.1** “**Acquirer**” means any Third Party that is a party to any Change of Control transaction and any of such Third Party’s Affiliates.

**1.2** “**Affiliate**” means, with respect to a particular Person, a person, corporation, partnership, or other entity that controls, is controlled by, or is under common control with such first Person. For the purposes of this definition, (a) the word “control” (including, with correlative meaning, the term “controlled by”) means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of a Person, whether by the ownership of fifty percent (50%) or more of the voting stock of such entity, or by contract or otherwise; and (b) the term “common control” includes ownership, directly, or indirectly, beneficially or legally, of outstanding voting securities or capital stock by the same Person or Persons.

**1.3** “**Agreement**” has the meaning set forth in the Preamble, and means this Agreement as in effect from time-to-time, including all Schedules, Exhibits, and other attachments hereto.

**1.4** “**Alliance Manager**” means the person appointed by each Party from within their respective organization to coordinate and facilitate the communication, interaction and cooperation of the Parties pursuant to this Agreement.

**1.5** “ **Ancillary Therapy** ” means an approved (including a standard of care) therapy. For clarity, Ancillary Therapy excludes all therapies that have not received Regulatory Approval.

**1.6** “ **Applicable Law** ” means all applicable statutes, ordinances, regulations, directives, rules, or orders of any kind whatsoever of any Governmental Authority applicable to any activity hereunder, including the EU Data Protection Directive and the regulations issued under the U.S. Health Insurance Portability and Accountability Act of 1996 (“ **HIPAA** ”), the U.S. Federal Food, Drug, and Cosmetic Act (21 U.S.C. §301 et seq.) (“ **FFDCA** ”), the Prescription Drug Marketing Act of 1987 (21 U.S.C. §§331, 333, 353, 381), the Generic Drug Enforcement Act of 1992 (21 U.S.C. §335(a) et seq.), U.S. Patent Act (35 U.S.C. §1 et seq.), the Federal False Claims Act (31 U.S.C. §3729 et seq.), and the Anti-Kickback Statute (42 U.S.C. §1320a-7b et seq.), and the Foreign Corrupt Practices Act of 1977 (15 U.S.C. §§ 78dd-1, et seq.), all as amended from time to time, together with any rules, regulations, and guidance documents, and regulatory standards (including GCP, GLP, and GMP) promulgated relating to any of the foregoing, all as amended from time to time.

**1.7** “ **Approved PD-1 Antibodies** ” means, collectively, all PD-1 Monoclonal Antibodies that have received Regulatory Approval (it being understood that this shall reflect on an ongoing basis any Regulatory Approvals that are received during the Term) in a given territory. As of the Execution Date, the Approved PD-1 Antibodies are pembrolizumab and nivolumab.

**1.8** “ **Biosimilar Product** ” means, with respect to a Licensed Product that has received Marketing Approval in a country in the Territory, (a) a biologic therapeutic containing the same amino acid polymer as any Licensed Product; (b) a biologic therapeutic containing an amino acid polymer that is highly similar, or similar enough to one contained in a reference Licensed Product, notwithstanding minor differences in clinically inactive components, to permit an applicant for Regulatory Approval for such biologic therapeutic to refer to and rely on clinical and other scientific Information regarding the safety, purity, potency and/or efficacy of the reference Licensed Product in order to allow such biologic therapeutic to receive Regulatory Approval in any jurisdiction within the Territory through an abbreviated regulatory pathway; or (c) a biologic therapeutic containing an amino acid polymer that is highly similar, or similar enough to one contained in a reference Product, notwithstanding minor differences in clinically inactive components, to permit such biologic therapeutic to be marketed in any jurisdiction within the Territory as generic-equivalent, functionally equivalent, biosimilar, biogeneric, biobetter, interchangeable, or by using any other description referring to the reference Product (and/or such Product’s clinical and other scientific Information) for support for safety, purity, potency and/or efficacy claims for such biologic therapeutic.

**1.9** “ **Breakthrough Designation** ” means, with respect to a Product, that such Product satisfies the requirements for a “breakthrough therapy”, as set forth in 21 U.S.C. § 356, as amended by § 902 of the Food and Drug Administration Safety and Innovation Act.

**1.10** “ **Business Day** ” means any day other than Saturday, Sunday or any other day on which banking institutions located in New York, New York are permitted or required by Applicable Law, executive order or governmental decree to remain closed.

**1.11** “ **Calendar Quarter** ” means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31; provided, however, that the first Calendar Quarter and the last Calendar Quarter may be partial quarters as applicable under the relevant Calendar Year.

**1.12** “ **Calendar Year** ” means the twelve (12) month period ending on December 31; provided, however, that the first Calendar Year and the last Calendar Year of the applicable period (such as the Royalty Term) may be a partial year, as the case may be.

**1.13** “[\*\*]” means, with respect to the Licensed Compound, the [\*\*] of (a) [\*\*] or (b) the [\*\*] of the [\*\*] in [\*\*].

**1.14** “ **Cancer Treatment Use** ” means any of the following uses or methods of cancer treatment or therapy: (a) dosing regimens, schedules, sequencing or amounts; (b) incorporation of specific supportive care regimens; (c) treatment of patients according to a specific biomarker, genetic disposition, or genetic profile; (d) stratification of patients who are likely or unlikely to benefit from such claimed combination; or (e) data or uses of data to undertake or conduct any of foregoing (a) – (d).

**1.15** “ **Centralised Approval Procedure** ” means, to the extent compulsory or permitted for Regulatory Approval of the Licensed Compound or a Licensed Product in Iceland, Liechtenstein, Norway or any country in the European Union, the procedure administrated by the EMA which results in a single marketing authorization that is valid in Iceland, Liechtenstein, Norway and all countries in the European Union.

**1.16** “ **Change of Control** ” shall occur if: (a) any Third Party acquires directly or indirectly the beneficial ownership of any voting security of a Party, or if the percentage ownership of such person or entity in the voting securities of a Party is increased through stock redemption, cancellation or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of voting securities representing more than fifty percent (50%) of the total voting power of all of the then outstanding voting securities of a Party; (b) a merger, consolidation, recapitalization, or reorganization of a Party is consummated, other than any such transaction that would result in stockholders or equity holders of such Party immediately prior to such transaction, owning at least fifty percent (50%) of the outstanding securities of the surviving entity (or its parent entity) immediately following such transaction; (c) the stockholders or equity holders of a Party approve a plan of complete liquidation of such Party, or an agreement for the sale or disposition by such Party of all or substantially all of such Party’s assets, other than to an Affiliate; (d) individuals who, as of the Effective Date, constitute the Board of Directors of a Party (the “ **Incumbent Board** ”) cease for any reason to constitute at least a majority of the Board of Directors of such Party (provided, however, that any individual becoming a director subsequent to the Effective Date whose election, or nomination for election by such Party’s shareholders, was recommended or approved by a vote of at least a majority of the directors then comprising the Incumbent Board shall be considered as though such individual were a member of the Incumbent Board, but excluding, for this purpose, any such individual whose initial assumption of office occurs as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation

of proxies or consents by or on behalf of any person other than the Board of Directors of such Party); or (e) the sale or transfer to a Third Party of (i) all or substantially all of such Party's assets taken as a whole or (ii) a majority of such Party's assets which relate to this Agreement, is effected.

**1.17** “ **Clinical Study** ” means a Phase I Study, Phase II Study, Phase III Study, Phase IV Study or Pivotal Study, as applicable.

**1.18** “ **Clinical Supply Shortage** ” means a failure by MacroGenics to Manufacture Committed Supply which has occurred or is reasonably likely to occur, and which results or is reasonably likely to result in the unavailability of Licensed Compound Bulk Drug Substance and/or Licensed Compound Drug Product when needed for use across: (a) Monotherapy Studies; (b) Incyte Combination Studies; (c) MacroGenics Combination Studies; or (d) Collaborator Combination Studies (in the case of (d), solely to the extent the request for such Licensed Compound Bulk Drug Substance or Licensed Compound Drug Product is made at least [\*\*] after commencement of Manufacture at the MacroGenics Large-Scale Supply Plant).

**1.19** “ **Collaborator** ” means a Third Party collaborator who conducts Collaborator Combination Study(ies) pursuant to an applicable Collaborator Contract.

**1.20** “ **Collaborator Combination Regimen** ” means a Combination comprising the Licensed Compound and at least one Collaborator Pipeline Asset (which Combination may also include any other compound that constitutes an Ancillary Therapy that is not a Collaborator Pipeline Asset ( *e.g.*, a triplet combination)).

**1.21** “ **Collaborator Combination Study** ” means a Clinical Study of a Collaborator Combination Regimen that is performed with, by, or on behalf of a Collaborator, pursuant to the terms of this Agreement and the applicable Collaborator Contract, but excluding any (a) Incyte investigator-sponsored Clinical Studies, (b) Clinical Studies conducted by Incyte with academic centers, or (c) Clinical Studies that include an Incyte Pipeline Asset. For clarity, any Clinical Study in which both an Incyte Pipeline Asset and a Collaborator Pipeline Asset are evaluated shall be considered an Incyte Combination Study.

**1.22** “ **Combination** ” means a combination of the Licensed Compound and a Pipeline Asset in concurrent or sequential administration (which combination, for clarity, may include any other compound that constitutes an Ancillary Therapy and is not a Pipeline Asset ( *e.g.*, a triplet combination)).

**1.23** “ **Combination Product** ” means a combination of the Licensed Compound and a Pipeline Asset sold in a single finished dosage form. For clarity, the term “Combination Product” shall not include any Combination Regimen(s), except that a single finished dosage Combination that is a component of such Combination Regimen may constitute a Combination Product.

**1.24** “ **Combination Regimen(s)** ” means, individually or collectively, as the context requires, any MacroGenics Combination Regimen, Incyte Combination Regimen, or Collaborator Combination Regimen.

**1.25 “Combination Sponsor”** means (a) with respect to any MacroGenics Combination Study, MacroGenics; (b) with respect to any Incyte Combination Study, Incyte; and (c) with respect to any Collaborator Combination Study, the applicable Collaborator or Incyte, as the case may be.

**1.26 “Combination Study(ies)”** means, individually or collectively, as the context requires, any MacroGenics Combination Study, Incyte Combination Study or Collaborator Combination Study.

**1.27 “Commercialization”** means any and all processes and activities directed to marketing, promoting, educating, pricing, payor contracting, market access, distributing, detailing, importing, exporting, offering for sale, having sold, or selling with respect to a Compound or Product, including the conduct of any Phase IV Studies with respect thereto, and Medical Affairs Activities, but shall not include any activities included within the Manufacture of such Compound or Product. When used as a verb, “**Commercialize**” means to engage in Commercialization activities.

**1.28 “Commercially Reasonable Efforts”** means, with respect to the efforts to be expended, or considerations to be undertaken, by a Party or its Affiliate with respect to any objective, activity or decision to be undertaken hereunder, reasonable, good faith efforts to accomplish such objective, activity or decision as such Party would normally use to accomplish a similar objective, activity or decision under similar circumstances, it being understood and agreed that, with respect to the Development, Manufacture, seeking and obtaining Regulatory Approval, or Commercialization of the Licensed Compound or any Licensed Product, such efforts and resources shall be consistent with those efforts and resources commonly used by such Party under similar circumstances for similar compounds or products to which it has similar rights, which compound or product, as applicable, is at a similar stage in its development or product life and is of similar market potential, taking into account: (a) issues of efficacy, safety, and expected and actual approved labeling; (b) the expected and actual competitiveness of alternative products sold by Third Parties in the marketplace; (c) the expected and actual product profile of the Licensed Compound or any Licensed Product; (d) the expected and actual patent and other proprietary position of the Licensed Compound or any Licensed Product; (e) the likelihood of Regulatory Approval of the Licensed Compound or any Licensed Product given the regulatory structure involved; and (f) the expected and actual profitability and return on investment of the Licensed Compound or any Licensed Product, taking into consideration expected and actual Third Party costs and expenses and pricing and reimbursement relating to the Licensed Compound or any Licensed Product.

**1.29 “Commercial Supply Commitment”** means, individually or collectively, as the context requires, (a) the MacroGenics Commercial Supply Commitment or (b) the Incyte Commercial Supply Commitment.

**1.30 “Compound(s)”** means, individually or collectively, as the context requires, (a) the Licensed Compound or (b) any Pipeline Asset.

**1.31 “Confidential Information”** means, subject to Article 11, all non-public or proprietary Information disclosed by a Party to the other Party under this Agreement, without regard as to whether any of the foregoing is marked “confidential” or “proprietary,” or disclosed in oral, written, graphic, or electronic form. Confidential Information shall include: (a) the terms and

conditions of this Agreement; and (b) Confidential Information disclosed by either Party pursuant to the Mutual Confidential Disclosure Agreement dated [\*\*] (the “**Prior CDA**”).

**1.32** “**Control**” or “**Controlled**” means, with respect to any Information, Know-How, Patent or other intellectual property right, (a) ownership by a Person or, subject to Section 15.3(d), any of its Affiliates, of such Information, Know-How, Patent or other intellectual property right, or (b) possession by a Person or, subject to Section 15.3(d), any of its Affiliates, of ownership of, or an exclusive license to, such Information, Know-How, Patent, or other intellectual property rights, in each case with the right (without taking into account any rights granted by one Party to the other Party under the terms of this Agreement) to grant access, a license or a sublicense to such Information, Patent or other intellectual property right without violating the terms of any agreement or other arrangement with, or necessitating the consent of, any Third Party, at such time that the Person would be first required under this Agreement to grant the other Person such access, license or sublicense; provided that, a Person or any of its Affiliates shall be deemed not to “Control” any Information, Know-How, Patent or other intellectual property right if such Person or its Affiliate is required to pay additional consideration to a Third Party licensor for the grant of any sublicense under such Information, Know-How, Patent or other intellectual property right (unless the other Person agrees in writing to pay such additional consideration).

**1.33** “**Controlling Party**” means (a) with respect to the conduct of any MacroGenics Combination Study or any related Development, regulatory (other than Licensed Compound Regulatory Discussions, for which Incyte shall be the Controlling Party), or other obligations, MacroGenics; (b) with respect to the conduct of any Incyte Combination Study or any related Development, regulatory or other obligations, Incyte; and (c) with respect to the conduct of any Collaborator Combination Study or any related Development, regulatory or other obligations, Incyte. For clarity, (i) except as set forth in subsection (a), MacroGenics shall be deemed to be the “Controlling Party” under subsection (a), and (ii) Incyte shall be deemed to be the “Controlling Party” under subsection (c), irrespective of which Party actually performs or causes to be performed the study or such other activity or obligation.

**1.34** “**Core Regulatory Authority**” means, individually or collectively, as the context requires, the FDA, EMA, MHLW, and Health Canada.

**1.35** “**Cover**” or “**Covering**” means, with respect to a product, technology, process or method, that, in the absence of ownership of or a license granted under a Valid Claim, the practice or exploitation of such product, technology, process or method would infringe such Valid Claim (or, in the case of a Valid Claim that has not yet issued, would infringe such Valid Claim if it were to issue).

**1.36** “**CPI Adjustment**” means the percentage increase or decrease in the Consumer Price Index-Urban Wage Earners and Clerical Workers, U.S. City Average, All Items 1982-84=100, published by the United States Department of Labor, Bureau of Labor Statistics (or its successor equivalent index), in the United States, comparing the levels of such index on the last days of the two most recently completed Calendar Years.

**1.37** “ **Development** ” means any and all research and pre-clinical, non-clinical, and clinical drug development activities and processes, including toxicology, pharmacology, project management, regulatory affairs, statistical analysis, Manufacturing Development, formulation development, delivery system development, the performance of Clinical Studies, or other activities reasonably necessary in order to obtain Regulatory Approval of Compounds or Products in the Field in the Territory. When used as a verb, “ **Develop** ” means to engage in Development activities.

**1.38** “ **Development Partner** ” means, with respect to a Party, a Third Party with which such Party has entered into a Development Agreement pursuant to Section 4.5 to conduct Clinical Studies.

**1.39** “ **Effective Date** ” means the first (1<sup>st</sup>) Business Day immediately following the date on which the Parties have actual knowledge that all applicable waiting periods under the HSR Act with respect to the transactions contemplated hereunder have expired or have been terminated.

**1.40** “ **EMA** ” means the European Medicines Agency or any successor agency(ies) or authority having substantially the same function.

**1.41** “ **European Major Markets** ” means, collectively, France, Germany, Italy, Spain, and the United Kingdom.

**1.42** “ **European Union** ” or “ **EU** ” means the European Union member states as then-currently constituted; provided, however, that the EU shall always be deemed to include the European Major Markets. As of the Execution Date, the European Union member states are Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and United Kingdom.

**1.43** “[\*\*]” means, with respect to the Licensed Compound, the [\*\*] of (a) [\*\*] or (b) the [\*\*] of [\*\*] across all [\*\*] in which the Licensed Compound has received Regulatory Approval.

**1.44** “ **Executive Officers** ” means, with respect to each Party, the Chief Executive Officer of such Party (or his or her designee).

**1.45** “ **Exploit** ” means to use, have used, Develop, have Developed, Commercialize, have Commercialized, and Manufacture or have Manufactured.

**1.46** “ **FDA** ” means the U.S. Food and Drug Administration and any successor agency(ies) or authority having substantially the same function.

**1.47** “ **Field** ” means all uses, including the diagnosis, treatment or prevention of any disease in humans and animals.

**1.48** “ **First Commercial Sale** ” means, with respect to a Licensed Product, on a country-by-country basis, the first sale for monetary value of such Licensed Product under this Agreement by Incyte, its Affiliates or its sublicensees to an end user for use, consumption or resale of such Licensed Product in such country in the Field after all Regulatory Approvals of such Licensed

Product (i.e., when all applicable approvals, licenses, registrations or authorizations described in the definition of Regulatory Approval that are necessary to sell the applicable Licensed Product) have been obtained in such country in the Field, where such sale results in the recognition of Net Sales. The sale of a Licensed Product under this Agreement by Incyte to an Affiliate of Incyte or a sublicensee of Incyte shall not constitute a First Commercial Sale unless such Affiliate or such sublicensee is the end user of such Licensed Product. For the avoidance of doubt, the transfer or disposition by Incyte, its Affiliates or its sublicensees of reasonable and customary quantities of samples of the Licensed Product below cost for promotional or educational purposes, or the sale of Licensed Product for clinical study purposes, early access programs (such as to provide patients with a Licensed Product prior to Regulatory Approval pursuant to treatment INDs or protocols, named patient programs or compassionate use programs), or any similar uses, shall not constitute a First Commercial Sale.

**1.49** “ **Force Majeure** ” means any event beyond the reasonable control of the affected Party, which may include embargoes; war or acts of war, including terrorism; insurrections, riots, or civil unrest; labor strikes or lockouts; epidemics, fire, floods, earthquakes or other severe acts of nature; widespread unavailability of raw materials or reagents affecting manufacturers generally, actions by a Regulatory Authority affecting the manufacture of Monoclonal Antibodies generally and the Licensed Compound specifically, and omissions or delays in acting by any Governmental Authority (other than delays incident to the ordinary course of drug development).

**1.50** “ **FTE** ” means [\*\*] hours of work devoted to or in direct support of specified Development, Manufacturing or other specified activities under this Agreement, conducted by one or more qualified employees, contractors, consultants or other personnel of a Party or its Affiliates. For clarity, any individual contributing less than [\*\*] hours per Calendar Year (or equivalent pro-rata portion thereof for the period beginning on the Effective Date and ending on the last day of the first Calendar Year) shall be deemed a fraction of an FTE on a pro-rata basis.

**1.51** “ **FTE Cost** ” means, with respect to any period and a Party or its Affiliate, the FTE Rate multiplied by the number of FTEs expended by such Party or its Affiliate during such period; provided that a Party shall not be charged twice for any FTE Cost if such FTE Cost is already included as a component of Manufacturing Expenses payable under this Agreement.

**1.52** “ **FTE Rate** ” means a rate of [\*\*] per FTE per Calendar Year (pro-rated for the period beginning on the Effective Date and ending on the last day of the first Calendar Year); provided, however, that such rate shall be increased or decreased annually beginning on [\*\*] by the applicable CPI Adjustment. The FTE Rate is “fully burdened” and covers employee salaries, benefits, travel and other such costs.

**1.53** “ **GAAP** ” means generally accepted accounting principles in the U.S., consistently applied.

**1.54** “ **Global Safety Database** ” means the global safety database for the Licensed Compound.

**1.55** “ **Good Clinical Practices** ” or “ **GCP** ” means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in the guideline adopted by the International Conference on Harmonization (“ **ICH** ”), titled “Guidance for Industry E6 Good

Clinical Practice: Consolidated Guidance” (or any successor document), including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by the EMA, PMDA or other Regulatory Authority applicable to the Territory, as they may be updated from time to time.

**1.56** “ **Good Laboratory Practices** ” or “ **GLP** ” means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in 21 C.F.R. Part 58 (or any successor statute or regulation), including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by the EMA, PMDA or other Regulatory Authority applicable to the Territory, as they may be updated from time to time, including applicable guidelines promulgated under the ICH.

**1.57** “ **Good Manufacturing Practices** ” or “ **GMP** ” means the then-current good manufacturing practices required by the FDA, as set forth in the FDCA, as amended, and the regulations promulgated thereunder, for the manufacture and testing of pharmaceutical materials, and comparable Applicable Law related to the manufacture and testing of pharmaceutical materials in jurisdictions outside the U.S., including the quality guideline promulgated by the ICH designated ICH Q7A, titled “Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients” and the regulations promulgated thereunder, as they may be updated from time to time.

**1.58** “ **Governmental Authority** ” means any multi-national, federal, state, local, municipal or other government authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

**1.59** “ **Health Canada** ” means Health Canada, the department of the government of Canada with responsibility for national public health, and any successor agency(ies) or authority having substantially the same function.

**1.60** “ **HSR Act** ” means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended from time to time, and any comparable Applicable Law in jurisdictions outside the U.S. related to the approval of transactions similar to those contemplated under this Agreement.

**1.61** “ **HSR Clearance Date** ” means the expiration or termination of all applicable waiting periods and requests for information (and any extensions thereof) under the HSR Act.

**1.62** “ **HSR Filing** ” means (a) filings by Incyte and MacroGenics with the U.S. Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice of a Notification and Report Form for Certain Mergers and Acquisitions (as that term is defined in the HSR Act) with respect to the matters set forth in this Agreement, together with all required documentary attachments thereto, or (b) equivalent filings with relevant foreign authorities.

**1.63** “ **Incyte Combination Regimen** ” means (a) a Combination comprising a Licensed Compound and at least one Incyte Pipeline Asset (which Combination may also include: (x) any other compound that constitutes an Ancillary Therapy that is not a MacroGenics Pipeline Asset (e.g., a triplet combination) or (y) a Collaborator Pipeline Asset (e.g., a triplet combination)); or (b) a Non-Proprietary Combination Regimen (which Combination may also include Ancillary

Therapy(ies), provided that, such inclusion shall not preclude any inclusion of Ancillary Therapy(ies) in MacroGenics Combination Regimens).

**1.64 “ Incyte Combination Study ”** means any (a) Clinical Study of an Incyte Combination Regimen or (b) other Clinical Study that is performed by or on behalf of Incyte that includes the Licensed Compound and any other specific molecule or molecules (as monotherapies or combinations) other than a Monotherapy Study, Collaborator Combination Study, or a Clinical Study that includes a MacroGenics Pipeline Asset. For clarity, an Incyte Combination Study shall only be performed by Incyte, its Affiliates or its sublicensees.

**1.65 “ Incyte Global Development Plan ”** means the high-level, non-binding, written plan attached hereto as Exhibit B-1 covering Incyte’s (a) planned development of the Licensed Compound and any Licensed Products and (b) planned conduct of any Incyte Combination Studies, as updated by Incyte from time to time in accordance with Sections 2.2 and 4.4. For clarity, a PowerPoint presentation summarizing such planned studies would be sufficient as a written plan.

**1.66 “ Incyte Pipeline Asset Criteria ”** means, with respect to a molecule, that Incyte: (a) has previously conducted, or is conducting, a Clinical Study evaluating a combination of such molecule and the Licensed Compound and has entered into, or shall enter into, a bona fide license agreement with a Third Party with respect thereto (provided that, such Third Party licensee shall be contractually obligated to at least the same development obligations as Incyte, pursuant to Section 4.2 or otherwise in Article 4); or (b) has previously entered into, or enters into, a bona fide collaboration with a Third Party that governs the research, development and/or commercialization of such molecule, where Incyte retains development rights to sponsor and fund a Clinical Study and to provide input on the development of such molecule.

**1.67 “ IND ”** means (a) an Investigational New Drug application as defined in the FDCA and applicable regulations promulgated thereunder by the FDA; (b) a clinical trial authorization application for a product filed with a Regulatory Authority in any other regulatory jurisdiction outside the U.S., the filing of which (in the case of (a) or (b)) is necessary to commence or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction; or (c) documentation issued by a Regulatory Authority that permits the conduct of clinical testing of a product in humans in such jurisdiction.

**1.68 “ Indication ”** means (a) with respect to [\*\*], any cancer with [\*\*], even if they are, [\*\*] or [\*\*] or [\*\*] ( e.g. , [\*\*], [\*\*], and [\*\*]) or (b) with respect to [\*\*], [\*\*], [\*\*] and [\*\*] ( e.g. , [\*\*], and [\*\*]), but [\*\*]. For the sake of clarity, treatment of [\*\*] within [\*\*] shall not be treated as [\*\*] ( e.g., [\*\*] and [\*\*] shall not be considered [\*\*] shall not be considered different [\*\*]).

**1.69 “ Information ”** means information, inventions, discoveries, ideas, developments, compounds, compositions, formulations, formulas, practices, procedures, processes, methods, knowledge, know-how, trade secrets, technology, inventories, machines, techniques, designs, drawings, correspondence, computer programs, skill, experience, documents, apparatus, results, strategies, Regulatory Documentation, information and submissions pertaining to, or made in association with, filings with any Governmental Authority or patent office, data, including pharmacological, toxicological, non-clinical and clinical data, analytical and quality control data,

manufacturing data and descriptions, market data, patent and legal data, financial data or descriptions, devices, assays, chemical formulations, specifications, material, product samples and other samples, physical, chemical and biological materials and compounds, and the like, in written, electronic, oral or other tangible or intangible form, now known or hereafter developed, whether or not patentable.

**1.70** “ **Initiation** ” means, with respect to a Clinical Study, the first dosing of the first subject enrolled in such Clinical Study.

**1.71** “ **Invention** ” means any Information, whether or not patentable, generated, made, conceived, or reduced to practice in the course of performance of this Agreement, whether made, conceived or reduced to practice solely by, or on behalf of, MacroGenics, Incyte, the Parties jointly, or any Affiliate, subcontractor, or sublicensee of the same (including Collaborators or any development or commercialization partner or collaborator of either Party).

**1.72** “[\*\*]” means, with respect to the Licensed Compound, the [\*\*] of (a) [\*\*] or (b) the [\*\*] of the [\*\*] in [\*\*].

**1.73** “ **Know-How** ” means any Information; provided that, with respect to any Party, Know-How excludes any intangible Information contained within such Party’s published Patents.

**1.74** “ **Knowledge** ” means, as applied to a Party, that such Party has actual knowledge of a particular fact or other matter, or that a reasonably prudent person with primary responsibility for the applicable subject matter (whether an officer or employee of such Party) knew or should have known of such fact or other matter.

**1.75** “ **Label Combination Patents** ” means Patents Controlled by MacroGenics or, subject to Section 15.3(d), any of its Affiliates (including, subject to Section 15.3(d), MacroGenics’ or its Affiliate’s interest in the Joint Patents) to the extent (a) such Patents Cover a MacroGenics Combination Regimen that has received Regulatory Approval; and (b) Incyte has exercised its right under Section 5.8(c) to expand the label of the Licensed Compound to include such Regulatory Approval.

**1.76** “ **Licensed Compound** ” or “ **MGA012** ” means: (a) the anti-PD-1 Monoclonal Antibody coded as “MGA012”, as further described in IND # 130952, or (b) any other anti-PD-1 Monoclonal Antibody (or any antigen-binding Fab fragment thereof) with at [\*\*] sequence identity to each of the [\*\*] in comparison to the anti-PD-1 Monoclonal Antibody coded as “MGA012”.

**1.77** “ **Licensed Compound API** ” means Licensed Compound active pharmaceutical ingredient of a Licensed Product.

**1.78** “ **Licensed Compound Approval** ” means the first instance on which Regulatory Approval is received with respect to the Licensed Compound as either (a) the Monotherapy Regimen or (b) part of a Combination Regimen.

**1.79** “ **Licensed Compound Bulk Drug Substance** ” means the Licensed Compound API as produced in bulk, in accordance with the Clinical Supply Agreement or Commercial Supply

Agreement (as applicable), as well as the applicable quality agreements and Quality Assurance processes.

**1.80** “ **Licensed Compound Drug Product** ” means the Licensed Compound Bulk Drug Substance in its final finished form, which has been separated into unlabeled vials in accordance with the Clinical Supply Agreement or Commercial Supply Agreement (as applicable), as well as the Clinical Quality Agreement and applicable Quality Assurance processes.

**1.81** “ **Licensed Compound Regulatory Discussion** ” means a material discussion with a Core Regulatory Authority related to the Licensed Compound in the context of any MacroGenics Combination Study.

**1.82** “ **Licensed Know-How** ” means all Know-How Controlled by MacroGenics or, subject to Section 15.3(d), any of its Affiliates as of the Execution Date or during the Term that is necessary or useful to (a) Develop (including seeking Regulatory Approval of) or Commercialize Licensed Products, as Monotherapy Regimens or as a component of Incyte Combination Regimens or Collaborator Combination Regimens, (b) seek Regulatory Approval of the Licensed Products as a component of MacroGenics Combination Regimens, or (c) Commercialize Licensed Products in accordance with any such Regulatory Approvals in (b) above in the Field in the Territory (for clarity, to Commercialize the Licensed Products to the extent it has an Indication in combination with any MacroGenics Pipeline Asset, but not to Develop or promote any MacroGenics Pipeline Asset), in each case (of (a)-(c)), excluding any such Know-How Controlled by MacroGenics to the extent such Know-How is solely related to any MacroGenics Pipeline Asset.

**1.83** “ **Licensed Patents** ” means all Patents, other than Label Combination Patents, that (a) are Controlled by MacroGenics or, subject to Section 15.3(d), any of its Affiliates (including, subject to Section 15.3(d), MacroGenics’ or its Affiliate’s interest in the Joint Patents), as of the Execution Date or during the Term; and (b) are necessary or useful to Develop, manufacture, use or Commercialize the Licensed Compound or Licensed Product, provided that Licensed Patents shall not include any Patents to the extent that the claims of such Patents Cover a MacroGenics Pipeline Asset. Notwithstanding the foregoing limitation, the Licensed Patents as of the Execution Date include (i) those set forth in Exhibit A and (ii) those licensed under Existing Third Party Licenses.

**1.84** “ **Licensed Product** ” means any pharmaceutical product, including all forms, presentations, strengths, doses and formulations (including any method of delivery), comprising the Licensed Compound. For clarity, in the case of a Combination Regimen, the Licensed Compound that is a component of such Combination Regimen shall constitute a Licensed Product, but neither the Combination Regimen as a whole, nor the applicable Pipeline Asset that is a component of such Combination Regimen, shall constitute a Licensed Product.

**1.85** “ **Licensed Technology** ” means, collectively, the Licensed Patents and the Licensed Know-How.

**1.86** “ **MacroGenics 1,000L Supply Plant** ” means MacroGenics’ existing two by five hundred (2x500) liter GMP Manufacturing plant, located at 15235 Shady Grove Road, Rockville, Maryland.

**1.87** “ **MacroGenics Combination Regimen** ” means a Combination comprising a Licensed Compound and at least one MacroGenics Pipeline Asset (which Combination may also include any other compound that constitutes an Ancillary Therapy that is not an Incyte Pipeline Asset (e.g., a triplet combination)).

**1.88** “ **MacroGenics Combination Regimen Detailing** ” means an interactive face-to-face meeting between a sales representative acting on behalf of Incyte and a health care professional having prescribing authority within the target audience that occurs after Regulatory Approval of a Licensed Product, which shall be conducted in a manner consistent with Applicable Law and industry standards and with the quality of similar presentations made by Incyte’s sales representatives for Incyte’s other products, if applicable. During such meeting, the Incyte sales representative shall only discuss the MacroGenics Pipeline Asset as it relates to a component of MacroGenics Combination Regimen as it relates to the following provisions incorporated in the “highlights of prescribing information” section of the Licensed Compound label: (a) recent major changes, (b) indications and usage, (c) warnings and precautions, (d) adverse reactions and (e) dosage and administration. Unless otherwise mutually agreed by the Parties or required by a Regulatory Authority, the Incyte sales representative shall not discuss any other data that relates to the MacroGenics Pipeline Asset, including information contained in the “clinical studies” section of the Licensed Compound label such as clinical results from any MacroGenics Combination Study or information in the “pharmacology” section of the Licensed Compound label related to the MacroGenics Pipeline Asset. The Incyte sales representative shall refer the health care professional to a sales representative acting on behalf of MacroGenics for the purpose of such discussion, unless and until such time as the Parties execute a definitive Co-Promotion Agreement that includes requisite terms with respect to promotion of the MacroGenics Combination Regimen by the Incyte sales representative. For clarity, MacroGenics Combination Regimen Detailing shall not include (i) sample drops made by sales representatives, (ii) medical affairs activities or related activities conducted by medical support staff (such as medical science liaisons), (iii) activities conducted at conventions, (iv) electronic details or (v) activities performed by market development specialists, managed care account directors or other personnel not performing face-to-face sales calls or not specifically trained with respect to a Product.

**1.89** “ **MacroGenics Combination Study** ” means a Clinical Study of a MacroGenics Combination Regimen (which study (i) may include a MacroGenics PD-1 Control Arm solely subject to the terms and conditions of this Agreement, including Section 4.3(c), (ii) may evaluate the Licensed Compound as a monotherapy arm, and (iii) may include an Ancillary Therapy control arm, provided that such Ancillary Therapy is not an Incyte Pipeline Asset) that is performed by or on behalf of MacroGenics or its Affiliates or sublicensees in accordance with Section 1.94, but excluding any Required Monotherapy Study and excluding a Clinical Study that includes an Incyte Pipeline Asset.

**1.90** “ **MacroGenics Global Development Plan** ” means the high-level, non-binding, written plan attached hereto as Exhibit B-2 covering MacroGenics’ planned conduct of any MacroGenics Combination Studies, as updated by MacroGenics from time to time in accordance with Sections 2.2 and 4.4. For clarity, a PowerPoint presentation summarizing such planned studies would be sufficient as a written plan.

**1.91** “ **MacroGenics Large-Scale Supply Plant** ” means MacroGenics’ proposed five by two thousand (5x2000) liter GMP Manufacturing plant, to be located at 9704 Medical Center Drive, Rockville, Maryland.

**1.92** “ **MacroGenics Manufacturing Facilities** ” means, individually or collectively, as the context requires, the MacroGenics 1,000L Supply Plant and the MacroGenics Large-Scale Supply Plant.

**1.93** “ **MacroGenics PD-1 Control Arm** ” means, in connection with a MacroGenics Combination Study, either: (a) both (i) a monotherapy arm of the Licensed Product and (ii) a separate monotherapy arm of a different PD-1/-L1 Monoclonal Antibody that is an Ancillary Therapy only ( e.g. , pembrolizumab), or (b) both (i) an arm that evaluates the Licensed Compound in combination with a given MacroGenics Pipeline Asset and (ii) a separate arm that evaluates a different PD-1/-L1 Monoclonal Antibody that is an Ancillary Therapy ( e.g. , pembrolizumab) in combination with the same MacroGenics Pipeline Asset.

**1.94** “ **MacroGenics Pipeline Asset Criteria** ” means, with respect to a molecule, that MacroGenics:

(a) (i) owned or Controlled such molecule for any period after the Effective Date, (ii) previously conducted, or is conducting, a Clinical Study with such molecule that evaluates a combination of such molecule and the Licensed Compound, and (iii) has entered into, or shall enter into, a bona fide collaboration with a Third Party that governs the research, development and commercialization of such molecule with respect thereto; or

(b) has previously entered into, or enters into, a bona fide collaboration with a Third Party that governs the research, development and/or commercialization of such molecule, where MacroGenics retains development rights to sponsor and fund a Clinical Study and to provide input on the development of such molecule;

provided that in each case (of (a) and (b)), such Third Party collaborator shall be contractually obligated to the same development obligations as MacroGenics, pursuant to Section 4.3 or otherwise in Article 4, except that in the case of (a), Incyte shall have the final decision-making authority pursuant to Section 4.3(b)(i)(3) and Section 4.3(b)(ii).

**1.95** “ **MacroGenics Pipeline Asset Information** ” means any commercially sensitive confidential information related to a MacroGenics Pipeline Asset, as reasonably determined by MacroGenics in its sole discretion.

**1.96** “ **Manufacture** ” means any and all activities and processes related to the manufacturing of Licensed Compound or Licensed Product, or any ingredient thereof, including manufacturing of Licensed Compound Bulk Drug Substance, or Licensed Compound Drug Product for Development or Commercialization, labeling, packaging, in-process and testing of finished Licensed Compound or Licensed Product, release of the Licensed Compound or Licensed Product or any component or ingredient thereof, quality assurance activities related to manufacturing and release of Licensed Compound or Licensed Product, and ongoing stability tests and regulatory

activities related to any of the foregoing. “Manufacture” shall exclude Manufacturing Development.

**1.97 “ Manufacturing Development ”** means any of the following with respect to Licensed Compound or Licensed Product: manufacturing process development and validation, process improvements, formulation development, associated analytical development and validation and the manufacture and testing of stability or consistency lots (including process development, qualification, QA, and test batches).

**1.98 “ Manufacturing Expenses ”** means, with respect to the Licensed Compound or any Licensed Product, the aggregate of fully burdened (excluding accounting expenses) internal costs (including actual direct labor based on internal FTE Costs) and Third Party Expenses (without mark-up) incurred by a Party and its Affiliates to Manufacture such Licensed Compound or Licensed Product, calculated as follows, in each case determined in accordance with GAAP, as consistently applied by such Party and its Affiliates: (a) to the extent that such Party or its Affiliates performs all or any part of the Manufacturing of the Licensed Compound or Licensed Product, (i) the direct material costs (including media and purification reagents) and direct FTE Costs for such Manufacturing of the Licensed Compound or Licensed Product, which may include, to the extent actually incurred in such Manufacture, cleaning costs of productions, Manufacturing administrative (including overhead costs allocable to the Manufacturing, but excluding all corporate general and administrative overhead costs), the costs of audits, and all directly incurred Manufacturing variances; (ii) a [\*\*] of the costs of [\*\*] of Licensed Compound (calculated by [\*\*]) ( e.g. , [\*\*]); and (iii) Manufacturing facilities costs (including depreciation, repairs and maintenance costs), scale-up directly allocable to the Manufacture of the Licensed Compound or Licensed Product (including API and drug product production), quality assurance and quality control and technical support, provided that, for commercial supply, each of (i) and (iii) may be included in Manufacturing Expenses only to the extent such costs and expenses are inventoriable under GAAP as consistently applied by such Party or its Affiliates; provided that, all costs of direct labor shall be calculated based on the FTE Rate; and (b) to the extent that a Third Party performs all or any part of the Manufacturing of the Licensed Compound or Licensed Product, the reasonable out-of-pocket costs paid to such Third Party for such activities determined in accordance with GAAP. All invoices for Manufacturing Expenses submitted under this Agreement will include a detailed calculation and description of the relevant overhead allocations. For clarity, Manufacturing Expenses shall not include: (A) any [\*\*]; (B) any costs, expenses or overhead associated [\*\*] (e.g., if Manufacturing activities [\*\*] Licensed Compound Bulk Drug Substance produced [\*\*] ([\*\*]) of the [\*\*] of the plant if the plant were [\*\*]); (C) any amounts [\*\*]; and (D) any costs or expenses [\*\*].

**1.99 “ Manufacturing Process ”** means the manufacturing process for (including any associated Know-How owned or Controlled by MacroGenics relating to the then-current process, and necessary or useful for) the Manufacture of the Licensed Compound Bulk Drug Substance or the Licensed Compound Drug Product at the time of the Manufacturing Technology Transfer as more fully described in Section 7.1 and as further Developed under this Agreement.

**1.100 “ Marketing Approval ”** means approval of a Regulatory Approval Application by the applicable Regulatory Authority.

**1.101** “ **Medical Affairs Activities** ” means medical and scientific information and responses to external inquiries or complaints, medical education, Health Economics and Outcomes Research (HECOR, HEMAR), advisory boards, educational grants and fellowships, opinion leader development activities, drug safety, local country government affairs, field-based medical science liaisons, medical doctors in field (separate from medical science liaisons), publications, medical communications and field medical education.

**1.102** “ **MHLW** ” means the Japanese Ministry of Health, Labour and Welfare and any successor agency(ies) or authority having substantially the same function.

**1.103** “ **Monoclonal Antibodies** ” means any monospecific antibodies, but shall exclude any bi- or multi-specific antibody forms ( e.g. , Biclomics®, DART® and TRIDENT™ constructs).

**1.104** “ **Monotherapy Regimen** ” means the Licensed Compound administered as a single agent therapy.

**1.105** “ **Monotherapy Study** ” means a non-clinical study (including Manufacturing Development), preclinical study, or Clinical Study of (a) solely the Monotherapy Regimen or (b) the Monotherapy Regimen that compares the Monotherapy Regimen to an Ancillary Therapy, in each case of (a) and (b), that is performed by or on behalf of Incyte (or by MacroGenics pursuant to Section 5.9(c)). For clarity, a monotherapy arm that is included as part of a Combination Study shall not be considered a Monotherapy Study.

**1.106** “ **Net Price** ” means, with respect to any Licensed Product, the [\*\*] (or its Affiliates or sublicensees) with payers.

**1.107** “ **Net Sales** ” means, with respect to any Licensed Product, the gross amounts invoiced by Incyte or any of its Affiliates or sublicensees for sales of such Licensed Product to unaffiliated Third Party purchasers in arms-length transactions, less the following deductions calculated in accordance with GAAP, to the extent actually taken, paid, accrued and allowed:

(a) cash, trade or quantity discounts, retroactive price reductions, coupons, charge-back payments, and rebates granted (in each case, whether in cash or in kind) to trade customers, hospitals, managed health care organizations, pharmaceutical benefit managers, group purchasing organizations, and national, state, or local governments;

(b) credits, rebates or allowances allowed upon prompt payment or on account of claims, damaged goods, rejections or returns of such Licensed Product, including in connection with recalls and withdrawals, and the amount of any write-offs for bad debt (provided, that an amount written off as bad debt but subsequently recovered will be treated as Net Sales);

(c) outbound freight, shipment and insurance costs, to the extent included in the price and separately itemized on the invoice price;

(d) taxes (other than income taxes), duties, tariffs, mandated contribution or other governmental charges levied on the sale of such Licensed Product, including Value-Added Taxes (“ VAT ”), customs duties, healthcare taxes, excise taxes, use taxes, and sales taxes;

(e) compulsory payments and cash rebates related to sales of such Licensed Product payable to a Governmental Authority (or agent thereof) pursuant to Applicable Law by reason of any national or local health insurance program or similar program, including that portion of the annual fee on prescription drug manufacturers imposed by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as amended) that Incyte, its Affiliate or its or their sublicensee, as applicable, allocates to sales of the Licensed Products in accordance with Incyte’s, its Affiliate’s or its or their sublicensee’s standard policies and procedures consistently applied across its products, as applicable; and

(f) any other similar and customary deductions ( e.g., currently, co-pay cards) that are consistent with GAAP and Incyte’s actual practice (or its Affiliates’ or licensees’) at the time in calculating and reporting its actual product net sales throughout its businesses (in the particular country, if applicable), provided that no item shall be deducted pursuant to this clause (f) if included in any another deduction provided for under this definition (for example, Incyte shall not deduct an allowance for bad debts pursuant to this clause (f), as actual bad debts are subject to deduction pursuant to clause (b)),

All of the aforementioned deductions shall be determined, on a country-by-country basis, as incurred in the ordinary course of business in type and amount consistent with Incyte’s or its applicable Affiliate’s or sublicensee’s (as the case may be) business practices consistently applied across its product lines and accounting standards, as applicable. All such deductions shall be fairly and equitably allocated to such Licensed Product and other products of Incyte and its Affiliates and sublicensees.

In the event a Licensed Product is sold as part of a Combination Product, the Net Sales from the Combination Product shall be determined by multiplying the Net Sales of the Combination Product, as calculated above without regard for this paragraph, by the fraction  $A/(A+B)$ , where A is the average sale price of the Licensed Product when sold separately in finished form, and B is the average sale price of the other therapeutic ingredient(s) included in the Combination Product when sold separately in finished form, in each case in the applicable country of sale or and during the applicable royalty reporting period, if sales of both the Licensed Product and the other therapeutic ingredient(s) did not occur in such period, then in the most recent royalty reporting period in which sales of both occurred. In the event that such average sale price cannot be determined for both the Licensed Product and all other therapeutic ingredient(s) included in the Combination Product, Net Sales shall be calculated by multiplying the Net Sales of the Combination Product, as calculated above without regard for this paragraph, by the fraction of  $C/(C+D)$  where C is the fair market value of the Licensed Product and D is the fair market value of all other therapeutic ingredient(s) included in the Combination Product. The Parties shall seek to determine such fair market values by mutual agreement and, in the absence of such mutual agreement, the Parties shall engage an independent valuation firm (and equally bear the costs of engaging such firm) to determine such fair market values.

Notwithstanding the foregoing, amounts invoiced by Incyte, its Affiliates, or its sublicensees for the sale of a Licensed Product among Incyte, its Affiliates or its sublicensees for resale shall not be included in the computation of Net Sales hereunder unless such Affiliate or such sublicensee is the end user of such Licensed Product and as long as such Licensed Product is subsequently resold by Incyte, its Affiliates or its sublicensee and considered Net Sales. Net Sales shall exclude reasonable and customary quantities ( e.g. , samples) of the Licensed Product transferred, disposed of or sold at no cost or at or below cost for (i) promotional or educational purposes, (ii) Clinical Study purposes, (iii) early access programs (such as to provide patients with a Licensed Product prior to Regulatory Approval pursuant to treatment INDs or protocols, named patient programs or compassionate use programs) or (iv) any similar uses.

**1.108 “ Non-Proprietary Combination Regimen ”** means a Combination that is evaluated in a Clinical Study comprising a Licensed Compound and at least one Ancillary Therapy that is not an Incyte Pipeline Asset, Collaborator Pipeline Asset, or MacroGenics Pipeline Asset (which Combination may also include any other compound that constitutes an Ancillary Therapy and is not an Incyte Pipeline Asset, Collaborator Pipeline Asset, or MacroGenics Pipeline Asset).

**1.109 “ Non-Registrational Study ”** means a Combination Study conducted by either Party that is not a Phase I Study, Phase II Study, Phase III Study, non-interventional Phase IV Study, Phase IV Study required by a Regulatory Authority for purposes of maintaining or changing the existing product label for the applicable Combination Regimen or Pivotal Study or otherwise in support of obtaining or maintaining Regulatory Approval ( e.g. , an early access, compassionate use, or special use program, or a Phase IV Study not required by a Regulatory Authority for purposes of maintaining or changing the existing product label for the applicable Combination Regimen).

**1.110 “ Patents ”** means all: (a) patents, including any utility or design patent; (b) patent applications, including provisionals, substitutions, divisionals, continuations, continuations in-part or renewals; (c) patents of addition, restorations, extensions, supplementary protection certificates, registration or confirmation patents, patents resulting from post-grant proceedings, re-issues and re-examinations; (d) other patents or patent applications claiming priority directly or indirectly to (i) any such specified patent or patent application specified in (a) through (c), or (ii) any patent or patent application from which a patent or patent application specified in (a) through (c) claim direct or indirect priority; (e) inventor’s certificates; and (f) other rights issued from a Governmental Authority similar to any of the foregoing; in each case of (a) through (f), irrespective of whether such patent, patent application or other right arises in the U.S. or any other jurisdiction in the Territory.

**1.111 “ PD-1 ”** means programmed cell death receptor 1.

**1.112 “ PD-L1 ”** means programmed cell death ligand 1.

**1.113 “ PD-1 IP ”** means any intellectual property that relates to anti-PD-1 Monoclonal Antibodies.

**1.114 “ Person ”** means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock

company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision, department or agency of a government.

**1.115 “ Phase I Study ”** means a human clinical trial of a Product in any country that would satisfy the requirements of 21 C.F.R. § 312.21(a) (FFDCA), as amended from time to time, or any foreign equivalent thereof.

**1.116 “ Phase II Study ”** means a human clinical trial of a Product, or relevant portion of such trial (including expansion cohorts from a Phase I Study for which patients are treated at a defined dose or a set of defined doses), for which the primary endpoints include a preliminary determination of efficacy in patients being studied, as described in 21 C.F.R. § 312.21(b) (FFDCA), as amended from time to time, or any foreign equivalent thereof.

**1.117 “ Phase III Study ”** means a pivotal human clinical trial with a defined dose or a set of defined doses of a Product that is designed to ascertain efficacy and safety of such Product, as described in 21 C.F.R. § 312.21(c) (FFDCA), as amended from time to time, or any foreign equivalent thereof, for the purpose of supporting the preparation and submission of a BLA or MAA.

**1.118 “ Phase IV Study ”** means a clinical trial of a Product, possibly including pharmacokinetic studies, which trial (a) is not required to be completed prior to obtaining Marketing Approval of such Product; and (b) either (i) is required by the applicable Regulatory Authority as mandatory to be conducted on or after the Marketing Approval of such Product, or (ii) is conducted voluntarily to enhance scientific knowledge of the Product ( *e.g.* , providing additional drug profile, safety data or marketing support information, or supporting expansion of Product labeling).

**1.119 “ Pipeline Asset ”** means any specific molecule ( *i.e.* , not a class of molecules), other than the Licensed Compound, that is: (a) Controlled (in accordance with Section 1.32(b)) by MacroGenics, or that otherwise satisfies the MacroGenics Pipeline Asset Criteria (either, a “ **MacroGenics Pipeline Asset** ”); (b) Controlled (in accordance with Section 1.32(b)) by Incyte, or that otherwise satisfies the Incyte Pipeline Asset Criteria (either, an “ **Incyte Pipeline Asset** ”); (c) Controlled (in accordance with Section 1.32(b)) by a Collaborator (a “ **Collaborator Pipeline Asset** ”); or (d) solely for purposes of Sections 4.3(c) and 15.3(b), Controlled (in accordance with Section 1.32(b)) by an Acquirer in a Change of Control transaction with respect to MacroGenics (“ **Acquirer Pipeline Asset** ”), as applicable.

**1.120 “ Pivotal Study ”** means (a) a Phase III Study or other human Clinical Study designed to be or that becomes a registration trial sufficient for filing a Regulatory Approval Application for a Licensed Product, as evidenced by (i) an agreement with or statement from the FDA or applicable Regulatory Authority, or (ii) other guidance of minutes issued by the FDA or such other Regulatory Authority for such registration trial, or (b) a Phase III Study or other human Clinical Study which Incyte intends to submit as the basis for Regulatory Approval of the Licensed Product.

**1.121 “ PMDA ”** means the Pharmaceuticals and Medical Devices Agency in Japan and any successor agency(ies) or authority having substantially the same function.

**1.122** “ **Product(s)** ” means, individually or collectively, as the context requires, (a) any Licensed Product or (b) any Combination Regimen.

**1.123** “ **Proof of Concept** ” means, with respect to any [\*\*] (but, for clarity, excluding the other [\*\*]), the establishment of a [\*\*] as established by the JDC on an [\*\*], subject to an [\*\*] ( e.g., [\*\*] or [\*\*]).

**1.124** “ **Qualifying Termination** ” means a termination of this Agreement in its entirety: (a) by MacroGenics pursuant to Section 12.3 (for Incyte’s material uncured breach); (b) by MacroGenics pursuant to Section 12.5 (for a patent challenge); (c) by MacroGenics pursuant to Section 12.6 (for Incyte bankruptcy); (d) by Incyte pursuant to Section 12.2 (for convenience); or (e) by Incyte pursuant to Section 12.4 (for safety reasons).

**1.125** “ **Regulatory Agreement** ” means that certain regulatory agreement to be entered into by the Parties to define the Parties’ respective roles and responsibilities related to regulatory strategy, labeling strategy (including a delineation of any product label(s) of a Party that will be expanded to include the other Party’s Regulatory Approvals, in accordance with Section 5.8), dossier preparation, interactions with Regulatory Authorities, coordination of Regulatory Approval Application submission contents, timing and other matters, to enable each Party to comply with its respective obligations under Applicable Law, with regard to filings and interactions with any Regulatory Authority related to Incyte seeking Regulatory Approval of the Licensed Compound as a component of a MacroGenics Combination Regimen and MacroGenics seeking Regulatory Approval of the MacroGenics Pipeline Asset as a component of a MacroGenics Combination Regimen.

**1.126** “ **Regulatory Approval** ” means any and all approvals (including supplements, amendments, pre- and post-approvals and pricing and reimbursement approvals, but excluding Manufacturing approvals), licenses, registrations or authorizations of any national, regional, state or local Regulatory Authority, department, bureau, commission, council or other governmental entity, that are necessary to Commercialize any Compounds or Products under this Agreement in any country or jurisdiction in the Territory, for one or more uses, including any pricing and reimbursement approvals that are necessary to conduct a launch of such Compound or Product in such country or jurisdiction (even if such approvals are not legally required to launch such Compound or Product in such country or jurisdiction).

**1.127** “ **Regulatory Approval Application** ” means (a) a New Drug Approval Application (“ **NDA** ”) or Biologics License Application (“ **BLA** ”) (each, as defined in the FDCA) in the U.S., or (b) any corresponding application for Regulatory Approval in any country or jurisdiction in the Territory outside the U.S., including, with respect to the European Union, a Marketing Authorization Application (“ **MAA** ”) filed with the EMA pursuant to the Centralised Approval Procedure or with the applicable Regulatory Authority of a country in Europe with respect to the decentralised procedure, mutual recognition or any national approval procedure.

**1.128** “ **Regulatory Approval in EU** ” means receipt of Regulatory Approval in at least three (3) of five (5) European Major Markets.

**1.129** “ **Regulatory Authority** ” means any applicable Governmental Authority involved in granting Regulatory Approval in a country or jurisdiction in the Territory, including (a) in the U.S., the FDA or any other applicable Governmental Authority having jurisdiction over any Compound or Product; (b) in the EU, the EMA or any other applicable Governmental Authority having jurisdiction over any Compound or Product; (c) in Japan, the PMDA or MHLW; and (d) in any country or jurisdiction other than the U.S., EU or Japan, any applicable Governmental Authority having jurisdiction over any Compound or Product.

**1.130** “ **Regulatory Documentation** ” means, with respect to any Compound or Product under this Agreement, all regulatory filings, applications, notifications, registrations, licenses, regulatory drug lists, advertising and promotion documents, adverse event files, complaint files, Manufacturing records, Regulatory Approvals or other regulatory submissions or supporting documents, including any written correspondence or meeting minutes, made to, made with, or received from an applicable governmental agency or Regulatory Authority relating to such Compound or Product, and all data contained therein. “Regulatory Documentation” includes INDs, Regulatory Approval Applications, and amendments and supplements for any of the foregoing.

**1.131** “ **Regulatory Exclusivity** ” means, with respect to a particular country, either exclusive marketing rights or data protection or other exclusivity rights conferred by any Regulatory Authority with respect to such Licensed Product in such country or jurisdiction in the Territory, including orphan drug exclusivity, pediatric exclusivity, rights conferred in the U.S. under the Biologics Price Competition and Innovation Act of 2009 (the “ **BPCI Act** ”) or in the European Union under Directive 2001/83/EC, as amended, and Regulation (EC) No. 1901/2006, as amended, or rights similar thereto in other countries or regulatory jurisdictions in the Territory. Regulatory Exclusivity shall not include exclusivity conferred by a Patent right.

**1.132** “ **Right of Reference** ” means the “right of reference” defined in 21 C.F.R. 314.3(b), or any analogous Applicable Law recognized outside of the U.S.

**1.133** “ **Royalty Term** ” means, on a Licensed Product-by-Licensed Product and country-by-country basis, the time period commencing on the Effective Date and continuing until the later of: (a) the expiration of the last Valid Claim of a Licensed Patent Covering the composition of matter or method of use of such Licensed Product in such country; (b) [\*\*] from the First Commercial Sale of such Licensed Product in such country; or (c) if Regulatory Exclusivity is granted with respect to such Licensed Product in such country, the expiration or termination of such Regulatory Exclusivity in such country.

**1.134** “ **Tax** ” or “ **Taxes** ” means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including any interest thereon).

**1.135** “ **Territory** ” means any country in the world.

**1.136** “ **Third Party** ” means any Person other than (a) Incyte, (b) MacroGenics or (c) an Affiliate of either of Incyte or MacroGenics.

**1.137 “Third Party Expenses”** means out-of-pocket expenses incurred by a Party or any of its Affiliates for services performed by a Third Party on behalf of Incyte or MacroGenics in the course of such Party’s performance of this Agreement.

**1.138 “U.S.”** means the United States of America, including its territories and possessions.

**1.139 “[\*\*]”** means, with respect to the Licensed Compound, the [\*\*] of (a) [\*\*] or (b) [\*\*] ([\*\*]%) [\*\*] “[\*\*]” (as such term is defined under applicable [\*\*] ([\*\*]), or if [\*\*] ceases to be [\*\*] in [\*\*], its equivalent successor) of [\*\*].

**1.140 “Valid Claim”** means (a) a claim of an issued and unexpired Patent, to the extent such claim has not been revoked, held invalid or unenforceable by a patent office, court or other Governmental Authority of competent jurisdiction in a final order, from which no further appeal can be taken, and which claim has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination, disclaimer, *inter-partes* review, post-grant review, other patent office administrative proceedings, or otherwise; or (b) a claim within a patent application that has not been pending for more than [\*\*] from the date of its first priority patent application filing anywhere in the Territory and which claim has not been revoked, cancelled, withdrawn, held invalid or abandoned.

**1.141 Additional Definitions**. Each of the following definitions is set forth in the Section of this Agreement indicated below:

<b>Term</b>	<b>Section</b>
13D Group	15.14(a)(iii)
Acquirer Combination Study	15.3(b)
Ancillary Agreements	14.1
Annual Global Commercial Supply Forecast	7.3(a)
Approval Milestone	8.2(d)
Approved CMO	7.1(a)
Bankruptcy Laws	12.6(b)
Binding Portion	7.2(e)(i)
[**] Conditions	3.2(c)
[**]	3.2(c)
[**]	8.10(c)
[**]	8.10(c)
[**]	10.2(j)
Breaching Party	12.3
[**]	6.2(d)
CCC	2.5(a)
Claim	14.1
Clinical Quality Agreement	7.2(a)
Clinical Supply Agreement	7.2(a)
Collaborator Contract	3.2(b)
Collaborator Development IP	3.2(b)

Collaborator Sublicense Fees	8.8
Commercial Supply Agreement	7.3(d)
Committed Supply	7.2(c)
Cooperating Party	11.5(b)
Co-Promotion Agreement	6.1(c)
Cure Period	12.3
Deadlocked Committee Matter	2.6(d)
Development Agreement	4.5
Development Milestone	8.2(b)
Disclosing Party	11.1
Dispute(s)	13.1
[**] Conditions	3.2(c)
[**]	3.2(c)
[**]	8.10(d)
[**]	8.10(d)
[**]	4.6(b)
[**]	6.2(b)
Existing Third Party Licenses	8.10(b)
Funded Collaborator Combination Studies	7.2(b)
Incyte CDx IP	3.4(b)
Incyte Commercial Supply Commitment	7.3(a)(ii)
Incyte Competing Product	15.3(b)(iii)
Incyte Development IP	9.1(b)
Incyte Facility	7.1(a)
Incyte Indemnitee	14.2
Incyte Know-How	3.4(b)
Incyte Method Claim	3.4(d)(i)
Incyte Objection	4.3(c)(i)
Incyte Patents	3.4(b)
Incyte PD-1 IP	3.4(b)
Incyte [**] Objection	4.3(b)(i)(1)
Incyte Technology	3.4(b)
IND Transition	4.1(b)
IND Transition Date	4.1(b)
IND Transition Plan	4.1(b)
Indemnifying Party	14.3(a)
Indemnitee	14.3(a)
Indication Population	4.6(b)
Information Transfer	5.1(a)
Infringement Recovery	9.3(f)
Insolvency Event	12.6(a)
Insolvent Party	12.6(b)
[**]	6.2(c)
JDC	2.2(a)

JIPC	2.4(a)
JMC	2.3(a)
Joint Committee	2.6(a)
Joint Inventions	9.1(d)
Joint Patents	9.2(e)(i)
JSC	2.1(a)
Long Term Forecast	7.2(e)(i)
MacroGenics CDx IP	3.4(a)
MacroGenics Commercial Supply Commitment	7.3(a)(ii)
MacroGenics Competing Product	15.3(c)
MacroGenics Development IP	9.1(c)
MacroGenics Indemnitee	14.1
MacroGenics Licensed Compound Data	5.2(c)(i)
MacroGenics Method Claim	3.4(d)(ii)
MacroGenics PD-1 IP	3.4(a)
MacroGenics-Responsible Joint Patents	9.2(e)(i)
Manufacturing Technology Transfer	7.1(a)
Manufacturing Transition Plan	7.1(a)
[**]	4.3(c)(ii)
[**]	4.3(b)(i)(1)
MGA012 IND	4.1(b)
Milestone	8.2
Monotherapy Sublicense Fees	8.7
Non-Insolvent Party	12.6(b)
Ongoing Clinical Study	4.1(a)
Opt Out Notice	9.2(b)(i)
Order	7.2(e)(ii)
Patent Extension(s)	9.4
Pharmacovigilance Agreement	5.6(c)
POC Development Milestone	8.2(a)
Prosecuting Party	9.2(f)(ii)
Quality Assurance Measures	7.6(a)
Receiving Party	11.1
Regulatory Filing Milestone	8.2(c)
Representatives	9.1(e)
Requested Licensed Patent	9.2(b)
Requesting Party	11.5(b)
Required Monotherapy Study	5.9
Required Regulatory Data	5.2(c)(iii)
Responsible Party	9.2(e)(ii)
Rolling Forecast	7.2(e)(i)
Royalty Floor	8.5(a)(iii)
Sales Milestone	8.2(e)
Section 365(n)	12.6(b)

Standstill Period	15.14(a)
Study Transition	4.1(c)
Study Transition Date	4.1(c)
Study Transition Plan	4.1(c)
Subject Patents	9.2(c)(i)
Term	12.1
Terminating Party	12.3
Third Party Infringement Claim	9.5(a)
Third Party License	8.10(a)
Third Party License Credit	8.10(a)
Third Party Patent Challenge	9.6(a)
Upstream License	12.8(d)
Transferred Documentation	5.1(a)
[**]	6.2(a)
[**]	6.2(a)

**ARTICLE 2  
GOVERNANCE**

**2.1 Joint Steering Committee**

- (a) **Formation and Purpose** . The Parties agree to establish and convene a joint steering committee (the “**JSC**”) within [\*\*] after the Effective Date. The JSC shall consist of representatives from each Party as further described in Section 2.6(a) and operate in accordance with this Section 2.1 and Section 2.6. The purpose of the JSC shall be to provide a forum for overall coordination and communication with respect to the Parties’ activities under this Agreement, including the resolution of Deadlocked Committee Matters properly referred to the JSC under this Agreement.
- (b) **Responsibilities of the JSC** . The JSC’s overall responsibility shall be to:
- (i) discuss any issues arising with respect to the Development or Commercialization of the Licensed Compound or any Licensed Products or Combination Regimens;
  - (ii) discuss the clinical and/or commercial supply needs of MacroGenics, Incyte and any Collaborators with respect to the Licensed Compound and the Manufacturing plans with respect thereto;
  - (iii) discuss and oversee the Study Transition Plan, IND Transition Plan, and Manufacturing Transition Plan (provided that the selection of any Approved CMO(s) shall require mutual agreement, such agreement not to be unreasonably withheld), including discussing any amendments with respect to either of the foregoing;

- (iv) coordinate the wind-down of efforts under this Agreement following termination in accordance with Section 12.8;
  - (v) decide matters and resolve disputes referred to the JSC which the JSC has authority to decide or resolve under this Agreement and resolve Deadlocked Committee Matters referred to the JSC in accordance with Section 2.6(d); and
  - (vi) perform other obligations specifically delegated to the JSC under this Agreement.
- (c) **JSC Decisions and Actions** . Actions to be taken and decisions to be made by the JSC (including the resolution of Deadlocked Committee Matters referred to the JSC in accordance with Section 2.6(d)) shall be taken or made only following unanimous agreement, with each Party having one (1) vote. If the JSC fails to reach unanimous agreement on a matter before it for decision within [\*\*] from the date that the matter is first presented to the JSC in writing, such matter shall be referred to the Executive Officers for discussion and resolution pursuant to Article 13 upon the request of either Party. Any resolution of such matter by the Executive Officers shall be final and binding on the Parties. If the Executive Officers are not able to resolve the matter within the [\*\*] period specified in Article 13, then Incyte shall have the final decision-making authority with respect to such matter, and Incyte's decision on such matter shall be final and binding on the Parties, subject to the limitations set forth in Section 2.10.

## **2.2 Joint Development Committee**

- (a) **Formation and Purpose** . The Parties agree to establish and convene a joint development committee (the "JDC") within [\*\*] after the Effective Date. The JDC shall consist of representatives from each Party as further described in Section 2.6(a) and operate in accordance with this Section 2.2 and Section 2.6. The primary purpose of the JDC shall be to oversee, coordinate and facilitate Development of the Licensed Compound and Licensed Products under this Agreement. For clarity, notwithstanding the establishment of the JDC, Incyte shall have the sole and unrestricted right to conduct or have conducted any Clinical Study or other Development with respect to the Monotherapy Regimen, the Incyte Combination Regimens and the Collaborator Combination Regimens and to modify the Incyte Global Development Plan without restriction.
- (b) **Responsibilities of the JDC** . The JDC shall:
- (i) oversee the Ongoing Clinical Study performed by or on behalf of MacroGenics with respect to the Licensed Compound;
  - (ii) discuss, coordinate and oversee the transition of Development responsibilities from MacroGenics to Incyte as contemplated under this Agreement, including discussing the IND Transition Date and Study

Transition Date, overseeing the Regulatory Transfer, and seeking approval of the IND Transition Plan and Study Transition Plan;

- (iii) discuss Incyte's plans with respect to the Development of the Licensed Compound and any Licensed Products in the Field in the Territory in accordance with the Incyte Global Development Plan;
- (iv) discuss MacroGenics' plans with respect to the Development of the MacroGenics Combination Regimens in the Field in the Territory in accordance with the MacroGenics Global Development Plan;
- (v) annually review the then-current Incyte Global Development Plan and MacroGenics Global Development Plan;
- (vi) discuss the protocol synopses for MacroGenics' proposed MacroGenics Combination Studies in accordance with Section 4.3;
- (vii) establish the [\*\*] and [\*\*] required for the achievement of Proof of Concept in a [\*\*] or [\*\*] of a [\*\*];
- (viii) discuss any issues arising with respect to the Development of any Monotherapy Regimen or any Combination Regimen;
- (ix) coordinate, and encourage and facilitate, communication and information sharing regarding the Parties' performance of their respective regulatory responsibilities in accordance with Article 5;
- (x) decide matters which the JDC has the express authority to decide under this Agreement; and
- (xi) perform other obligations specifically delegated to the JDC under this Agreement.

### **2.3 Joint Manufacturing Committee.**

- (a) **Formation and Purpose** . The Parties agree to establish and convene a joint manufacturing committee (the " **JMC** ") within [\*\*] after the Effective Date. The JMC shall consist of representatives from each Party as further described in Section 2.6(a) and operate in accordance with this Section 2.3 and Section 2.6. The primary purpose of the JMC shall be to oversee, coordinate and facilitate the Manufacture of the Licensed Compound Bulk Drug Substance and Licensed Compound Drug Product.
- (b) **Responsibilities of the JMC** . The JMC shall:
  - (i) discuss manufacturing matters with respect to the Licensed Compound Bulk Drug Substance and Licensed Compound Drug Product, including the

Manufacturing Process, and discuss and seek approval of the Approved CMO (as more fully set forth in Section 7.1);

- (ii) facilitate the sharing of the Rolling Forecasts and Long Term Forecasts pursuant to Section 7.2(e) (i), and review and seek approval of the Annual Global Supply Commitment pursuant to Section 7.3(a);
- (iii) discuss, coordinate and oversee the Manufacturing Technology Transfer (as more fully set forth in Section 7.1), including discussing and seeking approval of the Manufacturing Transition Plan; and
- (iv) perform other obligations specifically delegated to the JMC under this Agreement.

#### **2.4 Joint Intellectual Property Committee**

- (a) **Formation and Purpose** . The Parties agree to establish and convene a joint intellectual property committee (the “ **JIPC** ”) within [\*\*] after the Effective Date. The JIPC shall consist of representatives from each Party as further described in Section 2.6(a) and operate in accordance with this Section 2.4 and Section 2.6. The primary purpose of the JIPC shall be to coordinate, oversee, and provide a venue for discussion of intellectual property strategy, prosecution, maintenance, and enforcement matters relating to the Licensed Patents, Joint Patents, Incyte Patents and Patents within the Incyte Development IP.
- (b) **Responsibilities of the JIPC** . The JIPC shall:
  - (i) discuss, coordinate and oversee the preparation, filing, prosecution and maintenance of the Licensed Patents (as more fully set forth in Section 9.2);
  - (ii) discuss, coordinate and oversee the litigation strategy with respect to any suits or other actions against any Third Party engaged in any existing, alleged or threatened infringement of any Licensed Patent or Joint Patent (as more fully set forth in Section 9.3);
  - (iii) discuss, coordinate and oversee matters related to obtaining Patent Extensions (as more fully set forth in Section 9.4);
  - (iv) discuss, coordinate and oversee the litigation strategy with respect to any Third Party Infringement Claim or Third Party Patent Challenge (as more fully set forth in Sections 9.5 and 9.6); and
  - (v) perform other obligations specifically delegated to the JIPC under this Agreement.

**2.5 Commercialization Coordination Committee**

- (a) **Formation and Purpose** . The Parties agree to establish and convene a commercialization coordination committee (the “ CCC ”) at least [\*\*] prior to the earlier of the [\*\*] of either [\*\*] or [\*\*]. The CCC shall consist of representatives from each Party as further described in Section 2.6(a) and operate in accordance with this Section 2.5 and Section 2.6. The primary purpose of the CCC shall be to oversee, discuss and coordinate commercial activities with respect to MacroGenics Combination Regimens and Monotherapy Regimens under this Agreement; provided that, except in connection with forecasting global commercial demand for Licensed Compound Drug Product in connection with Commercialization of the Combination Regimens, pursuant to Section 7.3(a), neither Party shall be obligated to share with the CCC any information, materials or strategy, or to coordinate on any strategy or commercialization content, with respect to its Combination Regimens or the Monotherapy Regimen. Notwithstanding anything to the contrary herein, (a) MacroGenics shall have final decision-making authority with respect to commercial matters related to MacroGenics Pipeline Assets and, subject to the remainder of this Section 2.5(a), MacroGenics Combination Regimens, and (b) Incyte shall have final decision-making authority with respect to any matters related to the Monotherapy Regimen and any commercial matters related to the Licensed Product being sold in accordance with its approved label.
- (b) **Responsibilities of the CCC** . The CCC shall be advisory in nature and shall not have any decision-making authority, but shall:
- (i) oversee, discuss and coordinate commercial matters with respect to MacroGenics Combination Regimens and Monotherapy Regimens, including market landscape, strategic positioning, communications and promotional strategy and medical strategy;
  - (ii) oversee and coordinate procedures for sharing Information relating to the labeling of MacroGenics Combination Regimens; and
  - (iii) perform other obligations specifically delegated to the CCC under this Agreement.
- (c) **CCC Membership and operations** . During the JSC’s first meeting, the JSC will use good faith efforts to mutually agree upon procedures regarding the membership and operations of the CCC, it being understood that the CCC shall be advisory in nature and shall not have any decision-making authority.

**2.6 Joint Committee Membership and Operations**

- (a) **Membership** . Promptly after the Effective Date, each Party shall designate three (3) representatives to the JSC, up to three (3) representatives to each of the JDC and JMC, and up to two (2) representatives to the JIPC (each, a “ **Joint Committee** ”). Each Joint Committee may elect to vary the number of representatives from time to time. Each representative designated by a Party shall

be an employee of such Party or one of its Affiliates and shall have the appropriate level of experience in the subject area of the applicable Joint Committee, and at least one (1) representative shall have sufficient seniority within the applicable Party's organization to have the necessary decision-making authority in order for such Joint Committee to fulfill its responsibilities. Either Party may designate employees as substitutes for any of its Joint Committee representatives if one (1) or more of such Party's designated representatives is unable to be present at a meeting. From time to time, each Party may replace any of its Joint Committee representatives by written notice to the other Party specifying the prior representative(s) and their replacement(s). Each representative on a Joint Committee shall be bound by confidentiality and non-use obligations at least as restrictive as those set forth in this Agreement.

(b) **Joint Committee Chairperson** . Each Joint Committee will have a chairperson, to be designated by MacroGenics initially with respect to the JDC and Incyte initially with respect to the JSC, JMC, and JIPC, and to be designated by the two Parties on an alternating basis annually thereafter. The chairperson shall be responsible for calling and convening meetings of its Joint Committee, but shall have no special authority over the other members of its Joint Committee, and shall have no additional voting rights. The chairperson of each Joint Committee (or its designate) shall: (i) prepare and circulate an agenda reasonably in advance of each upcoming meeting of such Joint Committee; and (ii) prepare and issue minutes of such Joint Committee meeting within [\*\*] thereafter. Such minutes shall not be finalized until each representative on such Joint Committee reviews and approves such minutes, provided that any minutes shall be deemed approved unless a Joint Committee representative objects to the accuracy of such minutes within [\*\*] after the circulation of the minutes. The minutes of each Joint Committee meeting shall be the Confidential Information of each Party.

(c) **Meetings** .

(i) **Timing and Frequency** . Promptly following its formation, each Joint Committee will hold an in-person meeting to establish such Joint Committee's operating procedures. After its initial meeting, the JSC shall meet at least once every Calendar Quarter during the Term (or such other frequency as agreed upon by the Parties), and each other Joint Committee shall meet as frequently as agreed by each such Joint Committee, but no less frequently than annually. Additionally, at least once annually, the Parties will hold an in-person meeting (as set forth in Section 2.6(c)(ii)(A)) with all Joint Committees in attendance. Additional meetings of a Joint Committee may be held with the consent of each Party (such consent not to be unreasonably withheld, delayed or conditioned), as required under this Agreement or to attempt to resolve any matter or Deadlocked Committee Matter in accordance with this Agreement. In the case of any matter or Deadlocked Committee Matter referred to a Joint Committee, such meeting

shall be held within [\*\*] following referral to such Joint Committee, or as soon as reasonably possible thereafter.

- (ii) **Meeting Procedures** . Meetings of each Joint Committee shall be effective only if a majority of representatives of each Party are present or participating. Other than the initial meeting, each Joint Committee may meet either (A) in person at either Party's facilities or at such locations as the Parties may otherwise agree; or (B) by audio or video teleconference, provided that at least once annually, each Joint Committee shall meet in person as described in Section 2.6(c)(i). Each Party shall be responsible for all of its own expenses incurred in connection with its representatives' participation in each Joint Committee meeting, including all travel and lodging. All other Third Party Expenses incurred by a Joint Committee in furtherance of a Joint Committee meeting, such as expenses associated with off-site meetings, shall be shared equally by the Parties.
- (iii) **Non-Member Participation** . Additional non-members of a Joint Committee having relevant experience may from time to time be invited to participate in a Joint Committee meeting, provided that such participants shall have no voting rights or powers. Non-member participants who are not employees of a Party or its Affiliates shall only be allowed to attend if: (A) the other Party's representatives have consented to the attendance (such consent not to be unreasonably withheld, delayed or conditioned); (B) such non-member participants are subject to confidentiality and non-use obligations at least as restrictive as those set forth in this Agreement, including the provisions of Sections 11.10(a) and 11.10(b), and shall be deemed the "Representatives" of the Party inviting such participants to the meeting.
- (d) **Joint Committee Decisions and Actions** . Actions to be taken and decisions to be made by the JDC, JMC, or JIPC shall be taken or made only following unanimous agreement, with each Party having one (1) vote. If the JDC, JMC, or JIPC reaches unanimous agreement on a matter before it for decision, such decision by such Joint Committee shall be final and binding on the Parties. If the JDC, JMC, or JIPC fails to reach unanimous agreement on a matter before it for decision within [\*\*] from the date that the matter is first presented to such Joint Committee in writing, such matter (a "**Deadlocked Committee Matter** ") shall be referred to the JSC for resolution upon the request of either Party pursuant to Section 2.1(c).

**2.7 Additional Subcommittees and Working Groups** . Each Joint Committee may establish other subcommittees or working groups as needed to further the purposes of this Agreement, including any responsibilities assigned to such Joint Committee under this Agreement; provided, however, that the JSC shall not delegate its authority to resolve Deadlocked Committee Matters to a subcommittee or working group. The purpose, scope and procedures of any such subcommittee or working group shall be mutually agreed in writing by the Joint Committee that formed such subcommittee or working group. Actions to be taken and decisions to be made by such subcommittee or working group shall be taken or made only following unanimous agreement, with

each Party having one (1) vote. If a subcommittee or working group reaches unanimous agreement on a matter before it for decision, such decision by such subcommittee or working group shall be final and binding on the Parties. If a subcommittee or working group fails to reach unanimous agreement on a matter before it for decision within [\*\*] from the date that the matter is first presented to such a subcommittee or working group in writing, such matter shall be referred to the Joint Committee that established such subcommittee or working group for resolution pursuant to Section 2.6(d) upon the request of either Party.

**2.8 Authority.** The Parties agree that it shall be conclusively presumed that, unless otherwise explicitly stated, each voting member of each Joint Committee, or each subcommittee or working group established by a Joint Committee, has the authority and approval of such member's respective senior management in casting his or her vote. Each Joint Committee, and each subcommittee or working group established by such Joint Committee, shall each have only the powers assigned expressly to such Joint Committee in this Article 2 and elsewhere in this Agreement, and shall not have any power to amend, modify or waive compliance with this Agreement.

**2.9 Alliance Managers.** Promptly following the Effective Date, each Party shall designate in writing an Alliance Manager to serve as the primary point of contact for the Parties regarding all collaboration activities contemplated under this Agreement. Each Alliance Manager shall facilitate communication and coordination of the Parties' activities under this Agreement. The Alliance Managers shall not be a member of the CCC, or the JSC or any other Joint Committee. The Alliance Managers shall be allowed to attend, as a non-voting observer, meetings of the Joint Committees and the CCC, as well as any subcommittee or working group established by a Joint Committee of which the Alliance Manager is not a member.

**2.10 Decision-Making Limitations.** Notwithstanding anything to the contrary in this Agreement, to the extent that a Party has final decision-making authority with respect to any matter pursuant to Section 2.1(c), such Party shall not exercise such final decision-making authority to: (a) expand or reduce either Party's rights or obligations in a manner inconsistent with the terms and conditions of this Agreement or any Ancillary Agreement; (b) determine that such Party has fulfilled its obligations, or the other Party has breached its obligations, under this Agreement or any Ancillary Agreement (including regarding MacroGenics' performance with respect to the Manufacture and supply of the Licensed Compound); (c) make any decision that is expressly stated to require the other Party's approval or agreement or the approval or agreement of both Parties under this Agreement or any Ancillary Agreement; (d) make any decision for which the other Party has expressly been given final decision-making authority under this Agreement; (e) resolve any dispute regarding whether a Milestone has been achieved or the amount of any royalties or other payments owed by one Party to the other Party; (f) hold significantly more Joint Committee meetings at such Party's facility than the other Party's facility; (g) cause either Party to violate Applicable Law, regulatory requirements or guidance or industry codes; or (h) establish the [\*\*] required for the achievement of Proof of Concept in a [\*\*] or [\*\*] of a [\*\*]. If the Parties fail to mutually agree to the [\*\*] described in (h), then such matter will be submitted to an independent Third-Party expert (mutually agreed upon by both Parties) to establish [\*\*] based on an analysis of available or published data from all of the Approved PD-1 Antibodies, subject to the following parameters: (A) the [\*\*] shall be consistent with the applicable [\*\*] for which Approved PD-1

Antibodies have received Regulatory Approval as a Monotherapy Regimen, as derived from an assessment of monotherapy [\*\*] of Approved PD-1 Antibodies (as of the date on which the applicable Clinical Study data is being assessed with respect to Proof of Concept) observed in comparable patient populations and Indications; and (B) the [\*\*] shall be based on the Licensed Product as a single agent based on the treatment of at least [\*\*] in a specific Indication at a defined dose and schedule that does not exceed the maximum tolerated dose of the applicable Licensed Product. For clarity, the foregoing parameters apply only to the decision of the Third-Party expert, and the JDC may mutually agree to an [\*\*] or [\*\*] that falls outside of such parameters. Provided that the decision of such expert falls within the foregoing parameters, such decision will be conclusive and binding on the Parties, except in the case of fraud or manifest error. The Parties shall equally share the costs and expenses of such expert.

### **ARTICLE 3 LICENSES**

**3.1 License to Incyte.** Subject to the terms and conditions of this Agreement, MacroGenics hereby grants to Incyte: (a) an exclusive (subject to Section 3.3(a)), non-transferable (except in accordance with Section 15.4) license, with the right to grant sublicenses as provided in Section 3.2, under the Licensed Technology, to use, have used, Develop, have Developed, Manufacture or have Manufactured, the Licensed Compound and Licensed Products in the Field in the Territory, including as a Monotherapy Regimen or a component of an Incyte Combination Regimen, Collaborator Combination Regimen, or MacroGenics Combination Regimen (but for, clarity, not to use, have used, Develop, have Developed, Manufacture or have Manufactured, any MacroGenics Pipeline Asset, nor to conduct or have conducted any MacroGenics Combination Studies); (b) an exclusive, non-transferable (except in accordance with Section 15.4) license, with the right to grant sublicenses as provided in Section 3.2, under the Licensed Technology, to Commercialize or have Commercialized the Licensed Compound and Licensed Products in the Field in the Territory, including as a Monotherapy Regimen or a component of an Incyte Combination Regimen or Collaborator Combination Regimen (but, for clarity, not as a component of any MacroGenics Combination Regimen); (c) an exclusive, non-transferable (except in accordance with Section 15.4) license, with the right to grant sublicenses as provided in Section 3.2, under the (x) Licensed Technology and (y) Label Combination Patents, to Commercialize or have Commercialized the Licensed Compound and Licensed Products in the Field in the Territory as a component of a MacroGenics Combination Regimen in accordance with its approved label, provided that Incyte shall have no right to conduct any Medical Affairs Activities or activities directed to marketing, detailing, promoting, educating or any Phase IV Studies with respect to the Licensed Compound or Licensed Products as a component of a MacroGenics Combination Regimen other than MacroGenics Combination Regimen Detailing; (d) a co-exclusive (with MacroGenics), non-transferable (except in accordance with Section 15.4) license, with the right to grant sublicenses as provided in Section 3.2, under the (x) Licensed Technology and (y) Label Combination Patents, to obtain Regulatory Approval of the Licensed Compound as a component of MacroGenics Combination Regimens and include such Regulatory Approval in the Licensed Compound label; and (e) a co-exclusive (with MacroGenics), non-transferable (except in accordance with Section 15.4) license, with the right to grant sublicenses as provided in Section 3.2, under the Licensed Technology, to conduct or have conducted (by Third Party contractors, licensees or other research or Development Partners, as applicable) preclinical and nonclinical

studies with the Licensed Compound and Licensed Product solely for research and development purposes.

**3.2 Sublicensing.**

- (a) Incyte shall have the right to grant sublicenses of the rights granted to Incyte under Sections 3.1 and 3.4 to: (i) its Affiliates through multiple tiers; and (ii) Third Parties through multiple tiers, subject to the conditions in this subsection (a). Incyte may, in its discretion, grant any such sublicense to a Collaborator (pursuant to subsection (b)) and to any bona fide Development Partners, commercial partners and distributors. Each sublicense shall refer to this Agreement and, except to the extent MacroGenics may otherwise agree in writing, be consistent in all material respects with the terms and conditions of this Agreement. Incyte shall remain responsible for the performance of its obligations under this Agreement and the performance of its sublicensees hereunder. Incyte shall provide to MacroGenics copies of all such sublicenses to Third Parties (whether granted directly by Incyte or by a Third Party which previously received a sublicense directly or indirectly from Incyte) within [\*\*] after the execution date of each sublicense; provided that Incyte shall have the right to redact commercially sensitive information from such copies, and provided further that Incyte shall provide financial terms to the extent reasonably necessary for MacroGenics to calculate amounts due to MacroGenics hereunder (including Monotherapy Sublicense Fees and Collaborator Sublicense Fees). Information regarding the scope of the license grants, territory or term of each such sublicense shall not be considered commercially sensitive.
- (b) Incyte shall require that each Collaborator agrees in writing to the all terms applicable to a Collaborator or Combination Sponsor under this Agreement, in addition to the following terms, all of which shall be set forth in a written agreement executed by Incyte and such Collaborator (the “**Collaborator Contract**”): (i) Collaborator or Incyte shall bear all costs and expenses associated with the conduct of any Collaborator Combination Studies (other than any Funded Collaborator Combination Studies); (ii) Collaborator shall not have any input or decision-making authority with respect to any governance matters related to the Licensed Compound or any Licensed Products under this Agreement; (iii) Collaborator shall provide to Incyte all data Controlled by Collaborator, derived from the conduct of any Collaborator Combination Studies as set forth in Section 5.2(b); (iv) irrespective of inventorship, Collaborator and Incyte shall jointly own any Invention that relates specifically to the Licensed Compound or any Licensed Product and results from the conduct of any Collaborator Combination Studies, together with any intellectual property rights therein (collectively, “**Collaborator Development IP**”) and, to the extent necessary to effectuate the foregoing, each of Incyte and the Collaborator, on behalf of itself and its Affiliates, shall agree to assign, and shall hereby assign, to the other party an undivided joint ownership interest in and to the Collaborator Development IP. Each party shall have the right to practice, Exploit and license, and assign or transfer its rights in, any Collaborator Development IP without a duty of accounting to the other party, and each party, on behalf of itself and its Affiliates,

shall hereby waive any right it or its Affiliates may have under Applicable Laws of any jurisdiction to require any such approval or accounting; (v) Collaborator shall be subject to oversight and review and/or approval rights by Incyte with respect to the Development of Collaborator Combination Regimens, in each case, that are no less stringent than the oversight and, review and/or approval rights applicable to the Development of MacroGenics Combination Regimens under this Agreement; and (vi) Incyte shall require that each Collaborator Contract be assignable upon termination of this Agreement at least in those instances where assignment is required pursuant to Section 12.8.

- (c) MacroGenics shall have the right, in its sole discretion, to grant sublicenses of any of the rights granted to MacroGenics under Section 3.4 solely in accordance with Section 3.3(b) and subject to the remainder of this subsection (c). Each sublicense shall refer to and be subordinate to this Agreement and, except to the extent the Parties may otherwise agree in writing, any sublicense must be consistent in all material respects with the terms and conditions of this Agreement. MacroGenics shall remain fully responsible for the performance of its obligations under this Agreement and the performance of its sublicensees hereunder. MacroGenics shall provide to Incyte copies of all such sublicenses to Third Parties within [\*\*] after the execution date of each sublicense; provided that MacroGenics shall have the right to redact commercially sensitive information from such copies. Information regarding the scope of the license grants, territory or term of each such sublicense shall not be considered commercially sensitive. MacroGenics shall not have the right, and shall not, without the prior written approval of Incyte ([\*\*]) (which approval shall not be unreasonably withheld, conditioned or delayed), grant any sublicenses or allow any Third Party to exercise on behalf of MacroGenics any of the rights to be sublicensed to MacroGenics hereunder with respect to the [\*\*] or [\*\*]. Promptly after the Effective Date, the Parties will meet to discuss and agree upon the conditions under which MacroGenics may, without the need to obtain Incyte's prior written approval, grant sublicenses or otherwise allow Third Parties to exercise on behalf of MacroGenics any of the rights to be sublicensed to MacroGenics hereunder with respect to the [\*\*] (the "[\*\*] **Conditions** ") or [\*\*] (the "[\*\*] **Conditions** "); provided that, each of the [\*\*] Conditions and the [\*\*] Conditions shall not be [\*\*] required under the [\*\*]. (i) Promptly after execution of the [\*\*] and [\*\*] as described in Section [\*\*], Incyte shall provide a [\*\*] of the [\*\*] which Incyte [\*\*] to MacroGenics, reasonably sufficient to [\*\*] the [\*\*]. Within [\*\*] following MacroGenics' receipt of such [\*\*], MacroGenics shall notify Incyte whether MacroGenics [\*\*] to [\*\*] under the [\*\*] and/or the right to [\*\*] or [\*\*] under the [\*\*] (the "[\*\*]"). MacroGenics may [\*\*] the [\*\*] on a [\*\*], subject to [\*\*] Conditions or the prior written agreement of Incyte in each instance. (ii) Promptly after execution of each [\*\*] between Incyte and [\*\*] as described in [\*\*], Incyte shall provide a [\*\*] of the [\*\*] under which Incyte [\*\*] to MacroGenics, reasonably sufficient to confirm the [\*\*]. Within [\*\*] following MacroGenics' receipt of such redacted [\*\*], MacroGenics shall notify Incyte whether MacroGenics [\*\*] under the [\*\*] and/or the [\*\*] or [\*\*] under the [\*\*] (the "[\*\*]").

MacroGenics may [\*\*] the [\*\*] on a [\*\*], subject to satisfaction of the [\*\*] Conditions or the [\*\*] of Incyte in each instance.

**3.3 Retained Rights**

**(a) General**

**(i) Retained Exclusive Rights** . Notwithstanding anything to the contrary herein, MacroGenics shall retain the exclusive right: (A) to conduct or have conducted (by Third Party subcontractors or licensees in accordance with Section 1.94, as applicable) the MacroGenics Combination Studies; and (B) subject to Section 3.1(a), to Exploit any MacroGenics Pipeline Asset, including as a component of a MacroGenics Combination Regimen.

**(ii) Other Retained Rights** . MacroGenics shall retain, subject to the terms and conditions of this Agreement: (A) the co-exclusive (with Incyte) right to conduct or have conducted (by Third Party contractors, licensees or other research or Development Partners, as applicable) preclinical and nonclinical studies with the Licensed Compound and Licensed Product solely for research and development purposes; (B) the non-exclusive right to conduct or have conducted (by Third Party contractors, licensees in accordance with Section 1.94 or other research or Development Partners, as applicable) the Ongoing Clinical Study prior to completion of the Study Transition in accordance with the Study Transition Plan; and (C) the non-exclusive, non-transferable right to (x) Manufacture the Licensed Compound Bulk Drug Substance and (y) Manufacture or have Manufactured the Licensed Compound Drug Product.

**(b) Sublicensing Rights** . MacroGenics shall have the right to grant licenses or sublicenses (as applicable) of the rights retained by or granted to MacroGenics under Sections 3.3 and 3.4, subject only to the following (and, as applicable, Section 3.2(c)). In the case of Section 3.3(a)(i)(A), such license or sublicense (as applicable) shall be solely to those Third Parties referenced in 3.3(a)(i)(A), and shall be solely for the purposes of either (i) Developing a MacroGenics Pipeline Asset as a component of a MacroGenics Combination Regimen or (ii) Commercializing a MacroGenics Pipeline Asset as a component of a MacroGenics Combination Regimen in accordance with its approved label (but, for clarity, the retained rights and such licenses or sublicenses shall not include the right to Develop or Commercialize the Licensed Compound or any Monotherapy Regimen, Incyte Pipeline Asset or Collaborator Pipeline Asset). In the case of Section 3.3(a)(ii)(C)(x), individual elements of the Manufacturing Process may be performed by Third Parties on behalf of MacroGenics, provided that MacroGenics shall in any case continue to conduct the majority of Manufacturing-related activities in connection with the Manufacture of the Licensed Compound Bulk Drug Substance, and MacroGenics shall not engage in any Manufacturing Process technology transfer with any such Third Parties other than with respect to the

specific Manufacturing Process to be conducted by such Third Parties and only to the extent reasonably required for such Third Parties to perform such Manufacturing Process.

- (c) Notwithstanding anything to the contrary herein, MacroGenics shall not have any right to, and shall not, (i) Exploit any Combination Product, or (ii) sell, have sold, or distribute Licensed Compound Bulk Drug Substance or Licensed Compound Drug Product other than (x) for use in those activities described in Section 3.3(a), or (y) to Incyte for use in the Development activities or the Manufacture of the Licensed Product. Furthermore, notwithstanding anything to the contrary herein, MacroGenics shall not have any right to, and shall not, directly or indirectly, conduct or perform, nor contract with any Third Party to conduct or perform (A) any Clinical Study of an Incyte Combination Regimen or any Collaborator Combination Regimen, nor (B) any other Clinical Study that includes the Licensed Compound and any other specific molecule or molecules (as monotherapies or combinations) other than a MacroGenics Combination Study (or a Monotherapy Study pursuant to Section 5.9(c)). In the event that MacroGenics enters into any collaboration or analogous relationship with respect to the Licensed Compound involving a Third Party collaborator who owns or Controls an Ancillary Therapy that is being studied in connection with a MacroGenics Combination Regimen, (x) MacroGenics shall provide to Incyte all data Controlled by MacroGenics derived from any arm of the Clinical Study that solely comprises both the Licensed Compound and the Ancillary Therapy, and (y) MacroGenics shall grant and hereby grants to Incyte a non-exclusive, irrevocable, perpetual, transferable, fully paid-up, royalty-free, sublicenseable license under any Information or any intellectual property Controlled by MacroGenics arising out of any arm of the Clinical Study that solely comprises both the Licensed Compound and the Ancillary Therapy for any use consistent with the license granted pursuant to Section 3.4(a), in each case (of (x) and (y)) to the extent that MacroGenics has the contractual right to extend such rights, licenses, or sublicenses to Incyte, as applicable (and MacroGenics shall use Commercially Reasonable Efforts to obtain such contractual rights from the applicable Third Party collaborator). Any such Clinical Study shall otherwise be subject to all of the requirements and limitations set forth herein with respect to MacroGenics Combination Studies (e.g., the obligations and limitations set forth in Section 4.3 and Article 5). MacroGenics shall be responsible for any failure of the Third Party collaborator to comply with the obligations set forth in Section 3.3(b) and in this Section 3.3(c).

#### **3.4 Freedom to Operate Licenses**

- (a) Subject to the terms and conditions of this Agreement and without limiting the license granted pursuant to Section 3.1, MacroGenics hereby grants to Incyte a non-exclusive, worldwide, fully-paid, royalty-free, non-transferable (except in accordance with Section 15.4) license, with the right to grant sublicenses to the extent provided in Section 3.2(a) and 3.2(b), under (i) any Patents Controlled by MacroGenics or, subject to Section 15.3(d), its Affiliates as of the Effective Date

or during the Term, including MacroGenics' interest in any Joint Patents that Cover the Exploitation of PD-1 Monoclonal Antibodies (the “ **MacroGenics PD-1 IP** ”) except that such license shall not extend to any claims in any Patents Controlled by MacroGenics that Cover a (x) MacroGenics Pipeline Asset, (y) Incyte Pipeline Asset or (z) MacroGenics Combination Regimen, unless such claims are necessary for Incyte to exercise the license granted pursuant to Section 3.1; and (ii) any other Patents or Know-How Controlled by MacroGenics or, subject to Section 15.3(d), its Affiliates, as of the Effective Date or during the Term, including MacroGenics' interest in any such Joint Patents that Cover or are embodied in any *in vitro* device or other companion diagnostic used to detect, identify and/or diagnose the presence of PD-1 or PD-L1 for the Exploitation of the Licensed Compound or Licensed Products (the “ **MacroGenics CDx IP** ”), in each case (of (i)-(ii)) to Exploit the Licensed Compound and Licensed Products in the Field in the Territory, including as a Monotherapy Regimen or a component of an Incyte Combination Regimen, Collaborator Combination Regimen or, solely to the extent permitted under Section 3.1, MacroGenics Combination Regimens (but, for clarity, not to Exploit any MacroGenics Pipeline Asset). Notwithstanding anything to the contrary herein, to the extent of any overlap between the license grants under this Section 3.4(a) and the license grant under Section 3.1, any payment obligations of Incyte in connection with the license grant under Section 3.1 shall remain unaffected and shall continue in full force and effect. For clarity, this Section 3.4(a) shall not be construed to limit the rights granted to Incyte under Section 3.1 to Exploit the Licensed Compound as a component of an Incyte Combination Regimen.

- (b) Subject to the terms and conditions of this Agreement, Incyte hereby grants to MacroGenics a non-exclusive, worldwide, fully-paid, royalty-free, non-transferable (except in accordance with Section 15.4) license, with the right to grant sublicenses to the extent provided in Section 3.2(c) and Section 3.3(b), under (i) any Patents Controlled by Incyte or its Affiliates, as of the Effective Date or, subject to Section 15.3(d), during the Term, that Cover the manufacture of the Licensed Compound, including Incyte's interest in any such Joint Patents (the “ **Incyte PD-1 IP** ”) except that such license shall not extend to any claims in any Patents Controlled by Incyte that claim an Incyte Pipeline Asset or Incyte Combination Regimen, (ii) Incyte Development IP Controlled by Incyte or its Affiliates that relates specifically to the Licensed Compound (and not, for clarity, to any Combination Regimen or Pipeline Asset), including Incyte's interest in any such Joint Patents or Joint Inventions, (iii) any other Patents or Know-How Controlled by Incyte or its Affiliates, as of the Effective Date or, subject to Section 15.3(d), during the Term, that Cover or are embodied in any *in vitro* device or other companion diagnostic used to detect, identify and/or diagnose the presence of PD-1 or PD-L1 for the Development or Commercialization of the Licensed Compound or Licensed Products, including Incyte's interest in any such Joint Patents or Joint Inventions (the “ **Incyte CDx IP** ”) and (iv) any other Patents or Know-How Controlled by Incyte or its Affiliates, as of the Effective Date or, subject to Section 15.3(d), during the Term, that relate specifically to the Licensed Compound (and not, for clarity, to any Combination Regimen), including Incyte's interest in any

such Joint Patents or Joint Inventions (such Patents, “ **Incyte Patents** ” and such Know-How, “ **Incyte Know-How** ”; collectively, “ **Incyte Technology** ”), in each case (of (i)-(iv)) solely to Develop and Commercialize any MacroGenics Pipeline Asset as a component of a MacroGenics Combination Regimen in accordance with its approved label (but, for clarity, not to Develop or Commercialize the Licensed Compound or any Monotherapy Regimen, Incyte Pipeline Asset or Collaborator Pipeline Asset).

- (c) MacroGenics shall provide to Incyte reasonable access to MacroGenics CDx IP for the purpose of Incyte’s performance of the Incyte Global Development Plan. Incyte shall provide to MacroGenics reasonable access to Incyte CDx IP for the purpose of MacroGenics’ performance of the MacroGenics Global Development Plan.
- (d) (i) Subject to the terms and conditions of this Agreement, Incyte hereby grants to MacroGenics a non-exclusive, worldwide, fully-paid, royalty-free license, non-transferable (except in accordance with Section 15.4) license, with the right to grant sublicenses to the extent provided in Section 3.2(c) and Section 3.3(b), to any Incyte Method Claims under any Patent Controlled by Incyte or (subject to Section 15.3(d)) its Affiliates as of the Effective Date or during the Term, as necessary to Commercialize the MacroGenics Pipeline Asset in combination with the Licensed Compound or Licensed Product in accordance with the approved label of the applicable MacroGenics Combination Regimen. As used herein, an “ **Incyte Method Claim** ” shall mean any claim that claims the method of using the Combination of the Licensed Compound or Licensed Product with a MacroGenics Pipeline Asset for the treatment of cancer in the Territory, excluding claims: (A) for which Incyte does not have the contractual right to grant the license under this Section 3.4(d)(i); (B) that arise from an Incyte Pipeline Asset disclosed in the Incyte Global Development Plan under Exhibit B-1, as of the Effective Date; or (C) that read on or include as an element a Cancer Treatment Use.
- (ii) Subject to the terms and conditions of this Agreement and without limiting the license granted pursuant to Section 3.1, MacroGenics hereby grants to Incyte a non-exclusive, worldwide, fully-paid, royalty-free, non-transferable (except in accordance with Section 15.4) license, with the right to grant sublicenses to the extent provided in Section 3.2(a) and 3.2(b), to any MacroGenics Method Claims under any Patent Controlled by MacroGenics or (subject to Section 15.3(d)) its Affiliates as of the Effective Date or during the Term, as necessary to Commercialize the Licensed Compound or Licensed Product in combination with the Incyte Pipeline Asset in accordance with the approved label of the applicable Incyte Combination Regimen. As used herein, a “ **MacroGenics Method Claim** ” shall mean any claim that claims the method of using the Combination of the Licensed Compound or Licensed Product with an Incyte Pipeline Asset for the treatment of cancer in the Territory, excluding claims: (A) for which MacroGenics does not have the contractual right to grant the license under this Section 3.4(d)(ii); (B) that arise from a MacroGenics Pipeline Asset disclosed in the MacroGenics

Global Development Plan under Exhibit B-2, as of the Effective Date; or (C) that read on or include as an element a Cancer Treatment Use.

**3.5 No Implied Licenses**. All licenses and rights are granted only as expressly provided in this Agreement and no license or other right is or shall be created or granted under this Agreement by implication, estoppel, or otherwise. All rights not expressly granted by a Party under this Agreement are reserved by such Party and may not be used by the other Party for any purpose.

#### **ARTICLE 4 DEVELOPMENT**

##### **4.1 Transition of Ongoing Clinical Study**

- (a) **Ongoing Clinical Study**. During the period beginning on the Effective Date and ending on the Study Transition Date, MacroGenics shall use Commercially Reasonable Efforts to: (i) perform any Development activities assigned to MacroGenics in the Study Transition Plan; and (ii) subject to subsection (d) below, conduct (or have conducted by an Affiliate or Third-Party contract research organization) the ongoing Clinical Study of the Licensed Compound and all related Development activities that are identified (together with an estimate of the costs thereof through [\*\*]) on Exhibit E (collectively, the “**Ongoing Clinical Study**”).
- (b) **IND Transition**. Within [\*\*] after the Effective Date, or such other period defined by the JDC, but in any event no later than [\*\*] (the “**IND Transition Date**”), MacroGenics shall transfer to Incyte, and Incyte shall cooperate in good faith to support MacroGenics’ transfer of, all INDs for the Licensed Compound (the “**MGA012 IND**”), in accordance with a transition plan to be approved by the JDC promptly after the Effective Date (the “**IND Transition**”; such transition plan, the “**IND Transition Plan**”). Each Party shall bear all costs and expenses incurred by such Party in connection with the IND Transition. Upon the completion of the IND Transition, Incyte shall be solely responsible, at its sole cost and expense, for all filings, reports and communications with all Regulatory Authorities, with respect to the Licensed Products. Upon completion of the IND Transition, MacroGenics shall, and hereby does, assign to Incyte all such Regulatory Documentation and shall take all steps reasonably necessary to effectuate the assignment of all INDs, Regulatory Approval Applications and Regulatory Approvals included in such Regulatory Documentation to Incyte.
- (c) **Study Transition**. MacroGenics and Incyte shall jointly cooperate to complete the transfer to Incyte of the Ongoing Clinical Study, in accordance with a transition plan and budget to be approved by the JDC (the “**Study Transition**”; such transition plan, the “**Study Transition Plan**”), but in any event to be completed no later than [\*\*] (the “**Study Transition Date**”); provided that, MacroGenics may transfer certain responsibilities with respect to the Ongoing Clinical Study prior to the Study Transition Date, as determined by the JDC and set forth in the Study

Transition Plan. At all times during the Term, Incyte shall cooperate in good faith to support MacroGenics' transfer of the Ongoing Clinical Study to Incyte.

- (d) **Decision-Making; Costs** . At all times during the Term, whether prior to or after the IND Transition Date or the Study Transition Date: (i) Incyte shall have final decision-making authority with respect to matters related to the Ongoing Clinical Study (which Incyte shall exercise in good faith); and (ii) Incyte shall bear any and all FTE Costs and Third Party Expenses incurred by MacroGenics following the Effective Date directly related to the Ongoing Clinical Study in accordance with the Study Transition Plan, other than any costs specifically related and allocable to any MacroGenics Combination Regimen. Incyte shall reimburse MacroGenics within [\*\*] after receipt of any undisputed invoice from MacroGenics setting forth such costs.

#### **4.2 Incyte Development Responsibilities**

(a) **General** .

- (i) Following the Study Transition Date, subject to Sections 2.2, 3.3, and 4.1, Incyte shall, at its sole cost and expense, be solely responsible for and have sole authority over: (a) the Development of the Monotherapy Regimen in the Field in the Territory (other than pursuant to Section 5.9(c)); and (b) the Development of Incyte Combination Regimens and Collaborator Combination Regimens in the Field in the Territory, and will retain final decision-making authority with respect to each of the foregoing. Notwithstanding the foregoing, MacroGenics will continue to perform Manufacturing Development work as determined by the JMC with respect to the Licensed Compound following the Study Transition Date, and with respect to any such Manufacturing Development that relates [\*\*] to the Licensed Compound, Incyte shall pay any and all such costs to the extent required pursuant to subsection (ii) below, and will retain final decision-making authority with respect to such Manufacturing Development.
- (ii) Incyte shall bear any and all costs and expenses incurred in connection with: (a) any Development activities that relate to the Monotherapy Regimen (other than any costs and expenses associated (i) with any monotherapy arms that are included in any MacroGenics Combination Study or (ii) Monotherapy Studies conducted pursuant to Section 5.9(c)) or any Incyte Combination Regimens and Collaborator Combination Regimens, including the Development activities set forth in this Section 4.2; and (b) any Development activities that are needed to pursue Regulatory Approval of the Monotherapy Regimen (other than pursuant to Section 5.9(c)) or any Incyte Combination Regimens. For clarity, except as set forth in Section 4.1 and in clause (i) above, (x) MacroGenics shall have no obligation to perform any Development activities that relate to the Monotherapy Regimen or any Incyte Combination Regimens and Collaborator Combination Regimens

and (y) Incyte shall not be responsible for, and MacroGenics shall bear, any and all costs and expenses related to the conduct of (A) any MacroGenics Combination Studies or (B) other Development activities expressly required to be conducted by MacroGenics with respect to the Licensed Compound for which the Agreement does not specify that Incyte shall reimburse MacroGenics for such Development expenses.

- (b) **Clinical Study Registries** . Incyte shall be responsible, in accordance with Applicable Law, for registering in the appropriate clinical trial registry and posting the results of all Clinical Studies of the Monotherapy Regimen (other than pursuant to Section 5.9(c)) and Incyte Combination Regimens in the Field in the Territory. With respect to Clinical Studies of Collaborator Combination Regimens in the Field in the Territory, either Incyte or Collaborator shall be responsible (as set forth in the applicable Collaborator Contract), in accordance with Applicable Law, for registering in the appropriate clinical trial registry and posting the results of such Clinical Studies.
- (c) **Documentation** . Incyte shall prepare and maintain, or shall cause to be prepared and maintained, complete and accurate written records, accounts, notes, reports and data with respect to Development activities conducted by Incyte pursuant to this Agreement (including the Incyte Global Development Plan) in good scientific manner and in conformity with Applicable Law and Incyte's standard practices, provided that, in no case shall such records be maintained for less than [\*\*] following the Calendar Year to which such records pertain (or any longer period required by Applicable Law).
- (d) **Progress Reports** . No later than [\*\*] and [\*\*] of each Calendar Year, Incyte shall provide to MacroGenics in writing (PowerPoint presentations are acceptable) a report summarizing Incyte's efforts and progress during the [\*\*] prior to such date, as applicable, to Develop and seek Regulatory Approval of the Licensed Compound and any Licensed Products. Each such report shall describe, among other matters: (a) material Development activities completed since the last report, including the object and parameters of the Development, when initiated and when completed; (b) a summary of all material results of any Monotherapy Studies or Monotherapy Regimens; (c) material Development activities planned to be undertaken before the next report, including the type and object of any Clinical Studies to be conducted and their projected starting and completion dates; (d) a summary of all material updates or developments with respect to the Manufacturing Process since the date of the last report; and (e) material changes in Incyte's Development plans; provided, however, that (i) Incyte shall not be required to include in such reports any (A) information relating solely to the Incyte Pipeline Assets or (B) other confidential information related to the Incyte Pipeline Assets or Incyte Combination Regimens, in each case as reasonably determined by Incyte in its sole discretion; (ii) Incyte shall not be required to provide such a report for any Calendar Quarter in which it provided an update to the Incyte Global Development Plan pursuant to Section 4.4(a); and (iii) Incyte shall not be required to provide such a report for any

Calendar Quarter in which it provided materially similar information to any Joint Committee. In addition, Incyte shall promptly respond to reasonable requests by MacroGenics for information regarding Incyte's Development and Commercialization activities for the Licensed Compound and Licensed Products, to the extent such information is necessary to assess Incyte's compliance with its obligations hereunder.

**(e) Performance .**

**(i)** With respect to the performance of any Incyte Combination Study or Collaborator Combination Study hereunder, Incyte shall (and shall require that Collaborator shall, with respect to any Collaborator Combination Studies): (a) perform the Combination Study in accordance with this Agreement and all Applicable Law, including GCP; (b) obtain all approvals and clearances necessary to conduct each Combination Study, including obtaining customs clearances and approvals from Regulatory Authorities, institutional review boards and ethics committees; (c) ensure that all consents required under Applicable Law in connection with such Combination Study have been obtained prior to commencing any Combination Study; and (d) not employ or subcontract with any Person or Third Party that has been debarred by the FDA, is the subject of a conviction described in Section 306 of the FFDCRA or is subject to any similar sanction of other Governmental Authorities in the Territory, and promptly remove any such Person or Third Party from performing any activities related to any Combination Study.

**(ii)** Incyte shall require that Collaborators shall perform all Collaborator Combination Studies in accordance with the applicable Collaborator Contract and all applicable terms and conditions of this Agreement. For the avoidance of doubt, Incyte, as the Controlling Party, shall be responsible for the failure of a Collaborator to fulfill any obligation owed to MacroGenics pursuant to this Agreement in connection with any Collaborator Combination Studies, Collaborator Pipeline Assets or any Collaborator Combination Regimen, including any regulatory or other requirements related thereto, irrespective of which party performs the relevant obligation or to whom the relevant obligation is addressed.

**(f) Diligence .** Incyte shall use Commercially Reasonable Efforts to: (i) complete the Ongoing Clinical Study as described in Exhibit E, subject to amendments to the protocol therefor and to corresponding portions of the Incyte Global Development Plan by Incyte in the exercise of its reasonable business judgment and (ii) Develop the Monotherapy Regimen and one (1) or more Incyte Combination Regimens.

**4.3 MacroGenics Development Responsibilities**

(a) **General** . MacroGenics shall, at its sole cost and expense, have the sole right to conduct, or have conducted, MacroGenics Combination Studies and shall retain final decision-making authority with respect thereto, subject to the remainder of this Section 4.3. Notwithstanding anything to the contrary in this Section 4.3, the protocol synopses for the MacroGenics Combination Studies in Exhibit B-2 have been reviewed and pre-approved by Incyte prior to the Execution Date. Accordingly, Incyte will not have any further right to review, approve or object to the design or conduct of any such studies, unless the components outlined in the protocol synopsis reviewed by Incyte are materially different from the corresponding components in the protocol prior to its first submission to a Regulatory Authority, in which case Incyte shall be given a subsequent opportunity and right to review, comment on and object to the updated protocol synopsis before such submission.

(b) **MacroGenics Combination Studies** .

(i) For a period of [\*\*] following the Effective Date, MacroGenics shall provide to Incyte, through the JDC, a protocol synopsis (in a consistent format as included in Exhibit B-2) for each MacroGenics Combination Study (but for clarity, excluding any Phase IV Studies) proposed to be conducted by or on behalf of MacroGenics (which synopsis may be redacted by MacroGenics with respect to any MacroGenics Pipeline Asset Information), and:

(1) Without limiting Section 4.3(c), Incyte shall have the right to object to the design or conduct of such MacroGenics Combination Study in the event that Incyte [\*\*] that [\*\*] could [\*\*] to its [\*\*] ([\*\*], a “[\*\*]”; an objection pursuant to this Section 4.3(b)(i)(1), an “**Incyte [\*\*] Objection** ”), provided that, any such Incyte [\*\*] Objection: (A) specifically identifies, in reasonable detail, the potential [\*\*] such proposed MacroGenics Combination Study may pose; and (B) is provided in writing to MacroGenics within [\*\*] following the provision of the protocol synopsis to the JDC. MacroGenics may proceed with any such MacroGenics Combination Study in the event that Incyte does not provide written notice of an Incyte [\*\*] Objection within such [\*\*] period, unless the components outlined in the protocol synopsis reviewed by Incyte are materially different from the corresponding components in the full protocol prior to its first submission to a Regulatory Authority, in which case Incyte shall be given a subsequent opportunity and right to review and comment on an updated protocol synopsis within [\*\*] of receipt of such updated protocol synopsis.

(2) In the event Incyte timely delivers notice of an Incyte [\*\*] Objection to MacroGenics: (A) the Parties shall, within [\*\*] following the delivery of such notice, convene the JDC for the purpose of

discussing the MacroGenics Combination Study, and MacroGenics shall consider in good faith any comments from Incyte related to the design and conduct of such study, with MacroGenics using Commercially Reasonable Efforts to resolve the Incyte [\*\*] Objection, and (B) without the prior written approval of Incyte (not to be unreasonably withheld, conditioned or delayed; provided, however, that withholding, conditioning or delaying such approval based on the continued existence of a [\*\*] shall be deemed not unreasonable), MacroGenics shall not conduct or have conducted such MacroGenics Combination Study.

- (3) In the event of any dispute relating to a matter set forth in this subsection (i), if such dispute remains unresolved after discussion through the JDC and escalation pursuant to Section 2.1(c), MacroGenics shall have final decision-making authority with respect thereto. Notwithstanding anything to the contrary herein, the time period for review of the protocol synopsis, from MacroGenics' first provision of the protocol synopsis to Incyte and any final casting vote in the JDC in the event of a dispute shall never exceed [\*\*].
- (4) For a period ending on the earlier (x) [\*\*] following the Effective Date or (y) achievement of the first Licensed Compound Approval by either the FDA or EMA, after the first submission of any MacroGenics Combination Study protocol to a Regulatory Authority in accordance with Section 4.3(a) and Section 4.3(b), MacroGenics shall provide to Incyte an updated protocol synopsis to reflect any material amendments to the corresponding protocol as may be adopted from time to time, and Incyte shall have the right to review and comment on such amendments.
- (ii) With respect to any MacroGenics Combination Study, but without limiting the rights of Incyte pursuant to Section 4.3(c) with respect to Clinical Studies including a MacroGenics PD-1 Control Arm, MacroGenics shall employ a dosage or schedule of the Licensed Compound that (A) is consistent with a dosage or schedule of the Licensed Compound that has been previously tested in a Phase II Study or Phase III Study, (B) is consistent with a dosage or schedule previously recommended or required by a Regulatory Authority, or (C) has not been previously tested in any Clinical Study and is reasonably expected by the JDC not to pose any [\*\*]. In the event of any dispute relating to a matter set forth in this subsection (ii), if such dispute remains unresolved after discussion through the JDC and escalation pursuant to Section 2.1(c), MacroGenics shall have final decision-making authority with respect thereto; provided that, the time period from the start of such dispute to its resolution shall never exceed [\*\*].

- (c) **MacroGenics Combination Studies that Include a MacroGenics PD-1 Control Arm** . Without limiting Incyte’s rights under Section 4.3(b), commencing on the Effective Date and lasting until achievement of the Licensed Compound Approval by either the FDA or EMA, MacroGenics shall provide to Incyte, through the JDC, (i) a copy of the detailed full protocol of each Clinical Study that includes a MacroGenics PD-1 Control Arm planned to be conducted by or on behalf of MacroGenics (which protocol may be redacted by MacroGenics with respect to any MacroGenics Pipeline Asset Information), and (ii) a written statement explaining why such Clinical Study design is likely to be required or recommended by a Core Regulatory Authority in order to achieve Regulatory Approval of the applicable MacroGenics Combination Regimen:
- (i) Incyte shall have the right to reasonably object to the conduct of such Clinical Study that includes a MacroGenics PD-1 Control Arm, in the event that Incyte provides notice of such objection in writing to MacroGenics within [\*\*] following the provision of the detailed full protocol to the JDC (the “ **Incyte Objection** ”). Subject to the provisions of Section 4.3(b), MacroGenics may proceed with any such study in the event that Incyte does not provide written notice of an Incyte Objection within such [\*\*] period.
  - (ii) In the event Incyte timely delivers notice of an Incyte Objection to MacroGenics, the Parties shall, within [\*\*] following the delivery of such notice, convene the JDC for the purpose of discussing the basis of the Incyte Objection. To the extent applicable, Incyte shall inform MacroGenics [\*\*] that such MacroGenics PD-1 Control Arm is reasonably expected to [\*\*] the [\*\*] of the Licensed Compound (a “[\*\*]”).
  - (iii) If MacroGenics reasonably believes that the completion of the proposed MacroGenics PD-1 Control Arm will be required or recommended by a Core Regulatory Authority in order to achieve Regulatory Approval of a MacroGenics Combination Regimen, MacroGenics shall notify Incyte (via the JDC), and the Parties shall discuss in good faith whether reasonable modifications to the study protocol can be made or if alternative strategies can be employed (e.g., Incyte providing necessary components of care data to MacroGenics for submission to the applicable Regulatory Authority) in order to address the Incyte Objection or in order to avoid the necessity for the MacroGenics PD-1 Control Arm. MacroGenics shall reasonably incorporate into its protocol any modifications mutually agreed upon by the Parties.
  - (iv) If, following the procedures described in subsections (ii) and (iii) above, MacroGenics reasonably continues to believe that the completion of the proposed MacroGenics PD-1 Control Arm will be required in order to achieve Regulatory Approval of a MacroGenics Combination Regimen, MacroGenics shall have the right to proceed with the conduct of such proposed Clinical Study.

- (v) MacroGenics shall not conduct any Clinical Study that includes both the Licensed Compound and an anti-PD-1/PD-L1 Monoclonal Antibody owned or Controlled by MacroGenics (or any Acquirer of MacroGenics or its or their Affiliates), and MacroGenics shall not enable any Third Party to conduct any such study.
- (d) **Clinical Study Registries** . For all Clinical Studies of MacroGenics Combination Regimens in the Field in the Territory, MacroGenics shall be responsible, in accordance with Applicable Law, for registering in and maintaining the appropriate clinical trial registry and posting the results of such Clinical Studies.
- (e) **Documentation** . MacroGenics shall prepare and maintain, or shall cause to be prepared and maintained, complete and accurate written records, accounts, notes, reports, data and all related documentation pertaining to each MacroGenics Combination Study in good scientific manner and in compliance with Applicable Law and MacroGenics' standard practices; provided that in no case shall such records be maintained for less than [\*\*] following the Calendar Year to which such records pertain (or any longer period required by Applicable Law).
- (f) **Progress Reports** . No later than [\*\*] and [\*\*] of each Calendar Year, MacroGenics shall provide to Incyte in writing a report (PowerPoint presentations are acceptable) detailing MacroGenics' efforts and progress during the [\*\*] prior to such date, as applicable, to Develop and seek Regulatory Approval of any MacroGenics Combination Regimen and to conduct other research and Development activities with respect to the Licensed Compound pursuant to Section 3.3(a). Each such report shall describe, among other matters: (i) material Development activities completed since the last report, including the object and parameters of the Development, when initiated, when completed and, for a period of [\*\*] following the Effective Date, a summary of all material results (provided, however, that MacroGenics shall not be required to include in such summary of material results any MacroGenics Pipeline Asset Information, as reasonably determined by MacroGenics in its sole discretion); (ii) material Development activities planned to be undertaken before the next report, including the type and object of any MacroGenics Combination Studies to be conducted and their projected starting and completion dates; (iii) a summary of all material updates or developments with respect to the Manufacturing Process since the date of the last report; and (iv) material changes in MacroGenics' Development plans; provided however, that (x) MacroGenics shall not be required to provide such a report for any Calendar Quarter in which it provided an update to the MacroGenics Global Development Plan pursuant to Section 4.4(b); and (y) MacroGenics shall not be required to provide such a report for any Calendar Quarter in which it provided materially similar information to any Joint Committee. In addition, MacroGenics shall promptly respond to reasonable requests by Incyte for information regarding MacroGenics' Development activities for the MacroGenics Combination Regimen, to the extent such information is necessary to assess MacroGenics' compliance with its obligations hereunder.

- (g) **Performance** . With respect to the performance of any MacroGenics Combination Study, MacroGenics shall: (i) perform the Combination Study in accordance with this Agreement, the applicable protocol and all Applicable Law, including GCP; (ii) obtain all approvals and clearances necessary to conduct each Combination Study, including obtaining customs clearances and approvals from Regulatory Authorities, institutional review boards and ethics committees; (iii) ensure that all consents required under Applicable Law in connection with such Combination Study have been obtained prior to commencing any Combination Study; and (iv) not employ or subcontract with any Person or Third Party that has been debarred by the FDA, is the subject of a conviction described in Section 306 of the FFDCFA or is subject to any similar sanction of other Governmental Authorities in the Territory, and promptly remove any such Person or Third Party from performing any activities related to any Combination Study.

#### **4.4 Global Development Plans**

- (a) **Incyte Global Development Plan** . The Incyte Global Development Plan shall include, among other things: (i) material Development activities reasonably anticipated to be undertaken by Incyte to advance the Development of the Licensed Compound and any Products, including high level summaries of the design for any Clinical Study (which will specify key endpoints, projected dosing and/or scheduling for the Licensed Product, and number of patients expected to be enrolled); (ii) activities to be undertaken by Incyte to further develop the Manufacturing Process; and (iii) estimated timelines regarding the foregoing activities, including estimated timelines associated with the preparation of any material Regulatory Documentation. Incyte shall submit any updates and/or amendments to the then-current Incyte Global Development Plan to the JDC, for the JDC's review pursuant to Section 2.2. Incyte shall update the Incyte Global Development Plan no less frequently than [\*\*] during the Term; provided that, any amended Incyte Global Development Plan shall be consistent with Incyte's diligence obligations set forth in Section 4.2(e), 4.2(f) and 6.1(d). In addition to the [\*\*] update of the Incyte Global Development Plan, the JDC shall review any Incyte updates to the then-current Incyte Global Development Plan. Upon reasonable advance notice, at the request of the JDC, Incyte agrees to make its employees and consultants reasonably available at their respective places of employment to consult with MacroGenics on issues arising in connection with the Incyte Global Development Plan and the MacroGenics Global Development Plan. Notwithstanding anything to the contrary herein, Incyte shall have final decision-making authority on all matters related to Monotherapy Studies or Incyte Combination Studies being conducted by or on behalf of Incyte pursuant to the Incyte Global Development Plan.
- (b) **MacroGenics Global Development Plan** . The MacroGenics Global Development Plan shall include, among other things: (i) all material Development activities reasonably anticipated to be undertaken by MacroGenics to advance the Development of the MacroGenics Combination Regimens, including high level

summaries of (x) the design for any Clinical Study (which will specify key endpoints, projected dosing and/or scheduling for the Licensed Product, and number of patients expected to be enrolled, and (y) other research and Development activities to be conducted by MacroGenics in connection with the Licensed Compound pursuant to Section 3.3(a)); and (ii) estimated timelines regarding the foregoing activities, including estimated timelines associated with the preparation of any material Regulatory Documentation. MacroGenics shall submit any updates and/or amendments to the then-current MacroGenics Global Development Plan to the JDC, for the JDC's review and approval (to the extent required) pursuant to Section 2.2 and Section 4.3, MacroGenics shall update the MacroGenics Global Development Plan no less frequently than [\*\*] during the Term; provided that, any amended MacroGenics Global Development Plan shall be consistent with MacroGenics' obligations set forth in Section 4.1(a) and 4.3(g). In addition to the [\*\*] update of the MacroGenics Global Development Plan, the JDC shall review any MacroGenics updates to the then-current MacroGenics Global Development Plan. Upon reasonable advance notice, at the request of the JDC, MacroGenics agrees to make its employees and consultants reasonably available at their respective places of employment to consult with Incyte on issues arising in connection with the Incyte Global Development Plan and the MacroGenics Global Development Plan. Notwithstanding anything to the contrary herein, but subject to Section 4.3, MacroGenics shall have final decision-making authority on all matters related to MacroGenics Combination Studies being conducted by or on behalf of MacroGenics pursuant to the MacroGenics Global Development Plan.

**4.5 Delegation of Development Activities.** Each Party may delegate the performance of any Development activities conducted in accordance with this Article 4 to any bona fide licensee in accordance with Section 3.2 or Third Party subcontractor, provided that: (a) such licensee or subcontractor has entered or shall enter into, prior to performing activities under this Agreement, an appropriate written agreement (“ **Development Agreement** ”) that shall require, among other things, such licensee or subcontractor to be bound by obligations of confidentiality that are no less restrictive than the obligations set forth in Article 11; (b) such Party shall oversee the performance of any delegated activities in a manner that would be reasonably expected to result in their successful and timely completion; and (c) such Party shall at all times remain responsible for the performance of such delegated activities as if such activities were performed by such Party. In addition, if Incyte is the delegating Party, Incyte shall require that any Development Agreement executed between Incyte and any of its licensees or Third Party subcontractors shall permit the assignment of such agreement, in its entirety, to MacroGenics, upon the termination of this Agreement (other than in connection with Section 12.9), without any objection rights by the applicable licensee or subcontractor. For clarity: (i) MacroGenics may have funded or supported any MacroGenics Combination Studies and related activities pursuant to this Article 4 as investigator-sponsored Clinical Studies or conducted such Clinical Studies in collaboration with any academic institution; and (ii) Incyte may have funded or supported any Monotherapy Studies, Incyte Combination Studies, or related activities pursuant to this Article 4 as investigator-sponsored Clinical Studies or conducted such Clinical Studies in collaboration with any academic institution.

**4.6 Compliance with Law; Other Requirements.**

- (a) Each Party shall (and Incyte shall require that each Collaborator shall) conduct all Development activities related to any Compounds or Products, in good scientific manner and in compliance in all material respects with all Applicable Law, including applicable national and international ( e.g. , ICH, GCP, GLP, and GMP) guidelines.
- (b) With respect to the conduct of a Non-Registrational Study in or including the same Indication subtype and line of therapy (the “ **Indication Population** ”) for which the Licensed Compound has received Regulatory Approval in a country in which the Non-Registrational Study is being conducted, if the Non-Registrational Study [\*\*] (each of which meets the Indication Population criteria) in the Indication Population with the Licensed Product (on an Indication Population-by-Indication Population basis across all Clinical Studies and across all such country(ies) in which Regulatory Approval has been received) (the “[\*\*]”), then, for clinical supply of the Licensed Compound to be administered to Indication Population patients [\*\*] of the [\*\*] in such country(ies):
- (i) where MacroGenics is the Combination Sponsor, MacroGenics shall either (x) obtain such clinical supply from Incyte at [\*\*] of Incyte’s generally-applicable transfer price for commercial supply of the Licensed Compound in the applicable countries, or (y) continue to provide such clinical supply to such Non-Registrational Study and pay to Incyte an amount that results in Incyte receiving the same consideration that Incyte would receive pursuant to clause (x) above net of Incyte’s Manufacturing Expenses for such clinical supply; and
- (ii) In addition to paying MacroGenics its Manufacturing Expenses for such clinical supply under Article 7, where Incyte is the Combination Sponsor, Incyte shall pay to MacroGenics an additional amount equal to [\*\*] of Incyte’s generally-applicable transfer price for commercial supply of the Licensed Compound in the applicable countries.

For clarity, such use of the Licensed Compound under this Section 4.6(b) shall not give rise to any Net Sales.

- (c) Where MacroGenics is the Combination Sponsor, the restrictions in Section 4.6(b) above shall not apply to any Non-Registrational Study in an Indication Population to the extent MacroGenics achieved Regulatory Approval of a MacroGenics Combination Regimen in such Indication Population before Incyte, its Affiliates, or sublicensees (including Collaborators) achieved Regulatory Approval of a Licensed Product in such Indication Population. Where Incyte is the Combination Sponsor or conducting a Monotherapy Study, the restrictions in Section 4.6(b) above shall only apply to Non-Registrational Studies in an Indication Population to the extent MacroGenics achieved Regulatory Approval of a MacroGenics

Combination Regimen in such Indication Population before Incyte, its Affiliates, or sublicensees (including Collaborators) achieved Regulatory Approval of a Licensed Product in such Indication Population (and, for clarity, only when such Non-Registrational Studies otherwise meet the criteria set forth in the introductory paragraph to Section 4.6(b)).

**ARTICLE 5  
REGULATORY RESPONSIBILITIES**

**5.1 Data Sharing: Licensed Compound.**

- (a) **Initial Information Transfer** . Upon Incyte’s written request (but in no event later than [\*\*] after the Effective Date), MacroGenics shall deliver to Incyte electronic copies (unless otherwise required by Applicable Law) of all Regulatory Documentation relating [\*\*] to the Licensed Compound or Licensed Products that is Controlled by MacroGenics or its Affiliates, but excluding any MacroGenics Pipeline Asset Information or any Regulatory Documentation or Information relating specifically to a MacroGenics Pipeline Asset (the “ **Transferred Documentation** ”; such transfer, the “ **Information Transfer** ”); provided that, to the extent that, during the Term, MacroGenics or its Affiliates Control any other Information relating to the Licensed Compound or Licensed Products that is (i) solely related to the Licensed Compound or Licensed Product, (ii) necessary for Incyte to perform its obligations or exercise its rights under this Agreement, or (iii) reasonably requested by Incyte for such purpose in (i) or (ii), MacroGenics shall promptly provide such Information.
- (b) **Incyte Monotherapy Data** . During the Term, subject to Sections 5.2, 5.3 and 5.6, Incyte shall deliver to MacroGenics electronic copies (unless otherwise required by Applicable Law) of any then-current data Controlled by Incyte relating to the Licensed Compound and derived from Development of the Monotherapy Regimen, including any applicable preclinical safety data or clinical safety data in accordance with the Pharmacovigilance Agreement (including adverse event data), biocomparability data, biomarker data, response rate and other efficacy data, mechanistic data and other activity data, as reasonably requested by MacroGenics from time to time (subject to the Pharmacovigilance Agreement or as required by Applicable Law, such requests not to be made more frequently than [\*\*] per Calendar Quarter following the [\*\*] of the Effective Date). MacroGenics shall be free to use such Incyte data for any purpose consistent with the rights expressly retained by or granted to MacroGenics pursuant to Section 3.3 and the license granted pursuant to Section 3.4(b).
- (c) **MacroGenics Monotherapy Data and Ongoing Clinical Study Data** . During the Term, subject to Sections 5.2, 5.3 and 5.6, MacroGenics shall deliver to Incyte electronic copies (unless otherwise required by Applicable Law) of any then-current data Controlled by MacroGenics (i) relating to any anti-PD-1 Monoclonal Antibody being evaluated as a MacroGenics PD-1 Control Arm, or (ii) relating to

the Licensed Compound and arising out of or in connection with the Ongoing Clinical Study or a Required Monotherapy Study conducted by MacroGenics, including in all cases (of (i) through (ii)) any applicable preclinical safety data or clinical safety data in accordance with the Pharmacovigilance Agreement (including adverse event data), biocomparability data, biomarker data, response rate and other efficacy data, mechanistic data and other activity data, as reasonably requested by Incyte from time to time (but subject to the Pharmacovigilance Agreement or as required by Applicable Law, such request not to be made more frequently than [\*\*] per Calendar Quarter following the [\*\*] of the Effective Date). Incyte shall be free to use such data for any purpose consistent with the license granted pursuant to Section 3.1.

- (d) **MacroGenics Research and Development Activities** . In addition, as reasonably requested by Incyte in writing from time to time, MacroGenics shall deliver to Incyte electronic copies of all other material Information related to the Licensed Compound (but excluding Information related to the MacroGenics Combination Regimen or any MacroGenics Pipeline Asset, unless such Information is necessary for Incyte to receive Regulatory Approval of the Licensed Compound as a component of a MacroGenics Combination Regimen) arising out of MacroGenics' conduct of research and Development activities with respect to the Licensed Compound pursuant to Section 3.3. Subject to the Pharmacovigilance Agreement or as required by Applicable Law, such request shall not be made more frequently than [\*\*] per Calendar Quarter. Incyte shall be limited to use such MacroGenics data solely for purposes consistent with the license granted pursuant to Section 3.1.

## **5.2 Data Sharing: Combination Regimens**

- (a) **Incyte Responsibilities** . Within [\*\*] after Incyte's receipt of a written request from MacroGenics, Incyte shall provide to MacroGenics, subject to Section 5.3, copies of and other access to any then-current data Controlled by Incyte or (to the extent Incyte is able to obtain permission to grant such right and access from the Collaborator in connection with a Collaborator Combination Study, through the use of Commercially Reasonable Efforts, in the case of such data that Collaborator is not required to provide pursuant to an applicable Collaborator Contract) any Collaborator, derived from the conduct of any Incyte Combination Studies and/or Collaborator Combination Studies, that is [\*\*] related to the Licensed Compound or Licensed Products, including applicable safety data (including adverse event data), as necessary for MacroGenics to comply with applicable regulatory requirements or requests by Regulatory Authorities for the Development of, or seeking of Regulatory Approval of, any MacroGenics Pipeline Asset as a component of a MacroGenics Combination Regimen or for the Commercialization of any MacroGenics Pipeline Asset in accordance with such Regulatory Approval. If Incyte conducts a Clinical Study with respect to the Licensed Compound involving a Third Party collaborator who owns or Controls an Ancillary Therapy that is being studied in connection with an Incyte Combination Regimen, (x) Incyte shall provide to MacroGenics all data Controlled by Incyte derived from any arm

of the Clinical Study that solely comprises both the Licensed Compound and the Ancillary Therapy, and (y) Incyte shall grant and hereby grants to Incyte a non-exclusive, irrevocable, perpetual, transferable, fully paid-up, royalty-free, sublicenseable license under any Information or any intellectual property arising out of any arm of the Clinical Study that solely comprises both the Licensed Compound and the Ancillary Therapy for any use consistent with the license granted pursuant to Section 3.4(b), in each case (of (x) and (y)) to the extent that Incyte has the contractual right to extend such rights, licenses, or sublicenses to MacroGenics, as applicable (and Incyte shall use Commercially Reasonable Efforts to obtain such contractual rights from the applicable Third Party collaborator).

- (b) **Collaborator Responsibilities** . Without limiting the generality of the foregoing, Incyte shall require that each Collaborator Contract contains terms as least as protective of Incyte as the following terms set forth in this Section 5.2(b). Promptly, but in any event within [\*\*] after Collaborator’s receipt of a written request from Incyte, Collaborator shall provide to Incyte copies of and other access to any then-current Information Controlled by Collaborator, derived from the Development of any Collaborator Combination Studies, including any applicable preclinical safety data or clinical safety data (including adverse event data on terms generally consistent with the Pharmacovigilance Agreement), biocomparability data, biomarker data, response rate and other efficacy data, mechanistic data and activity data, as reasonably requested by Incyte from time to time, as necessary for Incyte to seek Regulatory Approval of the Licensed Compound as a component of the Collaborator Combination Regimen or Commercialize the Licensed Compound as a component of a Collaborator Combination Regimen.
- (c) **MacroGenics Responsibilities** .
- (i) Within [\*\*] after MacroGenics’ receipt of a written request from Incyte, MacroGenics shall provide to Incyte, subject to Section 5.3, copies (unless otherwise required by Applicable Law) of and access to any then-current Information Controlled by MacroGenics or its Affiliates or licensees derived from the conduct of the MacroGenics Combination Studies that relates [\*\*] to the Licensed Compound or Licensed Product, including any applicable preclinical safety data or clinical safety data (including adverse event data in accordance with the Pharmacovigilance Agreement), biocomparability data, biomarker data, mechanistic data and activity data as reasonably requested by Incyte from time to time (the “ **MacroGenics Licensed Compound Data** ”). Incyte shall be free to use such MacroGenics Licensed Compound Data for any purpose consistent with the license granted pursuant to Section 3.1.
- (ii) At least [\*\*] prior to the anticipated database lock of any MacroGenics Combination Study that MacroGenics intends to submit for Regulatory Approval of a MacroGenics Combination Regimen, the Parties shall initiate

discussions to negotiate and finalize a mutually agreeable Regulatory Agreement.

- (iii) Within [\*\*] after database lock of any such MacroGenics Combination Study, MacroGenics shall provide to Incyte, subject to Section 5.3, copies (unless otherwise required by Applicable Law) of and access to any then-current Information Controlled by MacroGenics or its Affiliates or licensees derived from the conduct of such MacroGenics Combination Study that relates to the Licensed Compound, a Licensed Product or any MacroGenics Combination Regimen, which may include applicable preclinical safety data or clinical safety data (including adverse event data in accordance with the Pharmacovigilance Agreement), biocomparability data, biomarker data, mechanistic data and activity data as reasonably requested by Incyte from time to time (but excluding, in all cases, Information that is solely related to any MacroGenics Pipeline Asset unless such Information is necessary for Incyte to seek Regulatory Approval of the Licensed Compound as a component of a MacroGenics Combination Regimen in accordance with Section 5.8) to the extent such Information is necessary for Incyte to (A) comply with any request or requirement by a Regulatory Authority, (B) seek Regulatory Approval of the Licensed Compound as a component of a MacroGenics Combination Regimen and expand the Licensed Compound label to include such Regulatory Approval in accordance with Section 5.8(c) or (C) to conduct MacroGenics Combination Regimen Detailing (and excluding in all cases, the right to Commercialize any MacroGenics Pipeline Asset) (the “ **Required Regulatory Data** ”). For clarity, each Party will separately submit any non-clinical and any chemistry, manufacturing and controls (CMC) information specific to its Compound directly to any Regulatory Authorities.

**5.3 Data Sharing Limitations**. Neither Party nor its Affiliates or sublicensees (including Collaborators) (the “ **delivering Party** ”) shall have the obligation to provide to any other Party or any Collaborator (the “ **receiving Party** ”), and the receiving Party shall have no right to access, any of the delivering Party’s data that is not [\*\*] related to the Licensed Compound or Licensed Products (unless, and to the extent, such Information is necessary for the other Party to perform its obligations or exercise its rights under this Agreement). Notwithstanding the foregoing, MacroGenics will provide all data under its Control that is necessary for Incyte to Develop and/or Commercialize the Monotherapy Regimen and seek Regulatory Approval of the Licensed Compound as a component of a MacroGenics Combination Regimen in accordance with Section 5.8. Incyte and Collaborators will each provide to MacroGenics copies of all data under Incyte’s Control related specifically and solely to the Licensed Compound that is derived from any Monotherapy Regimen as necessary for MacroGenics to Develop any MacroGenics Combination Regimen or Commercialize the MacroGenics Pipeline Asset as a component of a MacroGenics Combination Regimen. Notwithstanding the foregoing, any safety data that is related to the Licensed Compound or MacroGenics Combination Regimen shall not be excluded from the data sharing obligations under Sections 5.1, 5.2 and 5.3 but rather shall be shared to the extent set forth in the Pharmacovigilance Agreement. Additionally, notwithstanding anything to the contrary

herein, any data or other information disclosed by the delivering Party pursuant to Sections 5.1 or 5.2 shall, to the extent permissible: (A) be subject to reasonable redaction with respect to any information that the delivering Party deems commercially sensitive, confidential or proprietary, including any data or information relating [\*\*] to proprietary product(s) of the delivering Party, its Affiliates or any Third Party that is not a receiving Party hereunder ( e.g ., Pipeline Assets), to the extent the same would not unreasonably limit the receiving Party's ability (i) to interpret any Clinical Study results, and (ii) where Incyte is the receiving Party, to seek Regulatory Approval of the Licensed Compound as a component of the MacroGenics Combination Regimen; and (B) to the extent disclosed, constitute Confidential Information of the delivering Party (provided that, as between the Parties, any information disclosed by Collaborator shall be deemed Incyte's Confidential Information). Notwithstanding anything to the contrary herein, each Party shall provide the other Party with any Licensed Compound "components of care" data that is owned or Controlled by such Party, as required or requested by a Regulatory Authority to support Regulatory Approval by the other Party of any Monotherapy Regimen, Incyte Combination Regimen, Collaborator Combination Regimen, or MacroGenics Combination Regimen, as applicable. Nothing contained in this Section 5.3 shall limit the obligations of either Party or a Collaborator pursuant to Sections 5.1(a), 5.2 and 5.3 as applicable, except that in all cases, the delivering Party shall have no obligation pursuant to Section 5.2 to provide any data generated pursuant to a blinded Clinical Study until such time as the applicable Clinical Study has been unblinded.

**5.4 Right of Reference**

- (a) **Incyte Responsibilities** . Within [\*\*] after Incyte's receipt of a written request from MacroGenics, Incyte shall grant, and hereby grants, and shall require its sublicensees to grant, to MacroGenics and/or the applicable Regulatory Authorities, subject to Section 5.3, a cross-reference letter or similar communication to grant MacroGenics a Right of Reference to any Regulatory Documentation related specifically to the Licensed Compound or any Licensed Product, in connection with any Monotherapy Studies, Incyte Combination Studies or Collaborator Combination Studies, as necessary for MacroGenics to comply with applicable regulatory requirements or requests by Regulatory Authorities to Develop any MacroGenics Combination Regimen, seek Regulatory Approval of a MacroGenics Pipeline Asset as a component of a MacroGenics Combination Regimen or Commercialize a MacroGenics Pipeline Asset in accordance with its approved label (but, for clarity, not to Commercialize any Incyte Pipeline Asset or Collaborator Pipeline Asset).
- (b) **Collaborator Responsibilities** . Without limiting the generality of the foregoing, Incyte shall require that each Collaborator Contract contain the following terms set forth in this subsection (b). Promptly, but in no event later than [\*\*], following receipt of a written request from Incyte, Collaborator shall grant, and hereby grants to Incyte and/or all applicable Regulatory Authorities, subject to Section 5.3, a cross-reference letter or similar communication to grant Incyte a Right of Reference to any Regulatory Documentation (including INDs and NDAs) related to any Collaborator Combination Studies, to enable Incyte to comply with applicable regulatory requirements or requests by Regulatory Authorities, in connection with

- (i) the Development or Commercialization of the Monotherapy Regimen, and (ii) seeking Regulatory Approval of the Licensed Compound as a component of a Collaborator Combination Regimen, and Commercializing the Licensed Compound or any Licensed Product in accordance with such approved label (but, for clarity, not to Commercialize any Collaborator Pipeline Asset).
- (c) **MacroGenics Responsibilities** . Within [\*\*] after MacroGenics' receipt of a written request from Incyte, MacroGenics shall grant, and hereby grants, and shall require its sublicensees to grant, to Incyte and/or all applicable Regulatory Authorities, subject to Section 5.3, a cross-reference letter or similar communication to grant Incyte a Right of Reference to any Regulatory Documentation related to any MacroGenics Combination Studies, as necessary for Incyte to comply with applicable regulatory requirements or requests by Regulatory Authorities, in connection with (i) the Development or Commercialization of the Monotherapy Regimen, (ii) seeking Regulatory Approval of the Licensed Compound as a component of a MacroGenics Combination Regimen and expanding the label of the Licensed Compound to include such Regulatory Approval as a component of a MacroGenics Combination Regimen or (iii) conducting MacroGenics Combination Regimen Detailing (but, for clarity, not to otherwise Commercialize any MacroGenics Pipeline Asset).

**5.5 Regulatory Documentation; Regulatory Communications .**

- (a) **Regulatory Communications Relating to Ongoing Clinical Study** .
- (i) Prior to the IND Transition Date, MacroGenics shall notify Incyte in advance of any material communications with Regulatory Authorities, including telephone conferences or discussions, in each case with respect to the Ongoing Clinical Study, to the extent permitted by the applicable Regulatory Authority; provided that, if MacroGenics is unable to provide Incyte with prior notice of any such communication, MacroGenics shall notify Incyte as soon as practicable after the occurrence of such communication. Incyte shall have the right to participate in all such material communications with Regulatory Authorities (it being understood that Incyte shall have the sole right to lead any discussion, or portion thereof, that relates [\*\*] to the Monotherapy Regimen) and provide comments thereto, and MacroGenics shall consider such comments in good faith prior to responding to any Regulatory Authority.
- (ii) At all times during the Term after the IND Transition Date, Incyte shall be solely responsible, at its sole cost and expense, for all filings, reports and communications with all Regulatory Authorities with respect to the Ongoing Clinical Study, in its own name.
- (b) **Regulatory Communications Relating to Monotherapy Studies** . As between the Parties, at all times during the Term after the IND Transition Date, Incyte shall be

solely responsible, at its sole cost and expense, for all filings, reports and communications with all Regulatory Authorities with respect to any Monotherapy Studies, in its own name, provided however, with respect to Monotherapy Studies conducted by MacroGenics pursuant to Section 5.9(c), MacroGenics shall be solely responsible for all costs and expenses associated with the applicable Monotherapy Studies, and the Parties will discuss in good faith how to handle communications with Regulatory Authorities in connection therewith. Without limiting the foregoing, each Combination Sponsor shall notify Incyte in advance of any material communications with Regulatory Authorities, including telephone conferences or discussions, in each case with respect to matters related to the Monotherapy Regimen, to the extent permitted by the applicable Regulatory Authority; provided that, if Combination Sponsor is not permitted by the applicable Regulatory Authority to provide Incyte with prior notice of any such communication, Combination Sponsor shall notify Incyte as soon as practicable after the occurrence of such communication. Incyte shall have the right to participate in such material communications and provide comments thereto, which comments the Combination Sponsor shall consider in good faith prior to responding to any Regulatory Authority.

**(c) Regulatory Communications Relating to MacroGenics Combination Studies .**

- (i)** At all times during the Term, without limitation of any other obligations of MacroGenics under this Agreement, MacroGenics shall keep Incyte reasonably informed of any material interactions and documentation related thereto with any Core Regulatory Authority that relate [\*\*] to the Licensed Compound. Incyte will be given a reasonable opportunity to review and to provide input with respect to all such interactions and documentation related thereto, and MacroGenics will consider such input in good faith, to the extent reasonably practicable.
- (ii)** In addition to the rights described in paragraph (i) above, on a region-by-region basis, until the earlier of (x) [\*\*] after the Effective Date, or (y) achievement of the first Licensed Compound Approval by each of the applicable Core Regulatory Authorities, Incyte shall be entitled to either participate in or provide input on, at Incyte's choosing, any Licensed Compound Regulatory Discussions (except that, in the event of any Change of Control of Incyte, Incyte shall be permitted to participate in only those parts of any Licensed Compound Regulatory Discussions that relate [\*\*] to the Licensed Compound, as reasonably determined by MacroGenics in its sole discretion); provided that, Incyte shall not have the right to control or influence the timing or the agenda setting of any such regulatory discussion. MacroGenics shall notify Incyte in advance of each such Licensed Compound Regulatory Discussion and shall provide any such communications to Incyte, with respect to matters related to the Licensed Compound in connection with any MacroGenics Combination Studies (except that, in the event of any Change of Control of Incyte, MacroGenics

shall provide to Incyte any such communications with respect to matters [\*\*] related to the Licensed Compound in connection with any MacroGenics Combination Studies, as reasonably determined by MacroGenics in its sole discretion), to the extent permitted by the applicable Regulatory Authority; provided that, if MacroGenics is unable to provide Incyte with prior notice of any such Licensed Compound Regulatory Discussion, MacroGenics shall notify Incyte as soon as practicable after the occurrence of such Licensed Compound Regulatory Discussion. MacroGenics shall provide to Incyte copies of all material regulatory-related communications in connection with any Licensed Compound Regulatory Discussions, subject to reasonable redaction by MacroGenics with respect to any MacroGenics Pipeline Asset Information. Incyte shall have the right to lead, in coordination with MacroGenics, any such discussion, or portion thereof, that relates [\*\*] to the Licensed Compound as a monotherapy arm or as a component of a MacroGenics Combination Regimen, as reasonably determined by MacroGenics in its sole discretion, and provide comments thereto. MacroGenics shall consider such comments in good faith prior to responding to the applicable Regulatory Authority; provided, however, that Incyte shall not have the right to participate in any portion of any Licensed Compound Regulatory Discussion where any MacroGenics Pipeline Asset Information is discussed.

- (d) **Regulatory Documentation and Communications Relating to Combination Studies** . Without limitation of subsection (c) (in connection with MacroGenics Combination Studies), Combination Sponsor shall be solely responsible, at its sole cost and expense, for all filings, reports and communications with all Regulatory Authorities (including any INDs) with respect to its Pipeline Asset (including as a component of a Combination Regimen), as applicable, in its own name. Combination Sponsor shall sponsor its respective Combination Study under its existing IND for its Pipeline Asset or a separate IND for the Combination Regimen, with a Right of Reference to the IND of the Licensed Compound or Licensed Product solely if required by a Regulatory Authority and only as it relates specifically to the Licensed Compound or Licensed Product. Combination Sponsor shall be responsible for (i) drafting, and updating as necessary for its respective Combination Study, an investigator's brochure for its Pipeline Asset and (ii) preparing, obtaining and maintaining, as applicable, all necessary Regulatory Documentation to its existing IND for its Pipeline Asset (including as a component of a Combination Regimen), including submitting to such IND any serious adverse event and adverse drug reaction cases emerging from its Combination Study, as applicable. Where Incyte is not the Combination Sponsor, Incyte shall have the right to provide boilerplate language that relates specifically to the Licensed Compound, and MacroGenics will reasonably include such language in its applicable Regulatory Documentation.
- (e) **Regulatory Documentation and Communications Relating to Manufacturing Development** . Prior to the IND Transition Date, MacroGenics shall be solely

responsible for all filings and reports, and shall lead any discussions between the Parties, related to Manufacturing Development of the Licensed Compound. Following the IND Transition Date, both Incyte and MacroGenics shall prepare, and Incyte shall be solely responsible for making, all filings and reports, and shall lead any discussion between the Parties, related to Manufacturing Development for any Clinical Studies (including any Pivotal Studies) and commercial supply.

**5.6 Adverse Event Reporting and Safety Data Exchange**

- (a) **Incyte Responsibilities** . On and after the IND Transition Date, Incyte shall assume sole responsibility, at its sole expense, for monitoring all clinical experiences, maintaining the Global Safety Database, safety monitoring, pharmacovigilance surveillance, compliance and filing all required safety reports, including annual safety reports, to all applicable Regulatory Authorities with respect to the Development or Commercialization of the Licensed Compound and any Licensed Products in the Field in the Territory, and shall be responsible for compliance with all Applicable Law pertaining to safety reporting and all other safety-related matters, including its responsibilities under the Pharmacovigilance Agreement, with respect to the Licensed Compound and Licensed Products. Incyte shall provide MacroGenics with, and MacroGenics shall have the right to access, any safety Information related to the Licensed Compound or any Licensed Products for which Incyte is responsible pursuant to this subsection (a), pursuant to the terms of the Pharmacovigilance Agreement.
- (b) **Combination Sponsor Responsibilities** . Subject to subsection (a) above, each Combination Sponsor shall (and with respect to any Collaborator as the Combination Sponsor, Incyte shall require that Collaborator shall) be solely responsible for monitoring all clinical experiences, maintaining the global safety database, safety monitoring, pharmacovigilance surveillance, compliance and filing all required safety reports, including annual safety reports, to all applicable Regulatory Authorities with respect to the Development or Commercialization of its Pipeline Asset in the Territory (including as a component of a Combination Regimen), and shall be responsible for compliance with all Applicable Law pertaining to safety reporting and all other safety-related matters, including its responsibilities under the Pharmacovigilance Agreement, with respect to its Pipeline Asset, including as a component of a Combination Regimen.
- (c) **Safety Information Exchange; Pharmacovigilance Agreement** . The Parties will initiate negotiations and use Commercially Reasonable Efforts to execute a pharmacovigilance agreement (“**Pharmacovigilance Agreement**”) within [\*\*] after the Effective Date. The executed Pharmacovigilance Agreement shall be in an appropriate format to enable the Parties to fulfill local and international regulatory reporting obligations and to facilitate appropriate safety reviews. The Pharmacovigilance Agreement will include safety data exchange procedures governing the coordination of collection, monitoring, investigation, reporting, and exchange of information, consistent with Applicable Law. Such guidelines and

procedures shall be in accordance with, and enable the Parties and their Affiliates to fulfill, local and international regulatory reporting obligations to Governmental Authorities. Among other things, the Pharmacovigilance Agreement shall require MacroGenics and any Collaborators to submit safety data concerning any adverse experiences and any other safety information arising from or related to the use of the Licensed Compound as a single agent or as a component of any Combination Regimen in any MacroGenics Combination Study or Collaborator Combination Study, as applicable, as necessary for Incyte to maintain the Global Safety Database.

**5.7 Recalls and Voluntary Withdrawals**

- (a) **Licensed Product** . Incyte shall use reasonable efforts to notify MacroGenics promptly, but in no event later than [\*\*], following its determination that any event, incident, or circumstance related to safety issues or regulatory concerns has occurred that is reasonably likely to result in the need for a recall, market suspension or market withdrawal of the Licensed Compound or any Licensed Product in the Territory, provided that, prior to the implementation of such a recall, market suspension or market withdrawal, Incyte shall, to the extent practical, consult with MacroGenics and shall consider MacroGenics' comments in good faith, and shall include in such notice the reasoning behind such determination and any supporting facts. Incyte shall have the sole right to make the final determination of whether to voluntarily implement any such recall, market suspension or market withdrawal in the Territory. For all recalls, market suspensions or market withdrawals undertaken pursuant to this subsection (a), Incyte shall be solely responsible for the execution thereof, and MacroGenics shall reasonably cooperate in all such recall efforts. Subject to the provisions of Section 14.2 and except as may otherwise be set forth in the Clinical Supply Agreement or the Commercial Supply Agreement, Incyte shall be responsible for all costs of conducting any such recall, market suspension, or market withdrawal of the Licensed Product.
- (b) **Pipeline Asset** . The Controlling Party shall use reasonable efforts to notify the other Party promptly, but in no event later than [\*\*], following its determination that any event, incident, or circumstance related to safety issues or regulatory concerns has occurred that may result in the need for a recall, market suspension or market withdrawal of its Pipeline Asset, in whole or in part, in the Territory, and shall include in such notice the reasoning behind such determination, and any supporting facts. The Controlling Party shall have sole authority to decide whether to implement any recall, market suspension or market withdrawal of its Pipeline Asset, and shall be solely responsible for, and control, the execution thereof. The non-recalling Party shall reasonably cooperate in all such efforts to implement a recall, market suspension or market withdrawal of the Controlling Party's Pipeline Asset. The Controlling Party shall be responsible for all costs of any such recall, market suspension, or market withdrawal of its respective Pipeline Asset.

**5.8 Labeling**

- (a) If, at the time of submission of the Regulatory Approval Application for a MacroGenics Combination Regimen, there is no Monotherapy Regimen, Incyte Combination Regimen or Collaborator Combination Regimen that has received Regulatory Approval, Incyte shall use Commercially Reasonable Efforts to, contemporaneously and in coordination with MacroGenics, seek Regulatory Approval of a label for such Licensed Compound as a component of a MacroGenics Combination Regimen that, if such Licensed Compound label is approved, will sufficiently enable Commercialization by MacroGenics of the applicable MacroGenics Pipeline Asset as a component of a MacroGenics Combination Regimen and Commercialization by Incyte of the Licensed Compound as a component of a MacroGenics Combination Regimen (provided that, Incyte shall have no right to conduct any Medical Affairs Activities or activities directed to marketing, detailing, promoting, educating or any Phase IV Studies with respect to the Licensed Compound as a component of a MacroGenics Combination Regimen other than MacroGenics Combination Regimen Detailing).
- (b) For each Regulatory Approval of a MacroGenics Pipeline Asset as a component of a MacroGenics Combination Regimen, MacroGenics shall have the right to determine in its sole discretion, whether to include the Regulatory Approval for the MacroGenics Combination Regimen in its label for the applicable MacroGenics Pipeline Asset included in such MacroGenics Combination Regimen.
- (c) Without limiting Incyte's obligations under Section 5.8(a), Incyte may, at its discretion, reference all Regulatory Documentation and other Information submitted by MacroGenics to the applicable Regulatory Authority as required by Incyte for the purposes of (i) seeking Regulatory Approval of the Licensed Compound as a component of a MacroGenics Combination Regimen and expanding the label of the Licensed Compound to include such Regulatory Approval as a component of a MacroGenics Combination Regimen or (ii) exercising its rights under Section 3.1(c). Notwithstanding anything to the contrary herein, the rights granted to Incyte in this Section 5.8(c) to include in the label for the Licensed Compound newly-generated Regulatory Documentation and other Information submitted by MacroGenics to the applicable Regulatory Authority shall immediately terminate on a going-forward basis (but, for clarity, the right of Incyte to continue to exercise its rights under Section 3.1(c) shall continue) upon the following: (A) after any Change of Control of Incyte, except that the right of Incyte to include in the label for the Licensed Compound newly-generated Regulatory Documentation and other Information submitted by MacroGenics to the applicable Regulatory Authority shall continue with respect to any Regulatory Documentation and other Information submitted by MacroGenics in connection with a Pivotal Study by MacroGenics (or an Acquirer of MacroGenics) that was Initiated prior to date upon which the Change of Control of Incyte was publicly announced; or (B) on a MacroGenics Combination Regimen-by-MacroGenics Combination Regimen basis, in the event that the then-current label of the Licensed Compound includes a Regulatory Approval for an Indication Population based on a Combination Study, other than a Combination Study conducted by MacroGenics,

that is the same Indication Population for which MacroGenics seeks Regulatory Approval for the applicable MacroGenics Combination Regimen.

**5.9 Other Studies**. Notwithstanding anything to the contrary herein, in the event that an applicable Regulatory Authority requires or recommends, as a condition to the grant or maintenance of Regulatory Approval for a MacroGenics Combination Regimen, that a Monotherapy Study be conducted (the “ **Required Monotherapy Study** ”), then MacroGenics shall notify Incyte in writing, and:

- (a) Incyte shall provide reasonable assistance to MacroGenics, including provision of then-current Licensed Compound and Ancillary Therapy “components of care” data it Controls (subject to availability) and using Commercially Reasonable Efforts to continue the conduct of any then-current on-going Clinical Studies that include the Required Monotherapy Study that would provide relevant Licensed Compound and Ancillary Therapy “components of care” data it Controls, at Incyte’s sole cost and expense.
- (b) In the event that Incyte does not have any Monotherapy Study on-going that includes the Required Monotherapy Study, but the then-current Incyte Global Development Plan includes such a Monotherapy Study planned to be Initiated within the [\*\*] period following the date on which MacroGenics provides written notice pursuant to the first sentence in this Section 5.9, then Incyte shall use Commercially Reasonable Efforts to conduct such Monotherapy Study, and shall provide to MacroGenics relevant Licensed Compound and Ancillary Therapy “components of care” data derived from such Study and Controlled by Incyte (subject to availability) at Incyte’s sole cost and expense.
- (c) In the event that Incyte does not have any Monotherapy Study on-going that includes the Required Monotherapy Study, and the then-current Incyte Global Development Plan does not contemplate the Initiation of such Monotherapy Study within the [\*\*] period as described in subpart (b), then MacroGenics may design and conduct such Monotherapy Study solely to compare the Monotherapy Regimen to an Ancillary Therapy to produce the data required by the Regulatory Authority, at MacroGenics’ sole cost and expense, subject to Incyte’s prior right of review and approval of such Monotherapy Study (not to be unreasonably withheld, conditioned, or delayed), and Incyte shall provide reasonable assistance and cooperation to MacroGenics in connection therewith, at MacroGenics’ sole cost and expense.

## **ARTICLE 6 COMMERCIALIZATION**

### **6.1 Commercialization Activities**

- (a) **Licensed Product** . Subject to Sections 2.5, 5.2, 5.4, 5.8, 6.1(b), 6.1(c) and 6.1(d), Incyte shall be solely responsible for and have sole authority with respect to, at its

own expense, all aspects of the Commercialization of Licensed Products in the Field in the Territory, in accordance with its approved label, including as a component of a Collaborator Combination Regimen, and, subject to Section 3.1(c), as a component of a MacroGenics Combination Regimen, and will retain final decision-making authority with respect thereto, including: (i) developing and executing a commercial launch and pre-launch plan; (ii) marketing, promotion, and branding; (iii) booking sales and distribution and performance of related services; (iv) handling all aspects of order processing, invoicing and collection, inventory and receivables; (v) providing customer support, including handling medical queries, and performing other related functions; (vi) the review and approval of all promotional materials for compliance with Applicable Law, including submission, where appropriate, to applicable Regulatory Authorities and (vii) conforming its practices and procedures in all material respects to Applicable Law relating to the marketing, detailing and promotion of Licensed Products in the Field in the Territory.

- (b) **Pipeline Assets** . Subject to Sections 2.5, 6.1(a), and 6.1(c), each Combination Sponsor shall have sole authority over and control of the Commercialization of its respective Pipeline Asset in the Field in the Territory, in accordance with its approved label, and will retain final decision-making authority with respect thereto, including such activities set forth in Section 6.1(a)(i)-(vii) as applied to its Pipeline Asset.
- (c) **MacroGenics Combination Regimens** . MacroGenics shall have sole authority over and control of all promotional activities with respect to any MacroGenics Pipeline Asset as a component of a MacroGenics Combination Regimen in the Field in the Territory, in accordance with the MacroGenics Pipeline Asset approved label, and will retain final decision-making authority with respect thereto. In the event that a MacroGenics Pipeline Asset receives Regulatory Approval as a component of a MacroGenics Combination Regimen and is included in the Licensed Compound approved label, then without limiting Section 6.1, Incyte may conduct MacroGenics Combination Regimen Detailing with respect to the Licensed Product in accordance with Incyte’s approved label of the Licensed Product as component of a MacroGenics Combination Regimen; provided further, that to the extent Incyte elects to be involved in any additional promotional activities specific to the MacroGenics Combination Regimen, these activities shall be subject to MacroGenics’ sole discretion and, if agreed by the Parties, a separate co-promotion agreement to be negotiated by the Parties (such agreement, the “**Co-Promotion Agreement**”).
- (d) **Diligence** . Incyte shall use Commercially Reasonable Efforts to seek Regulatory Approval for, and if the applicable Regulatory Approval is granted, Commercialize a Licensed Product in each of the U.S., [\*\*] of the [\*\*] European Major Markets, and Japan. Incyte will, subject to MacroGenics satisfying its supply obligations hereunder to the extent necessary for Incyte to satisfy such obligation, use Commercially Reasonable Efforts to make the Licensed Product commercially

available in quantities sufficient to fulfill global market demand at all times during the Term after the date of Licensed Compound Approval.

**6.2 Pricing of Licensed Product.** Incyte shall have sole and exclusive control over the pricing of Licensed Products on a worldwide basis and shall retain final decision-making authority with respect to obtaining and maintaining pricing and reimbursement approval, subject to Section 8.5(b) and the following procedures and/or restrictions in subsections (a)-(e) below. Unless otherwise specified to the contrary, a reference price as it relates to the [\*\*] and [\*\*] calculations shall be established using the following criteria: (1) [\*\*]<sup>1</sup> [\*\*]; (2) for [\*\*]; and (3) the dosage of the Licensed Product for [\*\*]. By way of example, [\*\*], which is calculated using the following [\*\*]: (i) [\*\*]<sup>2</sup> [\*\*], (ii) [\*\*]<sup>3</sup> [\*\*]. To the extent permitted under Applicable Law:

- (a) For Licensed Products sold in the U.S., Incyte shall not be permitted to [\*\*] the [\*\*] of the Licensed Compound [\*\*] than [\*\*] ([\*\*]%) [\*\*] (the “[\*\*]”).
- (b) Subsequent to receipt of Regulatory Approval for a Licensed Product [\*\*], for a Licensed Product sold in [\*\*] for which the Licensed Compound has received Regulatory Approval, the monthly Net Price of the Licensed Compound shall not be, on average across [\*\*] in which the Licensed Compound has received Regulatory Approval, [\*\*] than [\*\*] ([\*\*]%) [\*\*] the [\*\*] of [\*\*] in which the Licensed Compound has received Regulatory Approval (the “[\*\*]”).
- (c) For Licensed Products sold in [\*\*], Incyte shall not submit a Net Price to the MHLW that is [\*\*] than [\*\*] ([\*\*]%) [\*\*] the [\*\*] of the [\*\*] in [\*\*] (the “[\*\*]”).
- (d) For Licensed Products sold in [\*\*], the monthly Net Price of the Licensed Compound shall not be [\*\*] than [\*\*] ([\*\*]%) [\*\*] the monthly [\*\*] price of the [\*\*] in [\*\*] (the “[\*\*]”).
- (e) Incyte shall calculate any [\*\*] of the Licensed Product (including any [\*\*], [\*\*], [\*\*], and [\*\*]) and any [\*\*] of the Licensed Product (including any [\*\*], [\*\*], [\*\*], and [\*\*]) in accordance with this Section 6.2 upon launch of the Licensed Product, and shall thereafter update such [\*\*] and [\*\*] on an annual basis and at any time the Licensed Compound Net Price is changed in the relevant territory. Any disputes regarding such calculation(s) shall be resolved pursuant to Article 13.
- (f) For Licensed Products sold in [\*\*], [\*\*], [\*\*] or [\*\*], Incyte shall not be restricted in setting the pricing of the Licensed Product through the use of a [\*\*] or be required to pay royalties similar to Section 8.5(b) as if there were a [\*\*], but rather, Incyte

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<sup>1</sup>For clarity, the [\*\*].

<sup>2</sup>[\*\*] as of the Execution Date are [\*\*] and [\*\*]. [\*\*].

<sup>3</sup>[\*\*] as of the Execution Date is [\*\*]. [\*\*].

shall use Commercially Reasonable Efforts to achieve a Net Price that is at [\*\*] the [\*\*] of [\*\*] in such market, assuming such [\*\*] is ascertainable.

- (g) Incyte will have the sole right to establish all terms of commercial sale (including pricing, discounts and rebates) in all other countries of the world, and subject to Section 8.5(a), royalties will be calculated based on actual Net Sales in such country pursuant to Section 8.3.
- (h) If at any time during the Royalty Term Incyte determines that it is not in compliance with the [\*\*], [\*\*], [\*\*] or [\*\*], Incyte shall initiate a process, and use Commercially Reasonable Efforts to complete such process, to bring Incyte into compliance with the applicable [\*\*] (for example, initiating pricing negotiations with an applicable regulatory authority); provided that Incyte's non-compliance with the [\*\*], [\*\*], [\*\*] or [\*\*] shall not constitute a material breach of this Agreement so long as Incyte utilizes Commercially Reasonable Efforts to resolve such non-compliance.

**6.3 Pricing of Pipeline Assets.** Each Controlling Party shall have sole and exclusive control over (a) the pricing of its Pipeline Asset and (b) any negotiation of the pricing, discounts and rebates applicable to its Pipeline Asset with any Regulatory Authorities or other Third Parties.

**6.4 Transparency Reporting.** Each Party shall be responsible for tracking and reporting transfers of value initiated and controlled by or on behalf of such Party's or its Affiliates' employees, contractors, and agents pursuant to the requirements of the marketing reporting laws of any Governmental Authority in the Territory, including Section 6002 of ACA, commonly referred to as the "Sunshine Act."

## **ARTICLE 7 MANUFACTURING**

### **7.1 Manufacturing Technology Transfer.**

- (a) Any time after the [\*\*] anniversary of the Effective Date, Incyte may request, upon [\*\*] written notice (which notice may be given prior to the [\*\*] anniversary of the Effective Date) to MacroGenics (or immediately upon writing notice to MacroGenics, in the case of a Clinical Supply Shortage), that MacroGenics transfer or have transferred the Manufacturing Process to a manufacturing facility under the control of Incyte (or its designee, which designee may be an Affiliate) or, subject to subsection (d) below, to a facility of a Third Party contract manufacturer that is mutually agreed upon by the Parties. MacroGenics shall not withhold such agreement to a proposed contract manufacturer that has not experienced any material documented safety, compliance or quality issues in the preceding [\*\*] and has demonstrated the ability to manufacture products at the volumes and quality anticipated under this Agreement (such Incyte facility or Third Party facility, the "**Incyte Facility**" and such Third Party, an "**Approved CMO**"). Such transfer and implementation shall be sufficient to enable Incyte or such designee to perform the

Manufacturing Process and Manufacture of Licensed Compound Bulk Drug Substance and Licensed Compound Drug Product in accordance with Applicable Law, as more fully described in this Section 7.1 (the “ **Manufacturing Technology Transfer** ”), and shall be subject to a written plan approved by the JSC with respect to the Manufacturing Technology Transfer (the “ **Manufacturing Transition Plan** ”), with Incyte having final decision-making authority on the Manufacturing Technology Transfer (provided that Incyte may not expand the scope of the Know-How and Information to be transferred pursuant to Section 7.1(b) beyond that which is required hereunder). The Parties shall use Commercially Reasonable Efforts to effect the Manufacturing Technology Transfer to Incyte or its designee pursuant to this Section 7.1. The implementation of the Manufacturing Technology Transfer and Manufacturing Transition Plan shall be subject to the Incyte Facility being suitable for the Manufacture of the Licensed Compound Bulk Drug Substance as determined in accordance with this Section 7.1(a), as applicable, using the Manufacturing Process in compliance with Applicable Laws.

- (b) MacroGenics shall provide all reasonable assistance requested by Incyte to enable Incyte to implement the Manufacturing Process at the Incyte Facility, including by transferring to Incyte or such designee all Know-How and Information necessary for the Manufacturing Technology Transfer. In connection with the Manufacturing Technology Transfer, MacroGenics shall cause appropriate employees and representatives of MacroGenics to meet with employees and/or representatives of Incyte and the Approved CMO (to the extent applicable) at reasonable times to assist with the working up and use of the Manufacturing Process and with the training of the personnel of the Incyte Facility to the extent reasonably necessary or useful to use and practice the Manufacturing Process. Incyte shall reimburse MacroGenics’ FTE Costs and reimburse all reasonable Third Party Expenses incurred by MacroGenics in order to complete the Manufacturing Technology Transfer, within [\*\*] after receipt of any undisputed invoice from MacroGenics setting forth such costs. Subsequent to the occurrence of the Manufacturing Technology Transfer, at any time during the Term, upon either Party’s reasonable request, the other Party will provide to the requesting Party updated manufacturing process (including associated Know-How) Controlled by such other Party necessary or useful for the Manufacture of the Licensed Compound Bulk Drug Substance or the Licensed Compound Drug Product, at the requesting Party’s cost and expense.
- (c) Notwithstanding the occurrence of the Manufacturing Technology Transfer pursuant to this Section 7.1, Incyte shall have the right to Manufacture or have Manufactured clinical and/or commercial supplies of Licensed Compound or Licensed Products, to the extent set forth in Sections 7.2(d), 7.3(a), 7.3(b), and 12.9.
- (d) Any time after the completion of the Manufacturing Technology Transfer during the Term, to the extent that either Party makes any material modifications, improvements or other alterations to the Manufacturing Process, such Party shall use Commercially Reasonable Efforts, at the other Party’s sole cost and expense,

to provide access to such modifications, improvements or other alterations to such other Party, and to reasonably cooperate with the other Party in its efforts to ensure (including through the implementation of subsequent modifications to the Manufacturing Process, to the extent required) that the Incyte Facility and the MacroGenics Manufacturing Facilities (as applicable) Manufacture the Licensed Compound using such modified and/or improved Manufacturing Process and yielding comparable product.

- (e) Incyte shall require that all agreements executed between Incyte and any Approved CMO with respect to such Approved CMO's performance under this Agreement shall permit the assignment of such agreement, in its entirety in the event of termination of this Agreement (other than by Incyte pursuant to Section 12.3 or 12.6), to MacroGenics, without any consent rights by the Approved CMO (subject to MacroGenics agreeing to such assignment and the assumption of relevant obligations under such agreement).

## **7.2 General Clinical Supply Terms.**

- (a) **Clinical Supply Agreement** . Except as otherwise provided herein, MacroGenics shall have the responsibility for Manufacturing clinical supplies of the Licensed Compound Bulk Drug Substance (and at any time prior to the completion of the Manufacturing Technology Transfer, MacroGenics shall also have the responsibility for Manufacturing clinical supplies of the Licensed Compound Drug Product) for (i) MacroGenics' use in connection with any MacroGenics Combination Studies, (ii) Incyte's use in connection with any Monotherapy Studies or Incyte Combination Studies, and (iii) Collaborator's or Incyte's use in connection with any Collaborator Combination Studies. Within [\*\*] after the Effective Date, the Parties shall initiate negotiations for a clinical supply agreement (the "**Clinical Supply Agreement**") that will set forth the terms and conditions for MacroGenics' (or Incyte's per Section 7.2(d)) provision of clinical supplies of the Licensed Compound Bulk Drug Substance and Licensed Compound Drug Product, as applicable, to Incyte, MacroGenics, and any Collaborators and which will include all applicable provisions set forth in this Article 7 with respect to clinical supply and such other provisions as are customary and reasonable under the circumstances. The Parties shall also initiate negotiations to execute a quality agreement that shall further address and govern issues related to the quality of the Licensed Compound Bulk Drug Substance and Licensed Compound Drug Product to be supplied by MacroGenics pursuant to the Clinical Supply Agreement (the "**Clinical Quality Agreement**"). All negotiations for the Clinical Supply Agreement and Clinical Quality Agreement shall be undertaken by each Party in good faith. MacroGenics (or Incyte, per Section 7.2(d)) will use Commercially Reasonable Efforts to supply, or cause to be supplied, the Licensed Compound Bulk Drug Substance or Licensed Compound Drug Product, as applicable, in accordance with the provisions of this Agreement, and once executed, the Parties shall comply with their respective obligations to supply, or cause to be supplied, the Licensed Compound Bulk Drug Substance or Licensed Compound Drug Product, as

applicable, in accordance with the provisions of the Clinical Supply Agreement and the Clinical Quality Agreement. MacroGenics shall supply all quantities of Licensed Compound Bulk Drug Substance from the MacroGenics Manufacturing Facilities, and shall not have the right to subcontract the Manufacture of the Licensed Compound Bulk Drug Substance. Further, MacroGenics shall supply all quantities of Licensed Compound Bulk Drug Substance that are required for any particular Incyte Monotherapy Study or Incyte Combination Study from the same MacroGenics Manufacturing Facility, provided that such supply requirements do not exceed the reasonably available then-current planned capacity of the applicable Manufacturing Facility.

- (b) **Clinical Supply Costs** . MacroGenics shall provide clinical supplies of the Licensed Compound Bulk Drug Substance and/or Licensed Compound Drug Product, in accordance with the Clinical Supply Agreement and Clinical Quality Agreement, (i) at a cost equal to [\*\*] of the Manufacturing Expenses incurred by MacroGenics with respect to such quantities of the Licensed Compound Bulk Drug Substance and/or Licensed Compound Drug Product, to (x) Incyte for Monotherapy Studies, Incyte Combination Studies and for any Combination Studies conducted by Incyte’s licensees and (y) any Collaborator for any Collaborator Combination Studies for which at least [\*\*] of the costs are co-funded by Incyte (“ **Funded Collaborator Combination Studies** ”), and (ii) at a cost equal to [\*\*] of the Manufacturing Expenses incurred by MacroGenics with respect to such quantities of the Licensed Compound Bulk Drug Substance and/or Licensed Compound Drug Product, to any Collaborator for Collaborator Combination Studies other than Funded Collaborator Combination Studies. Within [\*\*] after the end of each month during which MacroGenics is conducting activities under the Clinical Supply Agreement, MacroGenics shall submit an invoice to Incyte for amounts owed by Incyte pursuant to the Clinical Supply Agreement. Incyte or Collaborator, as applicable, shall pay MacroGenics the full undisputed amount of such invoice within [\*\*] after receipt of such invoice.
- (c) **Clinical Supply Shortage** . In the event of a projected Clinical Supply Shortage of clinical supplies of the Licensed Compound Bulk Drug Substance and/or Licensed Compound Drug Product, as determined by either Party in its reasonable discretion, the following shall occur: (i) MacroGenics shall provide to Incyte reasonable assurances that the projected Clinical Supply Shortage will not actually occur, or promptly alert Incyte as to the nature of the Clinical Supply Shortage and cause of such shortage; and (ii) the JMC shall convene and both Parties shall use Commercially Reasonable Efforts to remedy the situation giving rise to such Clinical Supply Shortage and to take action to minimize the impact of the Clinical Supply Shortage, including (1) the reallocation of any material from either Party’s safety stock to match actual projected usage in the applicable Clinical Study(ies) causing such Clinical Supply Shortage and (2) triaging any clinical supply allocation for ongoing Clinical Studies of either Party. If MacroGenics does not provide such assurances, or if the situation is not remedied through good faith efforts by both Parties within the [\*\*] following such notification in a manner to

avoid an actual Clinical Supply Shortage, then, without limiting any remedies available to Incyte under this Agreement or the Clinical Supply Agreement, during a period extending for [\*\*] from the Effective Date, the clinical supplies would first be allocated to fulfill [\*\*] of Incyte's clinical supply needs over the first [\*\*] of the actual Clinical Supply Shortage period and thereafter the Parties will prorate subsequent supplies of Licensed Compound Bulk Drug Substance and/or Licensed Compound Drug Product based on the then-Binding Portion (" **Committed Supply** "), as of the date of either Party's notification to the other Party of such projected Clinical Supply Shortage, as further described in the Clinical Supply Agreement. In the event that an actual Clinical Supply Shortage occurs with respect to MacroGenics' supply of Licensed Compound Bulk Drug Substance or Licensed Compound Drug Product for each of [\*\*] calendar years, Incyte shall thereafter have the right to Manufacture or have Manufactured up to [\*\*] percent ([\*\*]%) of Incyte's clinical supply requirements of Licensed Compound Bulk Drug Substance or Licensed Compound Drug Product. A Clinical Supply Shortage due to the following causes shall not be deemed to be a breach of MacroGenics' clinical supply obligations pursuant to this Article 7 but shall still constitute a Clinical Supply Shortage for the purposes of this Section 7.2(c) and Section 7.2(d): (A) events of Force Majeure or (B) a mutually-agreed change in the specifications for Manufacture of the Licensed Compound Bulk Drug Substance and/or Licensed Compound Drug Product which causes a Clinical Supply Shortage within [\*\*] following the implementation of such change in specifications.

- (d) **Incyte Clinical Supply Rights** . Notwithstanding anything to the contrary herein, Incyte shall have the right to Manufacture (or have Manufactured) clinical supplies of the Licensed Compound Bulk Drug Substance and/or Licensed Compound Drug Product at the Incyte Facility, (i) in the event of a Clinical Supply Shortage, solely to the extent necessary to cover the projected shortfall of Licensed Compound Bulk Drug Substance and/or Licensed Compound Drug Product relative to committed Orders, or as otherwise set forth in subsection (c) above, or (ii) for the purpose of any Pivotal Studies of Licensed Product that are funded by Incyte. In the event that Incyte Manufactures, or has Manufactured, clinical supplies of the Licensed Compound Bulk Drug Substance and/or Licensed Compound Drug Product for MacroGenics (it being understood that MacroGenics may request such Licensed Compound Bulk Drug Substance and/or Licensed Compound Drug Product for MacroGenics Combination Studies and Acquirer Combination Studies), Incyte shall use Commercially Reasonable Efforts to provide to MacroGenics the quantities of Licensed Compound Bulk Drug Substance and/or Licensed Compound Drug Product requested by MacroGenics pursuant to committed Orders, and MacroGenics shall reimburse Incyte, with respect to a MacroGenics Combination Study, [\*\*] ([\*\*]%) of Incyte's Manufacturing Expenses, irrespective of whether such Licensed Compound Bulk Drug Substance and/or Licensed Compound Drug Product is used by MacroGenics.

(e) **Forecasts and Orders .**

- (i) **Rolling Forecast .** Commencing on the Effective Date, and on or before the [\*\*] day of each Calendar Quarter thereafter, each Party shall furnish the other Party via the JMC with (A) a rolling forecast of the quantities of the Licensed Compound Bulk Drug Substance and/or Licensed Compound Drug Product for which the other Party (for Incyte on behalf of itself and any Collaborators) reasonably expects to submit Orders in each calendar month during the following [\*\*] calendar months (the “ **Rolling Forecast** ”), and (B) a rolling, non-binding forecast of the quantities of the Licensed Compound Bulk Drug Substance and/or Licensed Compound Drug Product for which the other Party reasonably expects to submit Orders in each calendar quarter for months [\*\*] through [\*\*] (the “ **Long Term Forecast** ”), in each case of (A) and (B), for the purpose of conducting Monotherapy Studies, Incyte Combination Studies, Collaborator Combination Studies, or MacroGenics Combination Studies, as applicable. For the avoidance of doubt, the Long Term Forecast and months [\*\*] through [\*\*] of the Rolling Forecast will not be binding on the Party submitting such forecast, and months [\*\*] through [\*\*] of the Rolling Forecast will be binding on the Party submitting such forecast (the “ **Binding Portion** ”).
- (ii) **Orders .** From time to time during the Term, Incyte and MacroGenics will enter into mutually-agreeable orders that reflect the Binding Portion of the Rolling Forecast (each, an “ **Order** ”) pursuant to which Incyte will order, and MacroGenics will agree to supply, (or, if Incyte is Manufacturing clinical supply for MacroGenics’ use, pursuant to which MacroGenics will order, and Incyte will agree to supply) such quantities of clinical supplies of the Licensed Compound Bulk Drug Substance and/or Licensed Compound Drug Product as specified in the Order, on the terms agreed upon by the Parties therein and the Clinical Supply Agreement. An Order shall be binding on the Parties in accordance with the terms and conditions of the Clinical Supply Agreement; provided that each Party shall submit and the other Party shall accept all orders consistent with the most recent Rolling Forecast and the provisions of this Section 7.2(e)(ii). Each Order will specify: (A) the quantities of Licensed Compound Bulk Drug Substance and/or Licensed Compound Drug Product to be supplied by MacroGenics, (B) the estimated cost of Licensed Compound Bulk Drug Substance and/or Licensed Compound Drug Product to be supplied, (C) the delivery date for such quantities of Licensed Compound Bulk Drug Substance and/or Licensed Compound Drug Product and (D) the testing to be conducted and documentation to be provided for the Licensed Compound Bulk Drug Substance and/or Licensed Compound Drug Product supplied under such Order. For all units of Licensed Compound Bulk Drug Substance and Licensed Compound Drug Product that MacroGenics Manufactures for its own use or use by its Development Partners in connection with a MacroGenics Combination Study, MacroGenics shall submit to Incyte in advance of such supply a confirmatory “Order” indicating the information set forth in (A) through (D) with respect to the quantities that it will supply.

**7.3 General Commercial Supply Terms**

**(a) Licensed Compound Bulk Drug Substance**

- (i) Beginning [\*\*] prior to the anticipated Initiation of the [\*\*] Pivotal Study, and at least [\*\*] prior to January 1<sup>st</sup> of each Calendar Year, Incyte, with input from MacroGenics, shall (x) determine the amounts of Licensed Compound Bulk Drug Substance to fulfill the annual projected global commercial supply of Licensed Compound Drug Product for such Calendar Year (the “**Annual Global Commercial Supply Forecast**”) and (y) provide a non-binding summary of the projected global commercial supply of Licensed Compound Drug Product for the following [\*\*] Calendar Years. Each applicable forecast shall reasonably reflect MacroGenics’ reasonably forecasted market demand for Licensed Compound Drug Product in connection with the Commercialization of MacroGenics Pipeline Assets as a component of a MacroGenics Combination Regimens in the applicable Calendar Year.
- (ii) Except as otherwise provided herein, (x) MacroGenics shall have the right, but not the obligation, to Manufacture, at its expense, the lesser of (A) up to [\*\*] of the global commercial supply of the Licensed Compound Bulk Drug Substance corresponding to the Annual Global Commercial Supply Forecast, and (B) the annual then-current planned capacity of the MacroGenics Manufacturing Facilities (such amount that MacroGenics elects to Manufacture as set forth in this Section 7.3(a), the “**MacroGenics Commercial Supply Commitment**”), and (y) subject to successful Manufacturing Technology Transfer, FDA or EMA site validation, and Incyte’s notification that it is prepared to deliver the Incyte Commercial Supply Commitment, Incyte shall have the right and obligation to Manufacture, or have Manufactured, at the Incyte Facility, the percentage of the global commercial supply of the Licensed Compound Bulk Drug Substance other than the MacroGenics Commercial Supply Commitment, which shall be at least [\*\*] (such amount, the “**Incyte Commercial Supply Commitment**”). On an annual basis, the Parties will review and update, upon mutual agreement taking into consideration the prior year delivery, the Commercial Supply Commitments, including the percentage allocations for each Party to Manufacture (or in the case of Incyte, have Manufactured) its share of the global commercial supply of Licensed Compound Bulk Drug Substance. MacroGenics shall notify Incyte of its percent MacroGenics Commercial Supply Commitment within [\*\*] after its receipt of the Annual Global Commercial Supply Forecast, and each Party shall be obligated to deliver the full quantity of its Commercial Supply Commitment.
- (iii) In the event that MacroGenics delivers [\*\*] the MacroGenics Commercial Supply Commitment in [\*\*] out of any [\*\*] consecutive Calendar Year period (a “**Commercial Shortfall**”), Incyte shall have the right to limit

MacroGenics' future annual commercial supply volume such that it does not exceed the [\*\*] volume that MacroGenics delivered in either of such [\*\*] in which the Commercial Shortfall occurred (i.e. Incyte may adjust MacroGenics' future right to manufacture [\*\*] by dividing the [\*\*] volume that MacroGenics delivered in either of such [\*\*] years in which the Commercial Shortfall occurred by the total projected volume demand for future years).

- (iv) In addition, in the event that (x) MacroGenics Manufactures [\*\*] the entirety of the MacroGenics Commercial Supply Commitment, or (y) Incyte Manufactures or has Manufactured [\*\*] the entirety of the Incyte Commercial Supply Commitment, then without limitation of any other rights or remedies available to the Parties, the other Party shall have the right (but not the obligation) to Manufacture, itself (in the case of MacroGenics) or through the Incyte Facility (in the case of Incyte), the remaining amount of the Licensed Compound Bulk Drug Substance, to fulfill demand for [\*\*] of the Licensed Compound Bulk Drug Substance relative to the Annual Global Commercial Supply Forecast, in accordance with the terms of the Commercial Supply Agreement; provided that, at all times during the Term, MacroGenics shall use Commercially Reasonable Efforts to fulfill the MacroGenics Commercial Supply Commitment, and Incyte shall use Commercially Reasonable Efforts to fulfill the Incyte Commercial Supply Commitment; provided further, that, neither Party shall reallocate its then-current planned Manufacturing capacity to fulfill its respective Commercial Supply Commitment to any other compounds or products.
- (v) In the event that Incyte Manufactures or has Manufactured [\*\*] the entirety of the Incyte Commercial Supply Commitment in a given Calendar Year, to the extent that MacroGenics has any Licensed Compound Bulk Drug Substance available at such time that is not committed for MacroGenics Clinical Studies, Incyte may purchase such Licensed Compound Bulk Drug Substance from MacroGenics in accordance with Section 7.3(c). MacroGenics shall supply all quantities of Licensed Compound Bulk Drug Substance from the MacroGenics Large-Scale Supply Plant or the MacroGenics 1,000L Supply Plant, and shall not have the right to subcontract the Manufacture of the Licensed Compound Bulk Drug Substance to any Third Party without Incyte's prior written approval.
- (b) **Licensed Compound Drug Product** . Incyte shall be solely responsible, at its sole cost and expense, for Manufacturing from the Licensed Compound Bulk Drug Substance, itself or through an Approved CMO, [\*\*] of the projected global commercial supply of the Licensed Compound Drug Product.
- (c) **Commercial Supply Costs** . To the extent MacroGenics provides any commercial supply of the Licensed Compound Drug Product to Incyte pursuant to Section

7.3(a), the provisions of this Section 7.3(c) shall apply. MacroGenics shall provide such supply at a cost equal to [\*\*] of the Manufacturing Expenses incurred by MacroGenics with respect to such quantities of the Licensed Compound Drug Product. MacroGenics shall thereafter provide Incyte with an invoice, and Incyte would have up to [\*\*] following its receipt of such invoice to request reasonable supporting documentation from MacroGenics to confirm the amount of Manufacturing Expenses set forth therein. MacroGenics shall provide any such reasonable supporting documentation within [\*\*] following Incyte's request. Incyte shall pay MacroGenics the full undisputed amount of any invoice with respect to commercial supply of the Licensed Compound Drug Product within the later of (i) [\*\*] after Incyte's receipt of such invoice from MacroGenics, or (ii) [\*\*] after Incyte's receipt of the supporting documentation in accordance with the procedure described above.

- (d) **Commercial Supply Agreement** . No later than [\*\*] after Initiation of the first Pivotal Study, the Parties shall use Commercially Reasonable Efforts to execute a commercial supply agreement (the “**Commercial Supply Agreement**”) that will set forth the terms and conditions governing the provision of commercial supply of the Licensed Compound Bulk Drug Substance and/or Licensed Compound Drug Product from MacroGenics to Incyte.
- (e) **MacroGenics Commercial Supply Rights** . Notwithstanding anything to the contrary herein, in the event that Incyte (as determined by Incyte in its reasonable discretion) is, or could reasonably be expected to be unable to Manufacture or have Manufactured the Incyte Commercial Supply Commitment, then Incyte shall promptly inform MacroGenics upon becoming aware of the events giving rise to such inability or expected inability, and (i) MacroGenics shall have the right to Manufacture such quantities of the Licensed Compound Bulk Drug Substance that Incyte is unable to Manufacture or have Manufactured until such time that Incyte is prepared to deliver the Incyte Commercial Supply Commitment, and (ii) Incyte shall Manufacture or have Manufactured quantities of the Licensed Compound Drug Product using the Licensed Compound Bulk Drug Substance provided by MacroGenics. In the event that Incyte notifies MacroGenics in writing that Incyte does not have an Incyte Facility that is equipped for commercial supply purposes (in Incyte's reasonable discretion), MacroGenics shall have the right to Manufacture such quantities of the Licensed Compound Drug Product, in order to meet [\*\*] of the global supply requirement for the MacroGenics Combination Regimen.

**7.4 Records; Audit Rights** . Incyte and MacroGenics shall (and Incyte shall require that each Collaborator shall) keep complete and accurate records pertaining to its use and disposition of the Licensed Compound (including its storage, shipping and chain of custody activities) and, upon request of the other Party, shall make such records open to review by the other Party for the purpose of conducting investigations for the determination of the safety and/or efficacy of the Licensed Compound or a Party's and the Collaborator's compliance with this Agreement with respect to the Licensed Compound.

**7.5 Operation of MacroGenics Manufacturing Facilities.**

- (a) Subject to MacroGenics' compliance with its obligations under this Agreement and the Ancillary Agreements, MacroGenics shall have the sole discretion in the operation and use of the MacroGenics Manufacturing Facilities to fulfill its obligations to supply the Licensed Compound Bulk Drug Substance under this Agreement and any Ancillary Agreements, including with respect to the following:
- (i) scheduling of production runs to fulfill Orders and meet forecasts;
  - (ii) scheduling of cleaning and maintenance and shut down to perform such activities; and
  - (iii) allocation of staff to activities and tasks to be performed in each MacroGenics Manufacturing Facility.

**7.6 Quality Assurance.**

- (a) **Clinical Supply** . MacroGenics shall use Commercially Reasonable Efforts to implement and perform operating procedures and controls for sampling, stability and other testing of the Licensed Compound Bulk Drug Substance and Licensed Compound Drug Product, and for validation, documentation and release of the Licensed Compound Bulk Drug Substance and Licensed Compound Drug Product and such other quality assurance and quality control procedures as are required by the specifications, GMP and the Clinical Quality Agreement (collectively, "**Quality Assurance Measures**"), for clinical supply purposes. To the extent any clinical or commercial supplies of the Licensed Compound are Manufactured at the Incyte Facility pursuant to this Article 7, all parties involved in such Manufacture shall adhere to the Quality Assurance Measures, subject to any modifications that may be mutually agreed upon by the Parties in writing from time to time. MacroGenics shall lead any discussions between the Parties related to Quality Assurance Measures for clinical supply of the Licensed Compound Bulk Drug Substance and Licensed Compound Drug Product for Phase I Studies and Phase II Studies. Incyte shall lead any discussions between the Parties related to Quality Assurance Measures for clinical supply of the Licensed Compound Bulk Drug Substance and Licensed Compound Drug Product for Phase III Studies and Pivotal Studies.
- (b) **Commercial Supply** . Both Parties shall use Commercially Reasonable Efforts to implement and perform Quality Assurance Measures for commercial supply of the Licensed Compound Bulk Drug Substance and Licensed Compound Drug Product. To the extent MacroGenics or an Approved CRO Manufactures any Phase III Study or Pivotal Study clinical supply or any commercial supplies of the Licensed Compound Bulk Drug Substance and Licensed Compound Drug Product pursuant to this Article 7, such parties shall adhere to the Quality Assurance Measures implemented by Incyte in its production of the Licensed Compound Bulk Drug

Substance and Licensed Compound Drug Product, subject to any modifications that may be mutually agreed upon by the Parties in writing from time to time. Incyte shall lead any discussions between the Parties related to Quality Assurance Measures for commercial supply of the Licensed Compound Bulk Drug Substance and Licensed Compound Drug Product.

**7.7 Compliance with Law**. Each Party shall conduct all Manufacturing activities related to the Licensed Compound Bulk Drug Substance and Licensed Compound Drug Product in compliance with all Applicable Law, including applicable national and international ( *e.g.* , ICH, GCP, GLP, and GMP) guidelines.

## **ARTICLE 8 CONSIDERATION**

**8.1 Upfront Payment**. MacroGenics shall invoice Incyte after the Effective Date and, within [\*\*] after receipt of such invoice, Incyte shall pay to MacroGenics, One Hundred Fifty Million Dollars (\$150,000,000) as a one-time, non-refundable, non-creditable upfront license payment.

**8.2 Milestone Payments**. The applicable Party will notify the other Party within [\*\*] following the achievement of each milestone set forth below (each, a “ **Milestone** ”). Thereafter, MacroGenics shall submit an invoice to Incyte for the applicable Milestone payment, and within [\*\*] after Incyte’s receipt of such invoice, Incyte shall remit the applicable Milestone payment to MacroGenics. In addition, except with respect to the Breakthrough Designation Milestone, if for any reason any other Development Milestone corresponding to a Milestone payment does not occur prior to the occurrence of Regulatory Approval, then such prior non-occurring Development Milestone shall be deemed to occur concurrently with Regulatory Approval, and the applicable Milestone payments for the applicable Development Milestones shall become due and payable in accordance with this Section 8.2.

- (a) **Proof of Concept Milestone** . The following payments shall be payable once as specified in the table below with respect to the first applicable Clinical Study (conducted by: (i) Incyte, its Affiliates, or sublicensees (excluding Collaborators); (ii) MacroGenics, in the case of the Ongoing Clinical Study, to the extent it meets the definition of a Phase II Study or Phase III Study; (iii) MacroGenics, if Incyte agrees in writing, in its sole discretion, that such study satisfies the POC Development Milestone; or (iv) MacroGenics, in the case of a MacroGenics Clinical Study in an Indication for which the then-current Incyte Global Development Plan also includes the Initiation of a Clinical Study in the same Indication within the [\*\*] period following the date on which MacroGenics’ Clinical Study achieved Proof of Concept) to achieve the corresponding Milestone:

<b>Proof of Concept Milestone</b>	<b>Payment (USD)</b>		
	<b>1<sup>st</sup> Indication</b>	<b>2<sup>nd</sup> Indication</b>	<b>3<sup>rd</sup> Indication</b>
[**] or [**] Establishing Proof of Concept (the “ <b>POC Development Milestone</b> ”)	[**]	[**]	[**]

- (b) **Development Milestones** . The following payments shall be payable once as specified in the table below with respect to the first applicable Monotherapy Regimen, or Incyte Combination Regimen Developed by Incyte, its Affiliates, or sublicensees (excluding Collaborators) to achieve the corresponding Milestone (together with the POC Development Milestone, each, a “**Development Milestone**”):

<b>Development Milestone</b>	<b>Payment (USD)</b>		
	<b>1<sup>st</sup> Indication</b>	<b>2<sup>nd</sup> Indication</b>	<b>3<sup>rd</sup> Indication</b>
Treatment of [**] cumulative subjects across all Incyte Clinical Studies (including Incyte Monotherapy Studies and Incyte Combination Studies) in a single Indication for greater than [**] continuously at a recommended Phase II or Phase III defined dose and schedule	[**]	[**]	[**]
Initiation of a Pivotal Study	[**]	[**]	[**]
Breakthrough Designation Granted	[**]	N/A	N/A

- (c) **Regulatory Filing Milestones** . The following payments shall be payable once as specified in the table below, with respect to the first Monotherapy Regimen or Incyte Combination Regimen Developed by Incyte, its Affiliates, or sublicensees (excluding Collaborators) to achieve the corresponding Milestone (each, a “**Regulatory Filing Milestone**”):

<b>Regulatory Filing Milestone</b>	<b>Payment (USD)</b>		
	<b>1<sup>st</sup> Indication</b>	<b>2<sup>nd</sup> Indication</b>	<b>3<sup>rd</sup> Indication</b>
First filing of BLA in the U.S.	[**]	[**]	[**]
First filing of MAA with EMA or in [**] European Major Market countries	[**]	[**]	[**]

- (d) **Regulatory Approval Milestones** . The following payments shall be payable once as specified in the table below, with respect to the first Monotherapy Regimen or

[\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

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Incyte Combination Regimen Developed by Incyte, its Affiliates, or sublicensees (excluding Collaborators) to achieve the corresponding Milestone (each, an “**Approval Milestone**”):

<b>Approval Milestone</b>	<b>Payment (USD)</b>		
	<b>1<sup>st</sup> Indication</b>	<b>2<sup>nd</sup> Indication</b>	<b>3<sup>rd</sup> Indication</b>
Receipt of Regulatory Approval in U.S.	[**]	[**]	[**]
Receipt of Regulatory Approval in EU	[**]	[**]	[**]
Receipt of Regulatory Approval in Japan	[**]	[**]	[**]

- (e) **Annual Net Sales Milestones** . The Milestone payments set forth in this Section 8.2(e) shall each be payable to MacroGenics one time only, upon the first time during the Term that the total aggregate Net Sales of Licensed Products in any Calendar Year in the Territory during the applicable Royalty Term for the Licensed Products in the applicable country exceed the amounts set forth in the following table (each, a “**Sales Milestone**”).

<b>Annual Aggregate Worldwide Net Sales Milestones</b>	
<b>Sales Milestone</b>	<b>Payment (USD)</b>
Upon the first occasion that aggregate annual Net Sales of Licensed Products exceeds [**]	[**]
Upon the first occasion that aggregate annual Net Sales of Licensed Products exceeds [**]	[**]
Upon the first occasion that aggregate annual Net Sales of Licensed Products exceeds [**]	[**]
Upon the first occasion that aggregate annual Net Sales of Licensed Products exceeds [**]	[**]

If more than one Sales Milestone described in this Section 8.2(e) is achieved during the same Calendar Year, then Incyte shall pay MacroGenics only the Sales Milestone payment that corresponds to the highest Sales Milestone that was achieved in such Calendar Year, and any Sales Milestone that was earned in such Calendar Year but not paid shall be paid with respect to the first Calendar Year in which no other Sales Milestone was achieved. For purposes of clarity, only one Sales Milestone payment shall be owed, on each of the first occasions that aggregate annual Net Sales of Licensed Products exceed [\*\*], [\*\*], [\*\*] and [\*\*] under this Section 8.2(e).

**8.3 Royalty Obligations.** Incyte shall pay to MacroGenics royalties on the aggregate annual Net Sales of Licensed Products in the Territory, on a Licensed Product-by-Licensed Product basis, at the following rates set forth in this Section 8.3, in each case, subject to Sections 8.5 and 8.10:

<b>Annual Net Sales</b>	<b>Royalty Rate</b>
On the portion of worldwide annual Net Sales of Licensed Products less than or equal to [**]	15%
On the portion of worldwide annual Net Sales of Licensed Products greater than [**] and less than or equal to [**]	[**]
On the portion of worldwide annual Net Sales of Licensed Product greater than [**] and less than or equal to [**]	[**]
On the portion of worldwide annual Net Sales of Licensed Product greater than [**] and less than or equal to [**]	[**]
On the portion of worldwide annual Net Sales of Licensed Product greater than [**]	24%

**8.4 Royalty Term.** Royalties under Section 8.3 shall be payable on Net Sales on a Licensed Product-by-Licensed Product and country-by-country basis during the Royalty Term applicable to such Licensed Product in the applicable country. Following the expiration of the Royalty Term with respect to a Licensed Product in the applicable country (but not following an earlier termination of this Agreement), subject to the terms and conditions of this Agreement, Incyte shall have a perpetual, irrevocable, non-exclusive, fully-paid and royalty-free right and license, with the right to grant sublicenses, under the Licensed Technology and Label Combination Patents, to Exploit such Licensed Product in the Field in such country, and Net Sales of such Licensed Product in such country shall not count toward the milestones or royalty thresholds under Sections 8.2 or 8.3.

**8.5 Royalty Rate Adjustments; Licensed Product Pricing.**

- (a) The royalty rates set forth in Section 8.3 shall be subject to reduction as follows:
  - (i) On a country-by-country basis, to the extent a Licensed Product is sold in a country in the Territory in which one (1) or more Third Parties is selling or has previously sold one or more Biosimilar Products, and such Biosimilar Products, collectively, have achieved a [\*\*] or more market share of the aggregate market share of such Licensed Product and such Biosimilar Products (based on data provided by IMS Health Incorporated, Fairfield, Connecticut) as measured on a units sold basis in any Calendar Quarter, or

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if such data is not available, such other methodology for estimating the percentage of unit sales based market share of such Biosimilar Products in such country as agreed upon by the Parties, then Incyte's royalty obligations with respect to sales of such Licensed Product in such country during such Calendar Quarter and all future Calendar Quarters shall be reduced by [\*\*] of the applicable rate set forth in Section 8.3 (as such rate may be adjusted pursuant to Section 8.5(b) below);

- (ii) On a country-by-country basis and Licensed Product-by-Licensed Product basis, the royalty rates shall be reduced by [\*\*], in each country in the Territory in which, at the time applicable Net Sales occur, no Valid Claim of Licensed Patents Covers the Commercialization of the applicable Licensed Product; and
  - (iii) In no event shall the reduction available to Incyte pursuant to Sections 8.5(a)(i) and 8.5(a)(ii) reduce the royalties payable to MacroGenics for a given Calendar Quarter to less than [\*\*] of the royalty amount otherwise payable with respect to the applicable Licensed Product (the “ **Royalty Floor** ”) for such Calendar Quarter during the Royalty Term, provided that Incyte may credit against royalty obligations payable with respect to one or more future Calendar Quarter(s) any royalty reductions that Incyte was unable to take in any previous Calendar Quarter due to the Royalty Floor to the extent such credited royalty deductions do not cause the payments owed to MacroGenics in such future Calendar Quarter to be reduced below the Royalty Floor.
- (b) Notwithstanding anything to the contrary herein, in the event that Incyte or its Affiliates or sublicensees sell the Licensed Compound [\*\*] in a Calendar Year such that the [\*\*] for such Calendar Year is [\*\*] the [\*\*], [\*\*], [\*\*] or [\*\*], as applicable, then, as Incyte's [\*\*] and MacroGenics' [\*\*] with respect to such sales, within [\*\*] following the end of such Calendar Year, Incyte shall pay MacroGenics a one-time payment in an amount equal to the shortfall of the royalty that would have been owed had the [\*\*] of the [\*\*] been equal to the [\*\*], [\*\*], [\*\*], or [\*\*], as applicable. By way of example, if MacroGenics received \$[\*\*] in U.S. royalties over the course of a Calendar Year based on a [\*\*], and the [\*\*] in such Calendar Year was [\*\*], then Incyte would owe MacroGenics a shortfall payment of \$[\*\*] ([\*\*]).

**8.6** **Manner of Royalty Payment**. Within [\*\*] following the end of each Calendar Quarter ending during an applicable Royalty Term as to a Licensed Product in the Territory, Incyte shall provide MacroGenics with a report setting forth, on a Licensed Product-by-Licensed Product and country-by-country basis: (a) the Net Sales of such Licensed Product in such country, calculated in accordance with GAAP and (b) a calculation of the royalty payment due with respect to such Net Sales. Such report shall also include the exchange rates and other methodology used in converting Net Sales into U.S. Dollars from the currencies in which such sales were made for purposes of calculating the appropriate royalty rate and the royalty payment due, and the

application of the adjustments, if any, made in accordance with the terms of Section 8.5 and Section 8.10. Following MacroGenics' receipt of an undisputed report, MacroGenics shall send an invoice to Incyte for the royalty payment due for such Calendar Quarter. Within [\*\*] after Incyte's receipt of such invoice, Incyte shall pay all undisputed amounts due to MacroGenics pursuant to Section 8.3 with respect to Net Sales by Incyte, its Affiliates and their respective sublicensees for such Calendar Quarter.

**8.7 Monotherapy Development Sublicense Fees**. Incyte shall pay to MacroGenics [\*\*] of upfront fees and milestones received following the Effective Date but prior to the end of the Royalty Term by Incyte and its Affiliates from any Third Party with which Incyte enters into, during the [\*\*] after the Effective Date, a bona fide collaboration (such collaboration being limited solely to Development of the Monotherapy Regimen in the U.S., EU or Japan), pursuant to which Incyte grants such Third Party a sublicense under this Agreement (“**Monotherapy Sublicense Fees**”).

**8.8 Collaborator Sublicense Fees**. With respect to each sublicense granted by Incyte under this Agreement with respect to a Collaborator Combination Regimen, throughout the Term, Incyte shall have the right, but not the obligation, to charge Collaborators an upfront fee, milestone or royalties on the net sales of the Collaborator's Pipeline Asset in exchange for access to use the Licensed Compound in a Collaborator Combination Regimen, and shall pay to MacroGenics [\*\*] of any such upfront fee, milestones or royalties received during the Royalty Term by Incyte and its Affiliates from such Collaborator in connection with the applicable Collaborator Contract (“**Collaborator Sublicense Fees**”).

**8.9 Currency**. All payments under this Agreement shall be payable in U.S. Dollars. With respect to sales of a Licensed Product invoiced in a currency other than U.S. Dollars, such amounts and the amounts payable hereunder shall be expressed in their U.S. Dollars equivalents using the exchange rate Incyte uses for its public financial accounting purposes.

**8.10 Third Party Financial Obligations**.

- (a) Subject to Section 8.10(b) and 8.10(c) below, in the event that Incyte in its reasonable discretion determines that it is necessary or useful to obtain a license under any Patents controlled by a Third Party in order to Exploit the Monotherapy Regimen (such license, a “**Third Party License**”), then Incyte may credit up to [\*\*] of the amount of [\*\*], milestone payments, royalties, and other amounts actually paid by Incyte or its applicable Affiliate or, solely to the extent passed through to Incyte, its sublicensee, as the case may be, to such Third Party in connection with such Third Party License in a given Calendar Quarter, in each case to the extent allocable to rights to Exploit the Monotherapy Regimen, against future milestone payments and royalty payments owed to MacroGenics under Section 8.3 (as such royalties may be adjusted pursuant to Section 8.5(b)) in such Calendar Quarter (such credit, the “**Third Party License Credit**”); provided, however, that in no event will such Third Party License Credit reduce any royalty or milestone payment payable to MacroGenics to less than [\*\*] of the royalty or milestone amount otherwise payable with respect to the applicable Licensed Product. Any

share of such Third Party obligations that [\*\*] due to the [\*\*]. For clarity, the Third Party License Credit shall not be [\*\*].

- (b) As of the Execution Date, MacroGenics has the existing Third Party licenses set forth in Exhibit C (such licenses, the “ **Existing Third Party Licenses** ”). Incyte shall be solely responsible for paying to MacroGenics, with respect to the Existing Third Party Licenses, all license fees, milestone payments, and royalties (including royalty buyout payments) payable to the applicable Third Party licensor under such Existing Third Party License, to the extent resulting from Incyte’s Exploitation of the Licensed Compound and/or Licensed Product; provided that, [\*\*] shall have [\*\*] of the amount of such fees as a [\*\*] in the manner provided in [\*\*], subject to the [\*\*] and [\*\*] set forth in such [\*\*].
- (c) Notwithstanding anything to the contrary herein, Incyte shall be solely responsible for the payment of any and all costs and expenses, including upfront fees, milestone payments and royalty payments (without deduction pursuant to subsection (a)), and the assumption of any and all liabilities owed or incurred by Incyte or its Affiliates prior to the Effective Date or during the Term in connection with obtaining from [\*\*] any Third Party License for the Exploitation of the Licensed Compound (including the promotion of the Licensed Compound as a component of a MacroGenics Combination Regimen) under those Patents identified on Exhibit G that are owned or Controlled by [\*\*] as of the Effective Date (such [\*\*], the “[\*\*]”; such license, the “[\*\*]”). During the Term, Incyte will use Commercially Reasonable Efforts to (x) [\*\*] a [\*\*] that [\*\*] the [\*\*] under the [\*\*] by [\*\*] to [\*\*], [\*\*] generally consistent with the license set forth in Section 3.4(b) (except that the [\*\*] will be solely for the Exploitation of the Licensed Compound and any further sublicensing thereof shall be subject to the provisions to Section 3.2(c)); and (y) maintain the [\*\*] for so long as it is commercially reasonable for Incyte to do so. For so long as Incyte maintains the [\*\*] in effect, Incyte will not amend or modify the [\*\*] in a manner that would have a material adverse effect on MacroGenics’ rights under this Agreement without MacroGenics’ prior written consent. For clarity, the [\*\*] hereunder with respect to the [\*\*] shall not include [\*\*] to the Exploitation of any Pipeline Asset or the Combination of any Pipeline Asset with the Licensed Compound.
- (d) [\*\*] . Notwithstanding Section 8.10(a) and 8.10(c), during the Term and in the event that Incyte determines it is necessary to obtain from [\*\*] any Third Party License for the Exploitation of the Licensed Compound (including the promotion of the Licensed Compound as a component of a MacroGenics Combination Regimen) under those Patents identified on Exhibit H that are owned or Controlled by [\*\*] as of the Effective Date (such [\*\*], the “[\*\*]”; such license, the “[\*\*]”), Incyte shall use Commercially Reasonable Efforts to [\*\*] and [\*\*] the [\*\*], either as an extension of the [\*\*] or a [\*\*], and ensure that the terms of the [\*\*] permit the [\*\*] under the [\*\*] by Incyte to MacroGenics, on terms generally consistent with the license set forth in Section 3.4(b) and the provisions of Section 8.10(c), except that the [\*\*] will be solely for the Exploitation of the Licensed Compound,

and any [\*\*] thereof shall be subject to the provisions of Section 3.2(c). To the extent Incyte determines it is necessary to obtain the [\*\*], Incyte shall be solely responsible for the payment of any and all costs and expenses, including upfront fees, milestone payments and royalty payments, without deduction pursuant to 8.10(a) or any other provision of this Agreement.

**8.11 Taxes.** All payments due and payable under this Agreement will be made without any deduction or withholding of Taxes, unless such deduction or withholding Tax is required by Applicable Law in effect at the time of payout. If the paying Party is so required to deduct or withhold any Taxes, such Party shall (a) promptly notify the other Party of such requirement; (b) pay to the relevant authorities the full amount required to be deducted or withheld promptly upon the earlier of determining that such deduction or withholding is required or receiving notice that such amount has been assessed against the other Party; and (c) promptly forward to the other Party an official receipt (or certified copy), or other documentation reasonably acceptable to the other Party evidencing such payment to such authorities. Notwithstanding the foregoing, if as a result of (i) the assignment or transfer by operation of law or otherwise, of this Agreement by either Party to an Affiliate or Third Party outside of the U.S., or (ii) the exercise by either Party of its rights under this Agreement through an Affiliate or Third Party outside the U.S., withholding Tax in excess of the withholding Tax amount that would have been payable in the absence of such assignment or exercise of rights becomes payable with respect to any amount due to the other Party under this Agreement, then: (x) where the paying Party is the assigning or exercising Party described in (i) and (ii), the paying Party shall pay to the other Party such additional amounts as are necessary so that the other Party receives the amounts it would have received if such payments were not subject to such withholding Tax as a consequence of such assignment or exercise; and (y) where the receiving Party is the assigning or exercising Party described in (i) and (ii), the paying Party shall not be required to pay any amount in excess of the aggregate payment it would have been required to make based on the withholding Tax amount that would have been payable in the absence of such assignment or exercise of rights.

**8.12 Audit.** Each Party shall maintain complete and accurate records in the ordinary course of such Party's operations in order to permit the other Party to confirm the accuracy of the calculation of royalties, milestones, FTE Costs, Third Party Expenses, Manufacturing Expenses and other payments under this Agreement. Upon reasonable prior notice, but not more than [\*\*] per Calendar Year, such records shall be available during regular business hours for a period of [\*\*] from the end of the Calendar Year to which they pertain for examination by a "Big Four" independent certified public accounting firm ( *i.e.*, PriceWaterhouseCoopers, Deloitte & Touche, Ernst & Young or KPMG) selected by the requesting Party, having no prior engagement with the requesting Party, and reasonably acceptable to the other Party for the sole purpose of verifying the accuracy of the financial reports and correctness of the payments furnished by the other Party pursuant to this Agreement (it being agreed that if the Parties have collectively engaged with more than [\*\*] of the foregoing Big Four firms at the time of selection for an audit hereunder, then at such time the Parties shall reasonably cooperate and determine additional acceptable certified public accounting firms who may conduct such audit pursuant to this Section 8.12). Any such auditor shall not disclose the other Party's Confidential Information, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by the other Party or the amount of payments due by the other Party under this Agreement. Any amounts shown to

be owed but unpaid shall be paid within [\*\*] from the accountant's report, plus interest, as set forth in Section 8.13, from the original due date. Any amounts shown to have been overpaid shall be refunded within [\*\*] from the accountant's report. The requesting Party shall bear the full cost of such audit unless such audit discloses an underpayment by the other Party of more than [\*\*] of the amount due, in which case the other Party shall bear the full cost of such audit.

**8.13 Manner of Payment.** All payments due to a Party hereunder shall be made in U.S. Dollars by wire transfer of immediately available funds into an account designated by the receiving Party. If a Party does not receive payment of any sum due to it on or before the due date, such Party shall notify the other Party, and the paying Party shall have [\*\*] following receipt of such notice to pay any undisputed amount. Thereafter, interest shall accrue on the undisputed sum due to such Party until the date of payment at the per annum rate of [\*\*] over the then current prime rate quoted by Citibank in New York City of the maximum rate allowable by Applicable Law, whichever is lower.

## **ARTICLE 9 INTELLECTUAL PROPERTY MATTERS**

### **9.1 Inventorship; Ownership and Disclosure of Inventions.**

- (a) **Inventorship** . For purposes of this Section 9.1, inventorship with respect to any Inventions made by a Party's (or its Affiliates') own employees, agents, licensees or independent contractors in the course of conducting its activities under this Agreement, together with all intellectual property rights therein, shall be determined in accordance with U.S. patent laws.
- (b) **Ownership by Incyte** . As between the Parties, any Invention made solely by Incyte's (or its Affiliates') own employees, agents, licensees or independent contractors that arises in the course of performing any Monotherapy Study, Incyte Combination Study and/or any Collaborator Combination Study under this Agreement or performing any other activity under this Agreement, together with all intellectual property rights in each of the foregoing (collectively, "**Incyte Development IP** ") and Incyte's interest in Collaborator Development IP shall, as between Incyte and MacroGenics, be solely owned by Incyte.
- (c) **Ownership by MacroGenics** . As between the Parties, any Invention made solely by MacroGenics' (or its Affiliates') own employees, agents, licensees or independent contractors that arises in the course of performing any MacroGenics Combination Study under this Agreement or, performing any other activity under this Agreement, together with all intellectual property rights therein (collectively, "**MacroGenics Development IP** ") shall, as between MacroGenics and Incyte, be solely owned by MacroGenics and, to the extent useful or necessary to Exploit the Licensed Compound or Licensed Product, shall, subject to Section 15.3(d), constitute Licensed Patents or Licensed Know-How (as applicable) for purposes of this Agreement.

- (d) **Joint Ownership** . The Parties shall jointly own any Inventions for which the inventors include at least one employee, agent, or independent contractor of each Party that arise in the course of performing activities under this Agreement, together with all intellectual property rights therein (“ **Joint Inventions** ”). Subject to any licenses granted under this Agreement, each Party will have the right to practice and exploit any Joint Inventions without the duty of accounting to the other Party or seeking consent (for licensing, assigning or otherwise exploiting Joint Inventions) from the other Party by reason of the joint ownership thereof; and each Party hereby waives any right such Party may have under the Applicable Law of any jurisdiction to require any such approval or accounting, and, to the extent Applicable Law prohibits such a waiver, each Party shall be deemed to so consent. In furtherance thereof, upon the reasonable written request of a Party, the other Party will in writing grant such consents and confirm that no such accounting is required to effect the foregoing regarding Joint Inventions. Each Party shall promptly disclose to the other Party any invention disclosures, or other similar documents, submitted to it by its employees, agents or independent contractors describing the Joint Inventions, and all Information relating to such Joint Inventions to the extent necessary for the use of such Joint Invention in the Development or commercialization of the Licensed Compounds or the Licensed Products in the Field and, to the extent patentable, for the preparation, filing and maintenance of any Patent with respect to such Joint Invention. Any such Information provided to the other Party pursuant to this Section 9.1(d) shall, to the extent it refers to or describes the Pipeline Asset of the Disclosing Party, be Confidential Information of the Disclosing Party, and the Disclosing Party shall have the right to require that any Confidential Information related to its Pipeline Assets be redacted from any Patent application(s) Covering Joint Inventions, provided that such Confidential Information shall not be redacted to the extent it is necessary to understand the Joint Invention, or is otherwise required for the patentability of the Joint Invention.
- (e) **Assignment by Representatives** . Each Party shall (and Incyte shall require that each Collaborator shall) bind its Affiliates, and its or their employees, agents, consultants and contractors (collectively, “ **Representatives** ”) to disclose to such Party, and to assign to such Party or its Affiliate (or to Collaborator, as applicable) all right, title and interest in, any Invention that is made by such Representative in the course of conducting its activities under this Agreement, together with all intellectual property therein.

## **9.2 Prosecution of Patents**

- (a) **Licensed Patents** . Subject to the oversight of the JIPC and in accordance with the remainder of this Section 9.2(a), MacroGenics shall have the primary right and authority to prepare, file, prosecute and maintain the Licensed Patents (other than the Joint Patents, which are the subject of Section 9.2(e)) on a worldwide basis, and shall prepare, file, prosecute or maintain the Licensed Patents in any jurisdiction requested by Incyte to the extent permitted under Applicable Law using independent outside counsel mutually agreed upon by the Parties.

- (b) **Costs** . Such activities under Section 9.2(a) shall be conducted by MacroGenics (including through outside counsel selected in accordance with Section 9.2(a) above) at MacroGenics' own expense; provided that, Incyte shall reimburse MacroGenics for [\*\*] of the reasonable, out-of-pocket costs incurred by MacroGenics in preparing, filing, prosecuting and maintaining the Licensed Patents in accordance with this Section 9.2, within [\*\*] after receipt of any undisputed invoice from MacroGenics setting forth such costs; provided, further, that if, pursuant to MacroGenics' agreement with any Third Party, MacroGenics is reimbursed by such Third Party for any such out-of-pocket costs in the preparing, filing, prosecution or maintenance of any such Licensed Patent, Incyte's share of such out-of-pocket costs will be determined by [\*\*]. Notwithstanding the foregoing, if Incyte wishes to seek Patent protection for a Licensed Patent in a jurisdiction other than those set forth on Exhibit F (a "**Requested Licensed Patent**"), then Incyte shall so notify MacroGenics in writing and shall reimburse MacroGenics for [\*\*] of the reasonable, out-of-pocket costs incurred by MacroGenics in preparing, filing, prosecuting and maintaining such Requested Licensed Patent in such jurisdiction in accordance with this Section 9.2, within [\*\*] after receipt of any undisputed invoice from MacroGenics setting forth such costs; provided that, if the Requested Licensed Patent Covers a MacroGenics Pipeline Asset, then Incyte shall only be required to pay [\*\*] of the reasonable, out-of-pocket costs incurred by MacroGenics in preparing, filing, prosecuting and maintaining the Requested Licensed Patents in accordance with this Section 9.2; provided, further, that if, pursuant to MacroGenics' agreement with any Third Party, MacroGenics is reimbursed by such Third Party for any such out-of-pocket costs in the preparing, filing, prosecution or maintenance of any such Requested Licensed Patent, Incyte's share of such out-of-pocket costs will be determined by [\*\*].
- (i) **Opt-Out Right** . Incyte may cease reimbursement of MacroGenics' costs associated with any Licensed Patent pursuant to Section 9.2(a) by providing MacroGenics with at least [\*\*] written notice (an "**Opt Out Notice**"). Upon receipt of an Opt Out Notice, MacroGenics may cease to pursue any efforts to prepare, file, prosecute or maintain the applicable Licensed Patent(s). Upon expiration of the notice period set forth in the Opt Out Notice, any Licensed Patent which is the subject of such Opt-Out Notice shall cease to be a Licensed Patent for all purposes under this Agreement, including for purposes of the licenses granted by MacroGenics to Incyte under Section 3.1.
- (ii) **Incyte Review and Comment Rights** . Subject to the oversight of the JIPC, MacroGenics shall provide Incyte with a reasonable opportunity to review and comment on its efforts to prepare, file, prosecute and maintain Licensed Patents, including by providing Incyte with a copy of material communications from any patent authority regarding any Licensed Patent, and by providing drafts of any material filings or responses to be made in advance of submitting such filings or responses. MacroGenics shall consider Incyte's comments and cooperate with Incyte regarding such

communications and drafts in good faith, and shall use Commercially Reasonable Efforts to address Incyte's comments. If MacroGenics determines in its discretion to abandon or not maintain any Licensed Patent(s) in any country(ies) of the world, then MacroGenics shall provide Incyte with written notice of such determination within a period of time reasonably necessary to allow Incyte to determine its interest in such Licensed Patent(s) (which notice from MacroGenics shall be given no later than [\*\*] prior to any final deadline for any pending action or response that may be due with respect to such Licensed Patent(s) with the applicable patent authority). If Incyte provides written notice indicating that it wishes to acquire such Licensed Patent(s), MacroGenics shall, free of charge, assign and transfer to Incyte the ownership of, and interest in, such Licensed Patent(s) in such country(ies), at Incyte's own expense, and MacroGenics shall cooperate with Incyte for assignment and transfer of such Licensed Patent(s) in such country. Thereafter, all such assigned and transferred Patents will be deemed Incyte Patents and not Licensed Patents, and Incyte shall have the right to prepare, file, prosecute and maintain such Patents as set forth in Section 9.2(e), at its sole expense. Notwithstanding the foregoing, Incyte shall have no right to prepare, file, prosecute or maintain (a) any Licensed Patents, in connection with settlement proceedings, oppositions, *inter-partes* proceedings and other similar circumstances; and (b) any Patents that are otherwise owned or Controlled by MacroGenics that are not Licensed Patents.

- (c) **Incyte Patents; Incyte Development IP** . Incyte shall have the sole right and authority to prepare, file, prosecute and maintain Incyte Patents and Patents within the Incyte Development IP on a worldwide basis at its own expense.
- (i) **MacroGenics Review and Comment Rights** . Incyte shall provide MacroGenics with a reasonable opportunity to review and comment on its efforts to prepare, file, prosecute and maintain Incyte Patents and Patents within the Incyte Development IP in each case that specifically relate to the Licensed Compound or Licensed Product (collectively, the “ **Subject Patents** ”), including by providing MacroGenics with a copy of material communications from any patent authority regarding any Subject Patent, and by providing drafts of any material filings or responses to be made in advance of submitting such filings or responses. Incyte shall consider MacroGenics' comments regarding such communications and drafts in good faith, and shall use Commercially Reasonable Efforts to address MacroGenics' comments where practicable. If Incyte determines in its discretion to abandon or not maintain any Subject Patent(s) in any country(ies) of the world, then Incyte shall provide MacroGenics with written notice of such determination within a period of time reasonably necessary to allow MacroGenics to determine its interest in such Subject Patent(s) (which notice from Incyte shall be given no later than [\*\*] prior to any final deadline for any pending action or response that may be due

with respect to such Subject Patent(s) with the applicable patent authority). If MacroGenics provides written notice indicating that it wishes to acquire such Subject Patent(s), Incyte shall, in return for MacroGenics' payment to Incyte of [\*\*] of Incyte's accrued costs for filing, prosecution, and maintenance of such Subject Patent, assign and transfer to MacroGenics the ownership of, and interest in, such Subject Patent(s) in such country(ies), at MacroGenics' own expense, and Incyte shall cooperate with MacroGenics for assignment and transfer of such Subject Patent(s) in such country. Thereafter, MacroGenics shall have the right to prepare, file, prosecute and maintain such Patents at its sole expense and Incyte shall have no further rights in or obligation to MacroGenics with respect to such Subject Patent(s). Notwithstanding the foregoing, MacroGenics shall have no right to prepare, file, prosecute or maintain (a) any Subject Patents, in connection with settlement proceedings, oppositions, *inter-partes* proceedings and other similar circumstances; and (b) any Patents that are otherwise owned or Controlled by Incyte or its Affiliates that are not Subject Patents.

- (d) **Collaborator Development IP** . As between the Parties, Incyte shall have the sole right and authority to prepare, file, prosecute and maintain Patents within the Collaborator Development IP on a worldwide basis at its own expense.
- (e) **Joint Patents** .
  - (i) Subject to the governance of the JIPC and in accordance with the remainder of this Section 9.2(e), Incyte shall have the primary right and authority to prepare, file, prosecute and maintain the Patents included in the Joint Inventions (“ **Joint Patents** ”) at its own expense; provided, however, to the extent that claims of Joint Patents Cover MacroGenics Pipeline Assets, that MacroGenics shall have the right and authority to prepare, file, prosecute and maintain the Patents included in the Joint Inventions that specifically relate to MacroGenics Combination Regimens or MacroGenics Pipeline Assets (but not to the Licensed Compound or Licensed Product) (“ **MacroGenics-Responsible Joint Patents** ”).
  - (ii) **Costs** . Such activities under Section 9.2(e)(i) shall be conducted by the responsible Party (the “ **Responsible Party** ”) (including through outside counsel) at the Responsible Party's own expense; provided that, the other Party shall reimburse the Responsible Party for fifty percent (50%) of the reasonable, out-of-pocket costs incurred by the Responsible Party in preparing, filing, prosecuting and maintaining the applicable Joint Patent(s) in accordance with this Section 9.2(e)(i), within [\*\*] after receipt of any undisputed invoice from the Responsible Party setting forth such costs.
  - (iii) **Review and Comment Rights** . Subject to the governance of the JIPC, the Responsible Party shall provide the other Party with a reasonable opportunity to review and comment on its efforts to prepare, file, prosecute

and maintain the Joint Patents, including by providing such Party with a copy of material communications from any patent authority regarding any Joint Patent, and by providing drafts of any material filings or responses to be made in advance of submitting such filings or responses. The Responsible Party shall consider the other Party's comments and cooperate with the other Party regarding such communications and drafts in good faith, and shall use Commercially Reasonable Efforts to address the other Party's comments. If the Responsible Party determines in its discretion to abandon or not maintain any Joint Patent(s) for which it has prosecution and maintenance right pursuant to Section 9.2(e)(i) in any country(ies) of the world, then the Responsible Party shall provide the other Party with written notice of such determination within a period of time reasonably necessary to allow the other Party to determine its interest in acquiring the Responsible Party's interest in such Joint Patent(s) (which notice from the Responsible Party shall be given no later than [\*\*] prior to any final deadline for any pending action or response that may be due with respect to such Joint Patent(s) with the applicable patent authority). Upon written notice from such Party that it wishes to acquire the Responsible Party's interest in such Joint Patent(s), the Responsible Party shall, free of charge, assign and transfer to the other Party the Responsible Party's interest in such Joint Patent(s) in such country(ies), at the other Party's own expense, and the Responsible Party shall cooperate with the other Party for assignment and transfer of such Joint Patent(s) in such country. Thereafter, all such assigned and transferred Patents will be deemed Patents of the assignee party and not Joint Patents, and the other Party shall have the right to prepare, file, prosecute and maintain such Patents at its sole expense and the Responsible Party shall have no further rights (including any license rights hereunder) in or obligation to the other Party (including payment obligations hereunder) with respect to such Joint Patent(s).

**(f) Cooperation in Prosecution .**

- (i)** Each Party shall provide the other Party all reasonable assistance and cooperation in the prosecution efforts with respect to Licensed Patents (including Joint Patents) provided above in Sections 9.2(a) through 9.2(e). The Parties will discuss and consider in good faith filing separate Patent Rights that include claims that Cover Licensed Compound, Licensed Product and Combinations thereof (e.g., methods of manufacturing and uses of such Licensed Compound and Licensed Product) specifically or generically and claims that Cover only other compounds and methods of making and using such other compounds. Each Party shall provide the other Party all reasonable assistance and cooperation in providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution, as well as further actions as set forth below. Such assistance and cooperation shall include making a Party's

inventors and other scientific advisors reasonably available to assist the other Party's Patent prosecution efforts.

- (ii) All communications between the Parties relating to the prosecution efforts provided above in Sections 9.2(a) through 9.2(e), including copies of any draft or final documents or any communications received from or sent to patent offices or patenting authorities with respect to the applicable Patents, shall be considered Confidential Information of the Party controlling the prosecution of the applicable Patents pursuant to Sections 9.2(a) through 9.2(e) (the "**Prosecuting Party**"), except that, other than as set forth in Section 9.1(d), such communications in connection with Joint Patents shall be considered the Confidential Information of both Parties.
- (iii) The Prosecuting Party shall keep the other Party reasonably informed of its prosecution activities with respect to the applicable Patents.

### **9.3 Infringement of Patents by Third Parties**

- (a) **Notification** . Each Party shall promptly notify the other Party in writing of any existing, alleged or threatened infringement of any Licensed Patent, Joint Patent, or Subject Patent, of which it becomes aware, and shall provide all Information in such Party's possession or control relating to such infringement.
- (b) **Infringement of Licensed Patents** .
  - (i) Subject to Section 9.3(b)(ii) through 9.3(b)(vii), Incyte shall have the first right, but not the obligation, to bring an appropriate suit or other action against any Third Party engaged in any existing, alleged or threatened infringement of any Licensed Patent or Joint Patent, including the filing by a Third Party of any Biosimilar Application under the BPCI Act, and to compromise or settle such action by counsel of its choice.
  - (ii) Incyte shall notify MacroGenics of its election to take any action in accordance with Section 9.3(b)(i) at least [\*\*] before any time limit set forth in Applicable Law or regulation, including the time limits set forth under the BPCI Act. Notwithstanding the foregoing sentence, Incyte shall not initiate any such suit or take such other action with respect to any Licensed Patent or Joint Patent without first consulting with MacroGenics and giving good faith consideration to any reasonable objection from MacroGenics regarding Incyte's proposed course of action. MacroGenics shall cooperate in the prosecution of any suit under this Section 9.3 as may be reasonably requested by Incyte. In the event that Incyte elects not to initiate a lawsuit or take other reasonable action with respect to an infringement described in Section 9.3(b)(i), MacroGenics shall have the right, but not the obligation, to initiate such suit or take such other action, after providing [\*\*] (or [\*\*] in the event there is a time limit) notice to Incyte and giving good-faith

consideration to Incyte's reason(s) for not initiating a suit or taking other action; provided, however, that if Incyte has notified MacroGenics that it is not proceeding with an action on the advice of competent outside counsel that has evaluated patent scope, validity, enforceability, and/or possible infringement defenses, then MacroGenics shall not commence an action as described in this Section 9.3(b)(ii) until such time that (A) the Parties have agreed that such action should be commenced or (B) a mutually-agreeable Third Party expert has mediated such disagreement and determined that such action is reasonably unlikely to have a material adverse effect on the Licensed Patents, Joint Patents, or Subject Patents. If, prior to the outcome of such determination by such Third Party expert, a time limit will expire or deadline occur that will prevent or limit the ability to initiate or conduct such suit or action, MacroGenics shall have the right to proceed with such suit or action until the outcome of the determination, at which point MacroGenics may continue with such suit or action only in accordance with the determination.

- (iii) Without limiting the obligations of the Parties under subsection (ii) above, if one Party elects to bring suit or take action under this Section 9.3(b) against an infringement, then the other Party shall have the right, prior to commencement of the suit or action, to join any such suit or action at its own cost and expense.
- (iv) Incyte will have sole decision-making authority with respect to the determination of which Incyte Patents, and primary decision-making authority with respect to the determination of which Licensed Patents or Joint Patents, to submit to a Third Party that files a Biosimilar Application, or any other act of patent information exchange or listing as required by the BPCI Act or other similar measure in any other country in the Territory; provided that (A) to the extent permitted by Applicable Law, Incyte shall confer in good faith with MacroGenics regarding which, if any, Licensed Patents or Joint Patents are listed pursuant to 42 U.S.C. § 262(1)(3)(A) (or any successor legislation) or included in any litigation with the Third Party applicant and (B) prior to the submission of such list to the Third Party, MacroGenics shall have the right to review and comment on and (if agreed by the Parties) require Incyte to include additional Licensed Patents or Joint Patents therein.
- (v) Each Party shall provide to the Party enforcing any such rights under this Section 9.3(b) reasonable assistance in such enforcement, at such enforcing Party's reasonable request and expense, including joining such action as a party plaintiff if required by Applicable Law to pursue such action. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts, shall reasonably consider the other Party's comments on any such efforts, and shall consult with the other Party in any important aspects of such enforcement, including

determination of material litigation strategy and filing of important papers to the competent court.

- (vi) Each Party shall bear all of its own internal costs incurred in connection with its activities under this Section 9.3(b). In the event that the Parties are joined in suit or action against the infringement or the non-enforcing Party elects to join such suit or action and, in either case, elects to be represented by the same outside counsel as the enforcing Party, then the enforcing Party shall be responsible for all expenses arising from such outside counsel, provided that the enforcing Party consents to such joint representation by outside counsel, such consent not to be unreasonably withheld, delayed or conditioned.
  - (vii) The Party not bringing an action with respect to infringement in the Territory under this Section 9.3(b) shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall at all times cooperate fully with the Party bringing such action.
  - (viii) Neither Party shall settle any claim, suit or action that it brought under this Section 9.3 involving Licensed Patents or Joint Patents that would either (A) involve any admission of invalidity or unenforceability of a Licensed Patent or Joint Patent or (B) result in the imposition of any liability on the non-enforcing party for which the enforcing party is not indemnifying the non-enforcing party pursuant to Article 14, without the prior written consent of the other Party, such consent not to be unreasonably withheld, delayed or conditioned.
- (c) **Infringement of Patents Claiming MacroGenics Pipeline Assets / MacroGenics Combination Regimens** . With respect to any infringement of any Patent that (i) Covers any MacroGenics Pipeline Asset or MacroGenics Combination Regimen and (ii) either (A) does not Cover the Licensed Compound or any Licensed Product or (B) did not exist as of the Execution Date and is being enforced with respect to activity that does not infringe (x) any composition of matter or formulation Patent with respect to the Licensed Compound nor (y) any method Patent that Covers the Licensed Compound as a Monotherapy Regimen, MacroGenics shall have the sole and exclusive right, but not the obligation, to bring, at MacroGenics' expense and in its sole control, an appropriate suit or other action against any Person engaged in such infringement of such Patent.
- (d) **Infringement of Incyte Patents; Incyte Development IP** . With respect to any infringement of any Incyte Patent or any Patent within the Incyte Development IP, Incyte shall have the sole and exclusive right, but not the obligation, to bring, at Incyte's expense and in its sole control, an appropriate suit or other action against any Person engaged in such infringement of such Patent.

- (e) **Infringement of Patents Claiming Incyte Pipeline Assets / Collaborator Pipeline Assets / Incyte Combination Regimens / Collaborator Combination Regimens** . With respect to any infringement of any Patent that Covers any Incyte Pipeline Asset, Collaborator Pipeline Asset, Incyte Combination Regimen or Collaborator Combination Regimen, as between the Parties, Incyte shall have the sole and exclusive right, but not the obligation, to bring, at Incyte's expense and in its sole control, an appropriate suit or other action against any Person engaged in such infringement of such Patent.
- (f) **Allocation of Proceeds** . If either Party recovers monetary damages or a monetary settlement from any Third Party in a suit or action brought under Section 9.3(b) or any royalties, milestones or other payments from a license agreement with a Third Party related to any alleged infringement as to which such Party had a right to bring a suit or other action pursuant to Section 9.3(b), then to the extent such damages or royalties result from the infringement of Licensed Patents, such recovery (“ **Infringement Recovery** ”) shall first be allocated to the reimbursement of any expenses incurred by the Parties in such litigation, action or license negotiations; then, any remaining amounts shall be allocated to Incyte and treated as Net Sales for purposes of this Agreement; provided, however, that if MacroGenics is the party bringing the applicable suit or action, any amounts remaining amounts shall be allocated [\*\*] to MacroGenics and [\*\*] to Incyte. For clarity, with respect to all other infringement suits or actions brought by a Party ( e.g., with respect Incyte Patents or Patents within the Incyte Development IP or MacroGenics Development IP), the owning Party shall keep all recoveries.

**9.4 Patent Term Extensions** . The Parties shall consult and cooperate with each other in obtaining patent term extensions, adjustments, or restorations or supplemental protection certificates or their equivalents (each a “ **Patent Extension** ” and collectively “ **Patent Extensions** ”) in the Territory for the Licensed Patents and Joint Patents to the extent they Cover Licensed Compounds, Licensed Products, or the Monotherapy Regimen; provided that, (a) Incyte shall have the primary right and authority to seek and apply for Patent Extensions with respect to Licensed Patents and Joint Patents that [\*\*] claim Monoclonal Antibodies, subject to review and comment by MacroGenics, which Incyte shall consider in good faith; (b) MacroGenics shall have the primary right and authority to seek and apply for Patent Extensions with respect to Licensed Patents and Joint Patents that [\*\*] claim bi- or multi-specific antibodies, subject to review and comment by Incyte, which MacroGenics shall consider in good faith; and (c) the Parties shall discuss in good faith and shall mutually agree upon whether to seek and apply for Patent Extensions with respect to any Patents [\*\*] Monoclonal Antibodies and [\*\*]. In the event that a Party does not intend to seek a Patent Extension that is or will become available for a Licensed Patent or Joint Patent, it shall so inform the other Party in writing in sufficient time to permit the other Party to seek such Patent Extension. The Party that does not apply for a Patent Extension hereunder will cooperate fully with the other Party in making such filings or actions, including making available all required regulatory data and Information and executing any required authorizations to apply for such Patent Extension. All out-of-pocket expenses incurred in connection with activities of each Party with respect to the Licensed Patent(s) or Joint Patent(s)

for which such Party seeks a Patent Extension pursuant to this Section 9.4 shall be entirely borne by such Party.

**9.5 Infringement of Third Party Rights in the Territory.**

- (a) **Notice** . In the event that a Third Party makes any claim, gives notice, or brings any suit or other *inter-partes* proceeding against MacroGenics or Incyte, or any of their respective Affiliates or sublicensees (including Collaborators) for infringement or misappropriation of any intellectual property rights of a Third Party arising out of the Exploitation of any Licensed Product in the Field (“ **Third Party Infringement Claim** ”), the Party receiving notice of a Third Party Infringement Claim shall promptly notify the other Party.
- (b) **Defense** . Subject to Article 14, the Party or its respective Affiliate or sublicensee against which such Third Party Infringement Claim is brought shall have the sole right to defend such Third Party Infringement Claim.

**9.6 Patent Oppositions and Other Proceedings.**

- (a) **Licensed Patents** . If any Licensed Patent or Joint Patent becomes the subject of any proceeding commenced by a Third Party within the Territory in connection with an opposition, reexamination request, action for declaratory judgment, nullity action, interference, *inter-partes* review, post-grant review, other patent office administrative proceedings or other attack upon the validity, title or enforceability thereof (a “ **Third Party Patent Challenge** ”) (except insofar as such action is a counterclaim to or defense of, or accompanies a defense of, an action for infringement against a Third Party under Section 9.5, in which case the provisions of Section 9.5 shall govern), the Prosecuting Party as to such Licensed Patent or Joint Patent shall have the discretion whether to defend and shall control any defense of such Licensed Patent or Joint Patent, at its own expense; provided, however, that if the Prosecuting Party, declines or fails to take any action to defend such Third Party Patent Challenge within [\*\*] of the commencement thereof, then the other Party shall have the right to defend and shall control any defense of such Licensed Patent or Joint Patent, at its own expense.
- (b) **Third Party Patent Rights** . Except with respect to any Patents within the [\*\*] or [\*\*] (in which case the provisions of Section 10.2(j) shall govern), if either Party desires to bring an opposition, reexamination request, action for declaratory judgment, nullity action, interference, *inter partes* review, post grant review, or other patent office administrative proceedings or other attack upon the validity, title or enforceability of a Patent owned or Controlled by a Third Party and that claims the Licensed Compound or a Licensed Product (either specifically or generically), or the use, manufacture, sale, offer for sale or importation of the Licensed Compound or a Licensed Product (either specifically or generically) (except insofar as such action is a counterclaim to or defense of, or accompanies a defense of, a Third Party’s claim or assertion of infringement under Section 9.5, in which case

the provisions of Section 9.5 shall govern), such Party shall so notify the other Party and the Parties shall promptly confer to determine whether to bring such action or the manner in which to settle such action. Each Party shall have the right, but not the obligation, to bring at its own expense such action in the Territory, provided that the Parties shall use reasonable efforts as practicable to coordinate and cooperate in bringing such action(s). The Party not bringing an action under this Section 9.6(b) shall be entitled to separate representation in such proceeding by counsel of its own choice and at its own expense, and shall cooperate fully with the Party bringing such action. Any awards or amounts received in bringing any such action shall be first allocated to reimburse the initiating Party's expenses in such action, and any remaining amounts shall be allocated between the Parties as provided in Section 9.3(f).

**ARTICLE 10  
REPRESENTATIONS, WARRANTIES AND COVENANTS**

**10.1 Mutual Representations, Warranties and Covenants**. Each of the Parties hereby represents and warrants to the other Party as of the Execution Date and, as applicable, hereinafter covenants that:

- (a) **Organization** . It is a corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement.
- (b) **Binding Agreement** . This Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity).
- (c) **Authorization** . The execution, delivery, and performance of this Agreement by such Party have been duly authorized by all necessary corporate action and do not conflict with any agreement, obligation, instrument, or understanding, oral or written, to which it is a party or by which it is bound, nor violate any Applicable Law or any order, writ, judgment, injunction, decree, determination, or award of any Governmental Authority presently in effect applicable to such Party.
- (d) **No Further Approval** . It is not aware of any government authorization, consent, approval, license, exemption of or filing or registration with any Governmental Authority under any Applicable Law, currently in effect, necessary for, or in connection with, the transactions contemplated by this Agreement or any other agreement or instrument executed in connection herewith, or for the performance by it of its obligations under this Agreement and such other agreements (save for Regulatory Approvals and similar authorizations from Governmental Authorities

necessary for the Exploitation of Licensed Compound and Licensed Products as contemplated hereunder), except as may be required to obtain clearance of this Agreement under the HSR Act.

- (e) **No Inconsistent Obligations** . It is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement, or that would impede the diligent and complete fulfillment of its obligations hereunder.
- (f) **Certain Actions** . It shall not take any actions between the Execution Date and the Effective Date that would, or would be reasonably likely to, cause any representations or warranties made by such Party in this Article 10 to be untrue or inaccurate in any material respect as of the Effective Date.

**10.2 Additional Representations and Warranties of MacroGenics** . MacroGenics represents and warrants as of the Execution Date and covenants to Incyte that:

- (a) To MacroGenics' Knowledge, there is no actual or threatened infringement or misappropriation of the Licensed Technology or Label Combination Patents by any Person in the Territory. MacroGenics (or its Affiliates) is the sole and exclusive owner of, or otherwise Controls pursuant to an Existing Third Party License, the Licensed Technology, Label Combination Patents and the Transferred Documentation. MacroGenics has all rights necessary to grant the licenses under the Licensed Technology and Label Combination Patents, and Rights of Reference to Regulatory Documentation that it grants to Incyte hereunder. During the Term, MacroGenics shall not, and shall cause its Affiliates not to, grant to any Third Party any rights that encumber or conflict with the rights granted to Incyte hereunder with respect to the Licensed Technology, Label Combination Patents or Transferred Documentation.
- (b) The Licensed Patents set forth on Exhibit A, together with the Label Combination Patents, represent all Patents Controlled by MacroGenics (or its Affiliates) that Cover or disclose the Licensed Compound or any Invention necessary or useful for the Exploitation of the Licensed Compound or Licensed Products in the Territory in the Field as of the Execution Date. The Licensed Patents and Label Combination Patents are free and clear of liens, charges or encumbrances other than licenses granted to Third Parties that are not inconsistent with the rights and licenses granted to Incyte hereunder. To MacroGenics' Knowledge, no Third Party has challenged or threatened in writing to challenge the scope, validity or enforceability of any Licensed Patent or Label Combination Patents (including, by way of example, through opposition or the institution or written threat of institution of interference, nullity or similar invalidity proceedings before the U.S. Patent and Trademark Office or any analogous foreign Governmental Authorities). MacroGenics or its Affiliates have timely paid all filing and renewal fees payable with respect to any Licensed Patents for which MacroGenics controls prosecution and maintenance, and with respect to all Label Combination Patents. The development of the

Licensed Patents and Label Combination Patents has not been funded, in whole or in part, by the U.S. government. To MacroGenics' Knowledge, as of the Execution Date, the Exploitation of the Licensed Compound as a Monotherapy Regimen does not infringe or misappropriate the intellectual property or proprietary rights of any Third Party in the Territory, [\*\*].

- (c) The Licensed Know-How is free and clear of liens, charges or encumbrances other than licenses granted to Third Parties that are not inconsistent with the rights and licenses granted to Incyte hereunder. MacroGenics and its Affiliates have taken commercially reasonable measures consistent with industry practices to protect the secrecy, confidentiality and value of all Licensed Know-How that constitutes trade secrets under Applicable Law (including requiring all employees, consultants and independent contractors to execute binding and enforceable agreements requiring all such employees, consultants and independent contractors to maintain the confidentiality of such Licensed Know-How), and, to MacroGenics' Knowledge, there has not occurred any unauthorized access, use, or disclosure of the Licensed Know-How. The development of the Licensed Know-How has not been funded, in whole or in part, by the U.S. government.
- (d) MacroGenics has not received any written notice or threat of any material suit, legal claim, action, proceeding or investigation against MacroGenics or any of its Affiliates that relates to the Licensed Technology or Label Combination Patents, and no judgment or settlement is owed by MacroGenics or any of its Affiliates in connection with the Licensed Technology or Label Combination Patents.
- (e) All current and former officers, employees, agents, advisors, consultants, contractors or other representatives of MacroGenics or any of its Affiliates who are inventors of or have otherwise contributed or are otherwise expected to contribute to the creation or development of any Licensed Technology or Label Combination Patents have or will have executed and delivered to MacroGenics or any such Affiliate, prior to contributing to the creation or development of any Licensed Technology or Label Combination Patents, a valid and enforceable assignment or other agreement regarding the protection of proprietary Information and the assignment to MacroGenics or any such Affiliate of such person's entire right, title and interest in and to any Licensed Technology and Label Combination Patents. To MacroGenics' Knowledge, no current officer, employee, agent, advisor, contractor, consultant or other representative of MacroGenics or any of its Affiliates is in violation of any term of any assignment or other agreement regarding the assignment, protection, or confidentiality of Licensed Patents, other Licensed Technology, or Label Combination Patents, or of any employment contract or any other contractual obligation relating to the relationship of any such Person with MacroGenics or any such Affiliate. Incyte has no obligation to contribute to any remuneration of any inventor employed or previously employed by MacroGenics or any of its Affiliates in respect of any such Inventions, Information and discoveries and intellectual property rights therein that are so assigned to MacroGenics or its Affiliate(s).

- (f) MacroGenics has prepared, maintained and retained all Transferred Documentation for the Licensed Compound and the Licensed Products in the Territory pursuant to and in accordance with all Applicable Law, including, as applicable, GLP. All activities conducted by or on behalf of MacroGenics with respect to Licensed Compound have been conducted in accordance with Applicable Law (including GLP and GMP).
- (g) To MacroGenics' Knowledge, other than under the Existing Third Party Licenses and [\*\*], no royalties, milestones, or other payments are owed to any Third Party for Patents controlled by such Third Party that are reasonably likely to be necessary or useful in order to Exploit the Licensed Compound or Licensed Products.
- (h) Neither MacroGenics nor any of its Affiliates has been debarred by the FDA, is the subject of a conviction described in Section 306 of the FFDCa or is subject to any similar sanction of other Governmental Authorities in the Territory, and neither MacroGenics nor any of its Affiliates has used, in any capacity, any Person who either has been debarred by the FDA, is the subject of a conviction described in Section 306 of the FFDCa or is subject to any such similar sanction. MacroGenics shall not engage, and shall ensure that its licensees and Representatives shall not engage in any capacity in connection with this Agreement or any ancillary agreements, any Person who either has been debarred by the FDA, is the subject of a conviction described in Section 306 of the FFDCa or is subject to any such similar sanction. MacroGenics shall inform Incyte in writing promptly if it or any Person engaged by MacroGenics or any of its Affiliates who is performing services under this Agreement or any ancillary agreements is debarred or is the subject of a conviction described in Section 306 of the FFDCa, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to MacroGenics' Knowledge, is threatened, relating to the debarment or conviction of MacroGenics, any of its Affiliates or any such Person performing services hereunder or thereunder.
- (i) MacroGenics is not subject to any agreement with any Third Party which would limit or restrict its ability to perform its obligations under this Agreement in any material respect.
- (j) MacroGenics covenants and agrees, and shall cause its Affiliates and any sublicensees (subject to the remainder of this subsection (j)) to covenant and agree, not to directly or indirectly challenge the validity, enforceability, patentability, or inventorship of any claim of any Patent within the [\*\*] or the [\*\*], except in response to a claim of infringement of the Patent within the [\*\*] or the [\*\*], as applicable. MacroGenics further agrees not to provide assistance or support, financial or otherwise, to any Third Party in bringing any such challenge to the infringement, validity, enforceability, patentability, or inventorship of any claim of any Patent within the [\*\*] or the [\*\*]. The foregoing restrictions with respect to the [\*\*] shall, subject to Section 10.3(e), apply until, upon inquiry by MacroGenics and confirmation by Incyte, the existence and continued effectiveness of the sublicense

granted to MacroGenics with respect to the [\*\*] and/or any [\*\*] thereto have terminated, changed or been amended otherwise. For clarity, the foregoing restrictions shall apply only to those [\*\*] that have received a [\*\*] or [\*\*], as applicable; provided further, that to the extent a Third Party who [\*\*] other than [\*\*] or [\*\*] within the [\*\*] or the [\*\*], the [\*\*] to such Third Party under such other intellectual property shall not be construed as an [\*\*] under this Section 10.2(j).

**10.3 Additional Representations and Warranties of Incyte**. Incyte represents and warrants as of the Execution Date and covenants to MacroGenics that:

- (a) Incyte has all rights necessary to grant to MacroGenics the licenses under the Incyte Patents and Rights of Reference to Regulatory Documentation related to the Licensed Compound or Licensed Products that it grants to MacroGenics hereunder.
- (b) Neither Incyte nor any of its Affiliates or any Collaborators, has been debarred by the FDA, is the subject of a conviction described in Section 306 of the FFDCA or is subject to any similar sanction of other Governmental Authorities in the Territory, and neither Incyte nor any of its Affiliates or any Collaborators has used, in any capacity, any Person who either has been debarred by the FDA, is the subject of a conviction described in Section 306 of the FFDCA or is subject to any such similar sanction. Incyte shall not engage, and shall ensure that its Affiliates, Representatives and Collaborators shall not engage, in any capacity in connection with this Agreement or any ancillary agreements, any Person who either has been debarred by the FDA, is the subject of a conviction described in Section 306 of the FFDCA or is subject to any such similar sanction. Incyte shall inform MacroGenics in writing promptly if it or any Person engaged by Incyte or any of its Affiliates or Collaborators who is performing services under this Agreement or any ancillary agreements is debarred or is the subject of a conviction described in Section 306 of the FFDCA, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to Incyte's Knowledge, is threatened, relating to the debarment or conviction of Incyte, any of its Affiliates or Collaborators performing services hereunder or thereunder.
- (c) Incyte is not subject to any agreement with any Third Party which would limit or restrict its ability to perform its obligations under this Agreement in any material respect.
- (d) To Incyte's Knowledge, [\*\*], no royalties, milestones, or other payments are owed to any Third Party for Patents controlled by such Third Party that are reasonably likely to be necessary or useful in order to Exploit the Licensed Compound or Licensed Products.

**10.4 No Other Representations or Warranties**. EXCEPT AS EXPRESSLY SET FORTH IN THIS ARTICLE 10, THE PARTIES MAKE NO REPRESENTATIONS OR WARRANTIES OF ANY KIND WHATSOEVER, EITHER EXPRESS OR IMPLIED, WRITTEN OR ORAL, IN

FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, INCLUDING ANY EXPRESS OR IMPLIED WARRANTY OF QUALITY, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR WARRANTY OF NON-INFRINGEMENT OR AS TO THE VALIDITY OF ANY PATENTS. EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE DEVELOPMENT, MANUFACTURE OR COMMERCIALIZATION OF ANY COMPOUND OR PRODUCT PURSUANT TO THIS AGREEMENT WILL BE SUCCESSFUL OR THAT ANY PARTICULAR SALES LEVEL WITH RESPECT TO ANY COMPOUND OR PRODUCT WILL BE ACHIEVED.

**ARTICLE 11  
CONFIDENTIALITY**

**11.1 Nondisclosure.** Each Party agrees that, during the Term and for a period of [\*\*] thereafter, the Party receiving Confidential Information (the “ **Receiving Party** ”) of the other Party (the “ **Disclosing Party** ”) shall (a) maintain in confidence such Confidential Information using not less than the efforts such Receiving Party uses to maintain in confidence its own confidential or proprietary Information of similar kind and value, (b) not disclose such Confidential Information to any Third Party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted below, and (c) not use such Confidential Information for any purpose except those permitted by this Agreement (it being understood that this Section 11.1 shall not create or imply any rights or licenses not expressly granted under this Agreement). Notwithstanding anything to the contrary in the foregoing, the obligations of confidentiality and non-use with respect to any trade secret within such Confidential Information shall survive such [\*\*] period for so long as such Confidential Information remains protected as a trade secret under Applicable Law.

**11.2 Exceptions.** The obligations in Section 11.1 shall not apply with respect to any portion of the Confidential Information that the Receiving Party can show by competent, written evidence:

- (a) is publicly disclosed by the Disclosing Party, either before or after it is disclosed to the Receiving Party hereunder;
- (b) is known to the Receiving Party or any of its Affiliates, without any obligation to keep it confidential or any restriction on its use, prior to disclosure to the Receiving Party or any of its Affiliates by the Disclosing Party;
- (c) is subsequently disclosed to the Receiving Party or any of its Affiliates on a non-confidential basis by a Third Party that to the Receiving Party’s Knowledge is not bound by a duty of confidentiality or restriction on its use;
- (d) is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party or any of its Affiliates, generally known or available, either before or after it is disclosed to the Receiving Party by the Disclosing Party;
- (e) is independently discovered or developed by or on behalf of the Receiving Party or any of its Affiliates without the use of or reference to the Confidential Information belonging to the Disclosing Party; or

- (f) is the subject of written permission to disclose provided by the Disclosing Party.

**11.3 Authorized Disclosure**. The Receiving Party may disclose Confidential Information belonging to the Disclosing Party only to the extent such disclosure is reasonably necessary in the following instances:

- (a) filing, prosecuting, maintaining, enforcing or defending Patents as permitted by this Agreement;
- (b) as reasonably required in generating Regulatory Documentation and obtaining Regulatory Approvals;
- (c) prosecuting or defending litigation, including responding to a subpoena in a Third Party litigation;
- (d) complying with Applicable Law or court or administrative orders;
- (e) complying with any obligation under this Agreement;
- (f) in communications with existing or bona fide prospective acquirers, merger partners, financing sources, investment bankers, lenders or investors, and consultants and advisors of the Receiving Party in connection with transactions or bona fide prospective transactions with the foregoing, in each case on a need to know basis and under appropriate confidentiality provisions substantially equivalent to those of this Agreement; provided, however, that the Receiving Party shall remain responsible for any violation of such confidentiality provisions by any Person receiving such Confidential Information; or
- (g) to its Affiliates, sublicensees or prospective sublicensees, subcontractors or prospective subcontractors, consultants, agents and advisors on a “need-to-know” basis in order for the Receiving Party to exercise its rights or fulfill its obligations under this Agreement, each of whom prior to disclosure must be bound by written obligations of confidentiality and restrictions on use of such Confidential Information that are no less restrictive than those set forth in this Article 11; provided, however, that, in each of the above situations, the Receiving Party shall remain responsible for any failure by any Person who receives Confidential Information pursuant to this Section 11.3(g) to treat such Confidential Information as required under this Article 11.

If and whenever any Confidential Information is disclosed in accordance with this Section 11.3, such disclosure shall not cause any such information to cease to be Confidential Information except to the extent that such disclosure results in a public disclosure of such information (other than by breach of this Agreement). Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party’s Confidential Information pursuant to Section 11.3(a) through Section 11.3(e), it will, except where impracticable or not legally permitted, give reasonable advance notice to the other Party of

such disclosure and use not less than the same efforts to secure confidential treatment of such information as it would to protect its own confidential information from disclosure.

**11.4 Terms of this Agreement**. The Parties acknowledge that this Agreement and all of the respective terms of this Agreement shall be treated as Confidential Information of both Parties, subject to the provisions of Section 11.3(f), 11.3(g) and 11.6.

**11.5 Publicity**. Without limiting the Parties' rights and obligations pursuant to Section 11.9 with respect to publications:

- (a) Each Party shall make a public announcement of the execution of this Agreement in the form attached as Exhibit D to this Agreement, which shall be issued at a time to be mutually agreed by the Parties, but no later than [\*\*] after the Execution Date. Except as required to comply with Applicable Law or as set forth in subsection (b), each Party agrees not to issue any other press release or other public statement disclosing other information relating to this Agreement or the transactions contemplated hereby without the prior written consent of the other Party, such consent not to be unreasonably withheld, delayed or conditioned.
- (b) The Parties acknowledge the importance of supporting each other's efforts to publicly disclose results and significant developments regarding the Licensed Products and other activities in connection with this Agreement that may include information that is not otherwise permitted to be disclosed under this Article 11, and that may be beyond what is required by Applicable Law, but in each case consistent with the need to keep investors informed regarding such Party's business in accordance with customary investor relations, and each Party may request to the right to make such disclosures from time to time. Such disclosures may include achievement of milestones, significant events in the Development and regulatory process, Commercialization activities and the like. Except for the initial press release(s) described in subsection (a), whenever a Party (the "**Requesting Party**") desires to make any such public disclosure, it shall first notify the other Party (the "**Cooperating Party**") of such planned press release or public announcement and provide a draft for review at least [\*\*] in advance of issuing such press release or making such public announcement (or, with respect to press releases and public announcements that are required by Applicable Law, or by regulation or rule of any public stock exchange (including NASDAQ), with as much advance notice as possible under the circumstances if it is not possible to provide notice at least [\*\*] in advance). The Requesting Party and Cooperating Party will discuss such proposed public disclosure in good faith. Unless otherwise permitted pursuant to Section 11.6 or required by Applicable Law, or by regulation or rule of any public stock exchange (including NASDAQ), the Requesting Party will not issue such press release or make such public announcement without the prior written consent of the Cooperating Party, not to be unreasonably withheld, conditioned or delayed, provided that the Requesting Party may issue such press release or make such public announcement if: (i) the contents of such press release or public announcement have previously been made public other than through a breach of

this Agreement by the Requesting Party, (ii) such press release or public announcement does not materially differ from, or relies solely on facts publicly disclosed in, a previously-approved press release or other publicly available information, and (iii) the Requesting Party notifies the Cooperating Party reasonably in advance of issuance. The principles to be observed in disclosures pursuant to this Section 11.5(b) shall include accuracy, compliance with Applicable Law and regulatory guidance documents, reasonable sensitivity to potential negative reactions of the FDA (and its foreign counterparts), and the need to protect competitively sensitive information regarding Licensed Products and the legal obligations and responsibility to keep investors informed regarding the Requesting Party's business.

**11.6 Securities Filings**. Notwithstanding anything to the contrary in this Article 11, in the event either Party proposes to file with the Securities and Exchange Commission or the securities regulators of any state or other jurisdiction a registration statement or any other disclosure document that describes or refers to the terms and conditions of this Agreement or any related agreements between the Parties, or requires the filing of this Agreement as an exhibit to such registration, statement or disclosure document, such Party shall notify the other Party of such intention and shall provide the other Party with a copy of relevant portions of the proposed filing at least [\*\*] prior to such filing (and any revisions to such portions of the proposed filing a reasonable time prior to the filing thereof), including any exhibits thereto that refer to the other Party or the terms and conditions of this Agreement or any related agreements between the Parties. The Party making such filing shall cooperate in good faith with the other Party to obtain confidential treatment of the terms and conditions of this Agreement or any related agreements between the Parties that the other Party reasonably requests be kept confidential or otherwise afforded confidential treatment, and shall only disclose Confidential Information that it is advised by outside counsel is legally required to be disclosed. Each Party acknowledges that the other Party may be required by securities regulators, including the Securities and Exchange Commission, or advised by such other Party's outside counsel that the financial terms, including the milestone amounts and/or royalty rates must be included in such filings. No notice shall be required under this Section 11.6 if the description of or reference to this Agreement or a related agreement between the Parties contained in the proposed filing has been included in any previous filing made by either Party in accordance with this Section 11.6 or otherwise approved by the other Party.

**11.7 Relationship to Confidentiality Agreement**. This Agreement supersedes the Prior CDA; provided, however, that all "Confidential Information" disclosed or received by the Parties and their Affiliates thereunder shall be deemed Confidential Information hereunder and shall be subject to the terms and conditions of this Agreement.

**11.8 Equitable Relief**. Given the nature of the Confidential Information and the competitive damage that could result to a Party upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages may not be a sufficient remedy for any breach of this Article 11. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 11.

**11.9 Publications.** The publishing Party shall have the right to publish results of all Clinical Studies and Development activities conducted pursuant to this Agreement, (a) with respect to Incyte as the publishing Party, in connection with any Incyte Pipeline Asset, Collaborator Pipeline Asset, Incyte Combination Regimen, Collaborator Combination Regimen or Monotherapy Regimen and any other activity Incyte is permitted to conduct under this Agreement related to the Licensed Compound or a Licensed Product and (b) with respect to MacroGenics as the publishing Party, in connection with any MacroGenics Pipeline Asset or MacroGenics Combination Regimen (and including, for clarity, any MacroGenics Combination Study (including translational data related thereto, pre-clinical data and other data related to Development activities conducted pursuant to this Agreement, but excluding pre-clinical data that is solely related to the Licensed Compound after the Study Transition Date), and the Ongoing Clinical Study (prior to the Study Transition Date)); provided, in each case ((a) and (b)) however, that the reviewing Party shall have the right to review all proposed publications with respect to the Licensed Compound or Licensed Products (including as a component of a Monotherapy Regimen or a MacroGenics Combination Regimen) prior to submission of such publication, for the purposes of identifying any relevant intellectual property or Confidential Information belonging in whole or in part to the reviewing Party and recommending any changes the reviewing Party reasonably believes are necessary to preserve any such intellectual property or Confidential Information. The publishing Party shall provide reviewing Party with a copy of the applicable proposed abstract, manuscript, or presentation no less than [\*\*] ([\*\*] in the case of abstracts) prior to its intended submission for publication. The reviewing Party shall respond in writing promptly and in no event later than [\*\*] after receipt of the proposed material with one or more of the following: (i) comments on the proposed material, which the publishing Party will consider in good faith but is not obligated to accept ([\*\*], for any such publications made or proposed to be made before the earlier of Licensed Compound Approval or [\*\*] after the Effective Date, to the extent [\*\*] to the proposed material (x) [\*\*] or [\*\*] and (y) may be incorporated consistent with the [\*\*], MacroGenics shall [\*\*]); or (ii) any concerns regarding patentability or protection of its Confidential Information. In the event of concern over Patent protection, the publishing Party agrees not to submit such publication or to make such presentation that contains such information until the reviewing Party is given a reasonable period of time, and in no event less than [\*\*], to seek Patent protection for any material in such publication or presentation which it believes is patentable. Subject to Section 11.3, any Confidential Information of the reviewing Party shall, absent the prior written consent of the reviewing Party, be removed by the publishing Party from such publication or presentation. In the case of conference abstracts and other rapid scientific communications, the Parties will use reasonable efforts to complete the review process in [\*\*] or less.

**11.10 Additional Obligations Relating to Competing Antibodies.**

- (a) In the event that MacroGenics or an Affiliate [\*\*] (i) [\*\*] owned or Controlled by MacroGenics (or its Affiliates); or (ii) [\*\*] by MacroGenics or an Affiliate, in each case (of (i) and (ii)) other than Licensed Compound, MacroGenics shall and shall cause its Affiliates to: (x) adopt reasonable written procedures to prevent any of MacroGenics' Representatives (excluding any MacroGenics [\*\*] or [\*\*], and [\*\*] or [\*\*], it being understood that such employees are otherwise subject to the applicable confidentiality obligations under this Agreement) involved in conducting such Clinical Studies or Commercialization from accessing or using any

Confidential Information of Incyte or its Affiliates or sublicensees, or any of their commercially-sensitive information or pricing information relating to the Licensed Compound or Licensed Products and (y) require such Representatives to [\*\*] and [\*\*] between MacroGenics and Incyte under this Agreement (including Joint Committee meetings) and [\*\*] to the Licensed Compound or any Licensed Product.

- (b) In the event that Incyte or an Affiliate directly or indirectly [\*\*], in each case which [\*\*] or [\*\*] ( e.g. [\*\*]), Incyte shall and shall cause its Affiliates to: (x) adopt reasonable written procedures to prevent any of Incyte's Representatives ([\*\*] or [\*\*], and [\*\*], it being understood that such employees are otherwise subject to the applicable confidentiality obligations under this Agreement) involved in conducting such Clinical Studies or Commercialization from accessing or using any Confidential Information of MacroGenics or its Affiliates or sublicensees, or any of their commercially-sensitive information or pricing information relating to the MacroGenics Pipeline Asset and (y) require such Representatives to [\*\*] and [\*\*] between MacroGenics and Incyte under this Agreement (including Joint Committee meetings) and [\*\*] to the MacroGenics Pipeline Asset.

## **ARTICLE 12 TERM AND TERMINATION**

**12.1 Term.** This Agreement shall become effective as of the Execution Date and, unless earlier terminated pursuant to this Article 12, shall continue in full force and effect as long as Incyte continues to Exploit the Licensed Compound or Licensed Products in accordance with the terms and conditions of this Agreement (the “ **Term** ”). The provisions of Article 1 (Definitions), Article 10 (Representations, Warranties and Covenants), Article 11 (Confidentiality), Article 13 (Dispute Resolution), Article 14 (Indemnification) and Article 15 (Miscellaneous), and Section 12.3 (Termination for Material Breach) and Section 12.7 (HSR Filing; Termination Upon HSR Denial), shall become effective on the Execution Date; the other provisions of this Agreement shall not become effective until the Effective Date.

**12.2 Unilateral Termination by Incyte.** Incyte shall have the right to terminate this Agreement in its entirety, or on a Licensed Product-by-Licensed Product basis, at any time after the Execution Date, for any or no reason, upon providing [\*\*] prior written notice to MacroGenics.

**12.3 Termination for Material Breach.** Either Party (the “ **Terminating Party** ”) may terminate this Agreement in its entirety, or on a country-by-country and Licensed Product-by-Licensed Product basis, in the event the other Party (the “ **Breaching Party** ”) has materially breached this Agreement, and such material breach has not been cured within [\*\*] after receipt of written notice of such breach by the Breaching Party from the Terminating Party (the “ **Cure Period** ”). The written notice describing the alleged material breach shall provide sufficient detail to put the Breaching Party on notice of such material breach. Any termination of this Agreement pursuant to this Section 12.3 shall become effective at the end of the Cure Period, unless the Breaching Party has cured any such material breach prior to the expiration of such Cure Period (or, if such material breach is not reasonably able to be cured within the Cure Period, the Breaching Party has notified the Terminating Party of its plan for curing such material breach, has

commenced and sustained its efforts to cure such material breach during the Cure Period and does cure such material breach within [\*\*] after the end of the Cure Period). The right of either Party to terminate this Agreement as provided in this Section 12.3 shall not be affected in any way by such Party's waiver of or failure to take action with respect to any previous breach under this Agreement.

**12.4 Termination by Incyte for Safety Reasons**. Incyte shall have the right to terminate this Agreement, at any time after the Effective Date at any time upon providing [\*\*] prior written notice to MacroGenics: (a) if [\*\*] responsible for Incyte's [\*\*] in good faith that the [\*\*] of the Licensed Product is such that the Licensed Product cannot continue to be Developed or administered to patients safely; or (b) upon the occurrence of [\*\*] serious safety-related events related to the use of the Licensed Product that cause Incyte [\*\*] safety [\*\*] of the Licensed Product [\*\*] of the Licensed Products.

**12.5 Termination for Patent Challenge**. MacroGenics may terminate this Agreement with respect to a Licensed Product (or this Agreement in its entirety if such Licensed Product is the only Product for which this Agreement is applicable), if Incyte or any of its Affiliates directly or indirectly disputes, or assists any Third Party to dispute, the validity of any granted Patent within the Licensed Patents in a litigation or other court proceeding with respect to such Licensed Product; provided, however, MacroGenics acknowledges and agrees that nothing in this Section 12.5 prevents Incyte from taking any of the actions referred to in this Section 12.5 and, provided further that MacroGenics shall not have the right to terminate if Incyte:

- (a) opposes, or assists any Third Party to oppose, the grant of a Patent pursuant to any application in relation to the Licensed Patents in an administrative proceeding, such as a patent re-examination, *inter-partes* review, or other post grant proceeding or opposition;
- (b) asserts invalidity as a defense in any court proceeding brought by MacroGenics, its Affiliates, sublicensees, successors or designees asserting infringement of a Licensed Patent; and/or
- (c) either (i) acquires a Third Party that has an existing challenge, whether in a court or administrative proceeding, against a Licensed Patent or (ii) licenses a product for which the licensor has an existing challenge, whether in a court or administrative proceeding, against a Licensed Patent.

**12.6 Termination for Bankruptcy**.

- (a) Either Party may terminate this Agreement in its entirety upon providing written notice to the other Party on or after the time that such other Party makes a general assignment for the benefit of creditors, files an insolvency petition in bankruptcy, petitions for or acquiesces in the appointment of any receiver, trustee or similar officer to liquidate or conserve its business or any substantial part of its assets, commences under the laws of any jurisdiction any proceeding involving its insolvency, bankruptcy, reorganization, adjustment of debt, dissolution, liquidation

or any other similar proceeding for the release of financially distressed debtors, or becomes a party to any proceeding or action of the type described above (each, an “**Insolvency Event**”), and such proceeding or action remains un-dismissed or un-stayed for a period of more than [\*\*].

- (b) All rights and licenses granted under or pursuant to this Agreement, including, for the avoidance of doubt, the licenses granted to Incyte pursuant to Section 3.1, are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the U.S. Code (“**Section 365(n)**”) and other similar laws in any jurisdiction outside the U.S. (collectively, the “**Bankruptcy Laws**”), licenses of rights to “intellectual property” as defined under the Bankruptcy Laws. Upon the occurrence of any Insolvency Event with respect to a Party (the “**Insolvent Party**”), the Insolvent Party agrees that the other Party (the “**Non-Insolvent Party**”), as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Laws. Further, each Party agrees and acknowledges that all payments hereunder, other than the upfront payment pursuant to Section 8.1, milestone payments pursuant to Section 8.2 the royalty payments pursuant to Section 8.3, and the payments pursuant to Section 8.10 do not constitute royalties within the meaning of Section 365(n) or relate to licenses of intellectual property hereunder. Each Party shall, during the term of this Agreement, create and maintain current copies or, if not amenable to copying, detailed descriptions or other appropriate embodiments, to the extent feasible, of all such intellectual property (Licensed Technology in the case of MacroGenics and Incyte Technology in the case of Incyte). Each Party agrees and acknowledges that “embodiments” of intellectual property within the meaning of Section 365(n) include laboratory notebooks, cell lines, product samples and inventory, research studies and data, Regulatory Approvals and Regulatory Documentation in each case to the extent related to the Licensed Compound and Licensed Products. If: (i) a case is commenced during the Term by or against a Party under the Bankruptcy Laws, (ii) this Agreement is rejected as provided for under the Bankruptcy Laws, and (iii) the Non-Insolvent Party elects to retain its rights hereunder as provided for under the Bankruptcy Laws, then the Insolvent Party (in any capacity, including debtor-in-possession) and its successors and assigns (including a Title 11 trustee), shall (x) provide to the Non-Insolvent Party immediately upon the Non-Insolvent Party’s written request copies of all such intellectual property (including embodiments thereof) held by the Insolvent Party and such successors and assigns, or otherwise available to them, and (y) not interfere with the Non-Insolvent Party’s rights under this Agreement, or any related agreements between the Parties, to such intellectual property (including such embodiments), including any right to obtain such intellectual property (or such embodiments) from another entity, to the extent provided in the Bankruptcy Laws. Whenever the Insolvent Party or any of its successors or assigns provides to the Non-Insolvent Party any of the intellectual property licensed hereunder (or any embodiment thereof) pursuant to this Section 12.6(b), the Non-Insolvent Party shall have the right to perform the Insolvent Party’s obligations hereunder with respect to such intellectual property, but neither such provision nor such performance by the Non-Insolvent Party shall release the

Insolvent Party from liability resulting from rejection of the license or the failure to perform such obligations. All rights, powers and remedies of the Non-Insolvent Party as provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including the Bankruptcy Laws) in the event of the commencement of a case by or against a Party under the Bankruptcy Laws. In particular, it is the intention and understanding of the Parties to this Agreement that the rights granted to the Parties under this Section 12.6 are essential to the Parties' respective businesses and the Parties acknowledge that damages are not an adequate remedy. The Parties agree that they intend the following rights to extend to the maximum extent permitted by Applicable Law, and to be enforceable under Section 365(n): (A) the right of access to any intellectual property (including embodiments thereof) of the Insolvent Party, or any Third Party with whom the Insolvent Party contracts to perform an obligation of the Insolvent Party under this Agreement, and, in the case of the Third Party, which is necessary for the Exploitation of the Licensed Compound or Licensed Products; and (B) the right to contract directly with any Third Party to complete the contracted work upon failure of the Insolvent Party to comply with its applicable obligations.

**12.7 HSR Filing; Termination Upon HSR Denial.** If Incyte or MacroGenics determines that an HSR Filing is necessary, it shall so notify the other Party, and each Party shall, within [\*\*] of the Execution Date (or such later time as may be agreed to in writing by the Parties), file with the U.S. Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice, and/or with equivalent foreign authorities, any HSR Filing required of it under the HSR Act in the reasonable opinion of either Party with respect to the transactions contemplated hereby. Each Party will use reasonable efforts to do, or cause to be done, all things necessary, proper and advisable to, as promptly as practicable, take all actions necessary to make the filings required of such Party or its Affiliates under the HSR Act. The Parties shall cooperate with one another to the extent necessary in the preparation of any such HSR Filing. Each Party shall be responsible for its own costs, expenses, and filing fees associated with any HSR Filing; provided, however, that [\*\*] shall be solely responsible for any [\*\*] (other than [\*\*] that may be incurred as a result of [\*\*] on the part of [\*\*]) required to be [\*\*] in connection with [\*\*]. If the Parties make an HSR Filing hereunder, then this Agreement shall terminate (a) at the election of either Party, immediately upon notice to the other Party, if the U.S. Federal Trade Commission or the U.S. Department of Justice, or an equivalent authority in the European Union, seeks a preliminary injunction under the Antitrust Laws against Incyte and MacroGenics to enjoin the transactions contemplated by this Agreement; or (b) at the election of either Party, immediately upon notice to the other Party, in the event that the HSR Clearance Date shall not have occurred on or prior to [\*\*] after the effective date of the HSR Filing. In the event of such termination, this Agreement shall be of no further force and effect.

**12.8 Effects of Termination.** All of the following effects of termination are in addition to the other rights and remedies that may be available to either of the Parties under this Agreement and shall not be construed to limit any such rights or remedies. In the event of termination of this Agreement (other than in connection with Section 12.7 and except as otherwise noted below), the

following provisions of this Section 12.8 shall apply from and after the effective date of termination:

- (a) Other than in the event of termination by Incyte pursuant to Section 12.3 or Section 12.6, without limiting the effect that such termination shall have on any provisions of this Agreement, other than those provisions that this Agreement expressly provides shall survive such termination, all rights and licenses granted herein to Incyte shall terminate, all such previously licensed rights shall revert to MacroGenics, and Incyte shall cease any and all Development, Manufacturing, and Commercialization activities with respect to the Licensed Compound and Licensed Products (to the extent such activities were being performed using such rights and licenses) as soon as is reasonably practicable under Applicable Law.
- (b) Other than in the event of termination by Incyte pursuant to Section 12.3 or Section 12.6 (in which events all payment obligations hereunder shall survive), all payment obligations hereunder shall terminate, other than those that are accrued and unpaid as of the effective date of such termination and royalties that become due under Section 8.3 with respect to Net Sales of the Licensed Compound and all Licensed Products made following the effective date of termination to the extent permitted under Section 12.8(f).
- (c) The Parties will enter into good-faith discussions with respect to any transition or conveyance of assets, rights, access to materials, or processes that are not otherwise transitioned pursuant to this Section 12.8 but may be necessary for the Parties' future development and commercialization activities with respect to the Licensed Compound and Licensed Products.
- (d) Solely in the event of a Qualifying Termination, Incyte hereby grants to MacroGenics, effective as of the effective date of such termination, a non-exclusive, transferable, fully paid-up, royalty-free, sublicenseable license in the Field in the Territory, under the Incyte Technology that Covers the Exploitation of, or is incorporated into, the Licensed Compound or any Licensed Product at the time of termination, solely to Exploit the Licensed Compound or Monotherapy Regimen; provided, however, that MacroGenics shall reimburse Incyte for any amounts paid by Incyte to any Third Party in connection with MacroGenics' exercise of its right to obtain such license (it being understood that MacroGenics shall have the right to decline to accept such license as to some or all of the rights in this subsection (d) if MacroGenics does not wish to assume the related Third Party obligation); provided further, that MacroGenics shall have the right, on a license-by-license basis, to terminate its license with respect to any Incyte Technology licensed under such Third Party license at any time subject to any limitations on termination rights and any notice and ongoing payment obligations under the applicable Third Party license. Notwithstanding the foregoing, any rights, licenses, or sublicenses granted by Incyte under the Incyte Technology under this subsection (d) shall continue only to the extent and only for so long as Incyte continues to have the contractual right under the applicable Third Party license (the

“ **Upstream License** ”) to extend such rights, licenses, or sublicenses to MacroGenics. Any assignee of Incyte’s rights under the applicable Upstream License will be required to take such assignment subject to the rights of MacroGenics under this subsection (d).

**(e) Wind-down .**

- (i)** The JSC shall coordinate the wind-down of the Parties’ activities under this Agreement.
- (ii)** Solely in the event of a Qualifying Termination: (A) Incyte, as soon as reasonably practicable after the effective date of such termination, upon MacroGenics’ written request, shall provide to MacroGenics, as applicable and to the extent permitted under any applicable Third Party contract, any material Information, including copies of all Clinical Study data and results, arising out of the performance by or on behalf of Incyte of activities under this Agreement and Controlled by Incyte to the extent solely relating to the Licensed Compound and any Licensed Products, including control of, and all Information relating to, the Global Safety Database; and (B) Incyte will reasonably cooperate with MacroGenics to provide a transfer of such material Information.
- (iii)** Other than in the event of termination by Incyte pursuant to Section 12.3 or Section 12.6, beginning on the date that notice of any termination of this Agreement is given by the terminating Party, (A) Incyte shall have no further right or obligation to commence or provide funding for any Clinical Study of the Licensed Compound, whether or not such Clinical Study had been Initiated on or before such date of notice of termination of this Agreement, except that: (x) if [\*\*]; and (y) if [\*\*] following the effective date of such termination or [\*\*], whichever is earlier; and (B) if [\*\*] as described in (y) above, [\*\*] (except to the extent otherwise provided above, [\*\*]).
- (iv)** Solely in the event of a Qualifying Termination, at MacroGenics’ request, but without expanding the provisions of Section 12.8(d) with respect to any Upstream License, Incyte shall use reasonable efforts to (x) assign to MacroGenics any and all Third Party agreements to which Incyte or any of its Affiliates are a party that relate exclusively to any Development, Commercialization or Manufacturing activities conducted in connection with the Licensed Compound or any Licensed Products prior to such termination (including agreements relating to the sourcing and Manufacture of the Licensed Compound or any Licensed Products or, to the extent the First Commercial Sale of the Licensed Compound or any Licensed Product has occurred, for sale, promotion, distribution, or use of such Licensed Compound or Licensed Product), or (y) if such assignment is not permitted under the relevant Third Party agreement: (1) grant to MacroGenics other

rights to provide to MacroGenics the benefit of such non-assignable agreement, at MacroGenics' expense, to the extent permitted under the terms of such non-assignable agreement; or (2) to the extent such grant is not permitted under the terms of such non-assignable agreement, discuss with MacroGenics in good faith an alternative solution to enable MacroGenics to receive, at MacroGenics' expense, the benefit of the terms of such non-assignable agreement.

- (v) Other than in the event of termination by Incyte pursuant to Section 12.3 or Section 12.6, in the event the Licensed Compound or Licensed Product are Manufactured by Incyte or its Affiliate or an Approved CMO, then, upon the written request of MacroGenics, Incyte shall supply MacroGenics with such Licensed Compound and Licensed Products and/or materials at a commercially reasonable price, until Incyte (or its Affiliate or Approved CMO) elects to cease Manufacturing of the Licensed Compound and Licensed Products, in which case: (x) Incyte will provide [\*\*] prior notice to MacroGenics of the election to cease such Manufacture, and (y) if necessary and at MacroGenics' cost and expense, Incyte will provide reasonable amounts of technical assistance reasonably necessary to assist MacroGenics in the start-up of Manufacturing of such the Licensed Compound and Licensed Products and/or materials, and/or obtaining Regulatory Approval of the Licensed Compound and Licensed Products.
- (f) Other than in the event of termination by Incyte pursuant to Section 12.3 or Section 12.6, at MacroGenics' request, Incyte shall transfer to MacroGenics, and [\*\*], any Licensed Compound or Licensed Product held by Incyte that has not been sold or used by Incyte within [\*\*] following such termination, [\*\*], with respect to such Licensed Compound and Licensed Products.
- (g) Other than in the event of termination by Incyte pursuant to Section 12.3 or Section 12.6, Incyte shall (i) transfer to MacroGenics any and all Regulatory Documentation and safety data Controlled by Incyte on the effective date of termination, to the extent such information relates solely to any Licensed Compound, Monotherapy Regimen, Licensed Products and, if applicable pursuant to Sections 5.8(a) or 5.8(c), MacroGenics Combination Regimens, (ii) transfer to MacroGenics any and all other related Know-How Controlled by Incyte on the effective date of termination, to the extent such Know-How relates solely to any Licensed Compound, Monotherapy Regimen or Licensed Products and (iii) upon MacroGenics' request, provide a Right of Reference to any Regulatory Documentation Controlled by Incyte on the effective date of termination, to the extent such Regulatory Documentation is necessary for MacroGenics or its licensees to Develop and/or Commercialize the Licensed Compound and, if applicable pursuant to Sections 5.8(a) or 5.8(c), MacroGenics Combination Regimens, and has not already been transferred to MacroGenics hereunder. MacroGenics shall [\*\*] and [\*\*] in order to complete the activities pursuant to this subsection (g), within [\*\*] after [\*\*] of any [\*\*].

- (h) Other than in the event of termination by Incyte pursuant to Section 12.3 or Section 12.6, Incyte shall return to MacroGenics all Licensed Know-How, including Transferred Documentation and Regulatory Documentation, previously provided to Incyte by or on behalf of MacroGenics.
- (i) Other than in the event of termination by Incyte pursuant to Section 12.3 or Section 12.6 (in which case Incyte's rights with respect to preparation, filing, prosecution, maintenance and enforcement activities under Article 9 with respect to Licensed Patents shall survive termination), MacroGenics shall have the right to assume all preparation, filing, prosecution, maintenance and enforcement activities under Article 9 with respect to Licensed Patents as to which Incyte has assumed the right and authority to prepare, file, prosecute, maintain or enforce; provided that MacroGenics shall notify Incyte in writing at least [\*\*] prior to the effective date of termination of this Agreement of those Licensed Patents for which MacroGenics wishes to assume such activities. During the period between delivery of such notice by MacroGenics and the effective date of termination, the Parties will discuss the list of Licensed Patents for which MacroGenics wishes to assume such activities, and following such discussion Incyte shall be free to continue, abandon or terminate without liability all preparation, filing, prosecution, maintenance and enforcement activities under Article 9 with respect to Licensed Patents (or the applicable activities) that are not included in such notice. Incyte will cooperate with MacroGenics and, if requested by MacroGenics, provide MacroGenics with reasonable assistance at MacroGenics' cost and expense, with the preparation, filing, prosecution, maintenance, and enforcement activities with respect to such Licensed Patents. In the event MacroGenics assumes any enforcement activities being conducted by Incyte prior to termination of this Agreement, then any amount received by MacroGenics in connection with a settlement, by award of a court, or pursuant to another dispute resolution with respect to such assumed activities shall first be used to reimburse the Parties for their respective costs incurred in connection with such action (whether before or after the effective date of termination), and any remaining amount shall be (i) allocated [\*\*] to MacroGenics and [\*\*] to Incyte to the extent the amount relates to infringing activity that occurred prior to the effective date of termination and (ii) retained [\*\*] by MacroGenics to the extent the amount relates to infringing activity that occurred after the effective date of termination.
- (j) Other than in the event of termination by Incyte pursuant to Section 12.3 or Section 12.6, for each Collaborator Contract that complies with the requirements of Section 3.2(b), Incyte shall assign such Collaborator Contract to MacroGenics, and MacroGenics shall assume such Collaborator Contract from Incyte; provided that MacroGenics shall not be obligated to participate in any cost-sharing arrangement in which Incyte had been participating under such Collaborator Contract; provided, however, that (i) in no event shall MacroGenics' obligations with respect to such Collaborator Contract be any greater than MacroGenics' obligations under this Agreement or its rights with respect to such Collaborator Contract be any less than MacroGenics' rights under this Agreement (it being understood that MacroGenics

shall not be required to supply any Licensed Compound Bulk Drug Substance or Licensed Compound Drug Product beyond the planned capacity of the MacroGenics Manufacturing Facilities allocated to such products, as applicable, prior to such termination); (ii) MacroGenics shall have no obligation to assume any Collaborator Contract if doing so would put MacroGenics in breach of such contract; and (iii) Incyte hereby agrees to defend, indemnify and hold harmless the MacroGenics Indemnitees from and against any and all Losses to which any MacroGenics Indemnitee may become subject as a direct result of any Claim by any Third Party (including any Collaborator) to the extent such Losses result from Incyte's breach of its obligations under the applicable Collaborator Contract prior to the date of assignment of such Collaborator Contract pursuant to this Section 12.8(j).

- (k) Other than in the event of termination by Incyte pursuant to Section 12.3 or Section 12.6, for each Development Agreement entered into between Incyte and a licensee or Third Party subcontractor of Incyte pursuant to Section 4.5, at MacroGenics' option, Incyte will assign such Development Agreement to MacroGenics; provided that MacroGenics shall notify Incyte in writing at least [\*\*] prior to the effective date of termination of this Agreement of those Development Agreement(s) which MacroGenics wishes to assume, and Incyte shall be free to terminate without liability any Development Agreement that is not included in such notice.

**12.9 Effect of Termination for MacroGenics Breach or Bankruptcy.** All of the following effects of termination are in addition to the other rights and remedies that may be available to either of the Parties under this Agreement and shall not be construed to limit any such rights or remedies. In the event of termination of this Agreement by Incyte pursuant to Section 12.3 or Section 12.6, the following provisions of this Section 12.9 shall apply from and after the effective date of termination:

- (a) The rights and licenses granted herein to MacroGenics pursuant to Section 3.4(b) or Section 5.4(a) or retained by MacroGenics, in each case, related to the Exploitation of the MacroGenics Pipeline Assets and the right to conduct or have conducted the MacroGenics Combination Studies shall continue in full force and effect, in accordance with and subject to the terms and conditions of this Agreement (including for clarity, the retained rights by MacroGenics in Section 3.3 and as applicable, the licenses in Section 3.4(b)); provided, however, that: (i) any such rights, licenses, or sublicenses granted by Incyte shall continue only to the extent and only for so long as Incyte continues to have the contractual right under the applicable Upstream License to extend such rights, licenses, or sublicenses to MacroGenics; and (ii) if MacroGenics' breach of its obligations under this Agreement constitutes a breach under an Upstream License, then MacroGenics shall not receive any rights under this Section 12.9(a) with respect to any rights, licenses, or sublicenses that are subject to such Upstream License. Any assignee of Incyte's rights under the applicable Upstream License will be required to take such assignment subject to the rights of MacroGenics under this Section 12.9(a). MacroGenics shall reimburse Incyte for any amounts paid by Incyte to any Third

Party in connection with MacroGenics' exercise of such licenses (it being understood that MacroGenics shall have the right to decline such license as to some or all of the rights in this subsection (a) upon written notice to Incyte if MacroGenics does not wish to assume the related Third Party obligation); provided further, that MacroGenics shall have the right, on a license-by-license basis, to terminate its license pursuant to this subsection (a) under such Third Party license at any time upon written notice to Incyte, subject to any limitations on termination rights and any notice and ongoing payment obligations under the applicable Third Party license.

- (b) All payment obligations hereunder shall survive, including those payment obligations that are accrued and unpaid as of the effective date of such termination; provided that Incyte may pursue remedies under Section 12.10 and, pending resolution of any claim for remedies under Section 12.10, Incyte may pay to a reputable Third Party escrow agent selected by Incyte and pursuant to a three-party agreement among Incyte, MacroGenics and the escrow agent up to [\*\*] of any royalties or milestones otherwise owed to MacroGenics hereunder (but in no event more than the amount reasonably being asserted by Incyte pursuant to Section 12.10 as damages arising from the applicable breach or bankruptcy), and such escrow agent shall hold all such payments pending resolution of the dispute hereunder; provided that, following resolution of the claim, the escrow agent will be instructed to allocate the payments between the Parties as follows: (i) first, the escrow agent will pay to Incyte the amount of damages, costs and other amounts that MacroGenics is required (or agrees) to pay to Incyte in connection with the applicable claim pursuant to Section 12.10, together with Incyte's costs and expenses in connection with bringing such claim, and (ii) any remaining amount will be paid to MacroGenics. The foregoing shall not be construed to limit Incyte's ability to recover any amount asserted against MacroGenics under Section 12.10 [\*\*] under this subsection (b).
- (c) All licenses granted to Incyte shall continue in full force and effect, in accordance with and subject to the terms and conditions of this Agreement.
- (d) At Incyte's option, in accordance with a commercially reasonable transition plan established by the JMC with the goal of allowing the Parties to continue to conduct their businesses following termination as contemplated under this Section 12.9, Incyte shall have the right, upon written notice to MacroGenics, to assume the Manufacture of one hundred percent (100%) of the global requirements of the Licensed Compound Bulk Drug Substance and Licensed Compound Drug Product (other than quantities that MacroGenics may manufacture for its own use in MacroGenics Combination Studies thereafter), following which MacroGenics shall not have the right to supply any Licensed Compound Bulk Drug Substance and Licensed Compound Drug Product unless expressly authorized by Incyte in writing. Until such time that Incyte so notifies MacroGenics that it is prepared to Manufacture all such global requirements, MacroGenics shall Manufacture and supply to Incyte up to [\*\*] ([\*\*]%) of MacroGenics' then-committed supply of

Incyte's global requirements of the Licensed Compound Bulk Drug Substance and/or Licensed Compound Drug Product, in accordance with the provisions of Section 7.2 and Section 7.3.

- (e) Incyte may at its sole discretion, in accordance with a commercially reasonable transition plan established by the JDC or JMC, as applicable, with the goal of allowing the Parties to continue to conduct their businesses following termination as contemplated under this Section 12.9, commence the Study Transition, IND Transition, Manufacturing Technology Transfer, and/or Information Transfer upon written notice to MacroGenics, if and to the extent the same have not been commenced as of the effective date of termination, as to which transitions Incyte may specify shortened timeframes to the extent compliance therewith by MacroGenics is reasonably practicable, and the obligations of MacroGenics in connection with the Study Transition, IND Transition, Manufacturing Technology Transfer, and/or Information Transfer shall continue until their completion in accordance with the terms and conditions of this Agreement.
- (f) Incyte (or its Collaborators, as applicable) shall have the sole right and responsibility to conduct any and all Clinical Studies Initiated by Incyte or its sublicensees or Collaborators prior to the effective date of such termination, but shall have no obligations in connection with any Clinical Studies being conducted by MacroGenics as of the effective date of such termination.

For clarity, any termination pursuant to this Section 12.9 shall not affect MacroGenics' rights with respect to maintaining continued access to the Global Safety Database.

**12.10 Remedies.** Except as otherwise explicitly set forth in this Agreement, termination or expiration of this Agreement shall not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination or expiration, nor prejudice either Party's right to obtain performance of any obligation. Each Party shall be free, pursuant to Article 13, to seek, without restriction as to the number of times it may seek, damages, costs and remedies that may be available to it under Applicable Law or in equity and shall be entitled to offset the amount of any damages and costs obtained against the other Party in a final determination under Article 13, against any amounts otherwise due to such other Party under this Agreement.

**12.11 Survival.** In the event of termination or expiration of this Agreement, in addition to the provisions of this Agreement that continue in effect in accordance with their terms, the following provisions of this Agreement shall survive: Article 1 (Definitions) (as applicable), Article 11 (Confidentiality), Article 12 (Term and Termination), Article 13 (Dispute Resolution), Article 14 (Indemnification) (solely as to activities arising during the Term or as to any activities conducted in the course of a Party's exercise of a license surviving the Term), Article 15 (Miscellaneous); Sections 3.3 (Retained Rights), 3.5 (No Implied Licenses), 7.4 (Records; Audit Rights), 7.7 (Compliance with Law), 8.9 (Currency), 8.11 (Taxes), 8.12 (Audit), 8.13 (Manner of Payment), 9.1 (Inventorship; Ownership and Disclosure of Inventions) and 10.4 (No Other Representations of Warranties), and any other provisions of this Agreement that are necessary to interpret or effectuate the intent of the foregoing provisions. For clarity, the indemnity in Section 14.1(d) shall

survive beyond the duration of the Term only with respect to any Losses arising from activities that occurred during the Term, irrespective of whether Incyte is continuing to extend [\*\*] or [\*\*] to MacroGenics at the time such Loss arises.

**ARTICLE 13  
DISPUTE RESOLUTION**

**13.1 Dispute Resolution Mechanism**. The Parties agree that the procedures set forth in this Article 13 sets forth certain binding and non-binding mechanisms for resolving any dispute, controversy or claim between the Parties that may arise from time to time pursuant to this Agreement relating to either Party's rights or obligations hereunder (each, a "**Dispute**", and collectively, the "**Disputes**") that is not resolved through good faith negotiation between the Parties. For the avoidance of doubt, this Article 13 shall not apply to any decision with respect to which a Party has final decision-making authority hereunder. The Parties shall first attempt in good faith to resolve any Dispute, including Disputes that may involve the parent company, subsidiaries or other Affiliates of any Party or sublicensees (including Collaborators) of a Party, in accordance with Section 13.2.

**13.2 Resolution by Executive Officers**. In the event of any Dispute regarding the construction or interpretation of this Agreement or the rights, duties or liabilities of either Party hereunder, the Parties shall first attempt in good faith to resolve such Dispute by negotiation and consultation between themselves. In the event that such Dispute is not resolved on such basis within [\*\*] (unless otherwise agreed by the Parties), either Party may, by written notice to the other Party, refer the Dispute to the Executive Officers for attempted resolution by good faith negotiation within [\*\*] after such notice is received (unless otherwise agreed by the Parties). Each Party may, in its discretion, seek resolution of any and all Disputes that are not resolved under this Article 13 in any court of competent jurisdiction.

**13.3 Provisional Remedies**. In addition, each Party has the right to seek from the appropriate court provisional remedies such as attachment, preliminary injunction, replevin, etc. to avoid irreparable harm, maintain the *status quo*, or preserve the subject matter of the Dispute.

**ARTICLE 14  
INDEMNIFICATION**

**14.1 Indemnification by Incyte**. Incyte hereby agrees to defend, indemnify and hold harmless MacroGenics and its Affiliates, and each of their respective directors, officers, employees, agents and representatives (each, a "**MacroGenics Indemnitee**") from and against any and all claims, suits, actions, demands, liabilities, expenses and/or losses, including reasonable legal expenses and attorneys' fees (collectively, the "**Losses**"), to which any MacroGenics Indemnitee may become subject as a direct result of any claim, demand, action or other proceeding by any Third Party (each, a "**Claim**"), to the extent such Losses result from: (a) the Exploitation of any Compound or Product by Incyte or its Affiliate or Third Party sublicensee (including any Collaborator); (b) the breach by Incyte of any warranty, representation, covenant or agreement made by Incyte in this Agreement or in the Clinical Supply Agreement, the Clinical Quality Agreement, the Commercial Supply Agreement, or the Pharmacovigilance Agreement (collectively, the "**Ancillary**

**Agreements** ”); (c) the negligence, illegal conduct or willful misconduct of Incyte or its Affiliate or Third Party sublicensee (including any Collaborator), or any officer, director, employee, agent or representative thereof in connection with this Agreement or any Ancillary Agreement; or (d) any claims that the Exploitation of the Licensed Compound pursuant to and in accordance with the provisions of this Agreement infringes the [\*\*] or the [\*\*] (except that, to the extent (i) MacroGenics does not [\*\*] as described in Section 3.2(c) in any instance and (ii) such sublicense to MacroGenics under the [\*\*] would have prevented the occurrence of such Loss, then Incyte shall be relieved of its obligations under this Section 14.1(d) in connection with any resulting claims of infringement); and except, with respect to each of clauses (a) through (d) above, to the extent such Losses arise directly or indirectly from the negligence, gross negligence, illegal conduct or willful misconduct of any MacroGenics Indemnitee or the breach by MacroGenics of any warranty, representation, covenant or agreement made by MacroGenics in this Agreement or any Ancillary Agreement.

**14.2 Indemnification by MacroGenics** . MacroGenics hereby agrees to defend, indemnify and hold harmless Incyte and its Affiliates and each of their respective directors, officers, employees, agents and representatives (each, an “ **Incyte Indemnitee** ”) from and against any and all Losses to which any Incyte Indemnitee may become subject as a direct result of any Claim to the extent such Losses result from: (a) the breach by MacroGenics of any warranty, representation, covenant or agreement made by MacroGenics in this Agreement or any Ancillary Agreement; (b) the negligence, illegal conduct, or willful misconduct of MacroGenics or its Affiliate or its licensee (other than Incyte or its Affiliate), or any officer, director, employee, agent or representative thereof in connection with this Agreement or any Ancillary Agreement; (c) the Exploitation of any Compound or Product by MacroGenics or its Affiliate or licensees, including in connection with the Ongoing Clinical Study, MacroGenics Combination Studies or any other activities conducted by MacroGenics or its Affiliate or licensees in connection with this Agreement or any Ancillary Agreement; except, with respect to each of clauses (a) through (c) above, to the extent such Losses arise directly or indirectly from the negligence, gross negligence, illegal conduct or willful misconduct of any Incyte Indemnitee or the breach by Incyte of any warranty, representation, covenant or agreement made by Incyte in this Agreement or any Ancillary Agreement.

**14.3 Indemnification Procedures** .

- (a) **Notice** . Promptly after a MacroGenics Indemnitee or an Incyte Indemnitee (each, an “ **Indemnitee** ”) receives notice of a pending or threatened Claim, such Indemnitee shall give written notice of the Claim to the Party from whom the Indemnitee is entitled to receive indemnification pursuant to Sections 14.1 or 14.2, as applicable (the “ **Indemnifying Party** ”). However, an Indemnitee’s delay in providing or failure to provide such notice shall not relieve the Indemnifying Party of its indemnification obligations, except to the extent it can demonstrate prejudice due to the delay or lack of notice.
- (b) **Defense** . Upon receipt of notice under this Section 14.3 from the Indemnitee, the Indemnifying Party will have the duty to either compromise or defend, at its own expense (and by counsel reasonably satisfactory to Indemnitee), such Claim. The Indemnifying Party will promptly (and in any event not more than [\*\*] after receipt

of the Indemnitee's original notice) notify the Indemnitee in writing that it acknowledges its obligation (which acknowledgment shall not be deemed or construed as an admission of liability, either under this Article 14 or otherwise) to indemnify the Indemnitee with respect to the Claim pursuant to this Article 14 and of its intention to compromise or defend such Claim. Once the Indemnifying Party gives such notice to the Indemnitee, the Indemnifying Party is not liable to the Indemnitee for the fees of other counsel or any other expenses subsequently incurred by the Indemnitee in connection with such defense, other than the Indemnitee's reasonable Third Party expenses related to its cooperation provided pursuant to Section 14.3(c) below. As to all Claims as to which the Indemnifying Party has assumed control under this Section 14.3(b), the Indemnitee shall have the right to employ separate counsel and to participate in the defense of a Claim (as reasonably directed by the Indemnifying Party) at its own expense.

- (c) **Cooperation** . The Indemnitee will cooperate fully with the Indemnifying Party and its legal representatives in the investigation and defense of any Claim. The Indemnifying Party shall keep the Indemnitee informed on a reasonable and timely basis as to the status of such Claim (to the extent the Indemnitee is not participating in the defense of such Claim) and conduct the defense of such Claim in a prudent manner.
- (d) **Settlement** . If an Indemnifying Party assumes the defense of a Claim, no compromise or settlement of such Claim may be effected by the Indemnifying Party without the Indemnitee's written consent (such consent not to be unreasonably withheld, delayed or conditioned), unless: (1) there is no finding or admission of any violation of law or any violation of the rights of any Person on the part of the Indemnitee and no effect on any other claims that may be made against the Indemnitee; (2) the sole relief provided is monetary damages that are paid in full by the Indemnifying Party; and (3) the Indemnitee's rights under this Agreement are not adversely affected. If the Indemnifying Party fails to assume defense of a Claim within a reasonable time, the Indemnitee may settle such Claim on such terms as it deems appropriate with the consent of the Indemnifying Party (such consent not to be unreasonably withheld, delayed or conditioned), and the Indemnifying Party shall be obligated to indemnify the Indemnitee for such settlement as provided in this Article 14.

**14.4 Insurance** . Each Party shall, at its own expense, with respect to any Product, procure and maintain during the period commencing on the Execution Date through the period of Commercialization and for a period of not less than [\*\*] following the termination or expiration of this Agreement, insurance policies, including product liability insurance, in amounts not less than [\*\*] per claim and annual aggregate. All such insurance shall include worldwide coverage and shall include the other Party as an additional insured under its respective program(s). Prior to the Initiation of any Clinical Study, the Party responsible for such Clinical Study shall secure, and maintain in full force and effect, clinical trial insurance as required by Applicable Law in those territories where such Clinical Study shall be conducted. Upon request, each Party shall provide the other Party with a certificate of insurance evidencing the coverage required under this Section

14.4. Such insurance shall not be construed to create a limit of a Party's liability with respect to its indemnification obligations under this Article 14. Each Party shall provide the other Party with prompt written notice of cancellation, non-renewal or material change in such insurance that could materially adversely affect the rights of such other Party hereunder, and shall provide such notice within [\*\*] after any such cancellation, non-renewal or material change. The Parties acknowledge and agree that Incyte may meet its obligations under this Section 14.4 through self-insurance.

**14.5** **Limitation of Liability**. EXCEPT TO THE EXTENT INCLUDED IN LOSSES RESULTING FROM A THIRD PARTY CLAIM FOR WHICH ONE PARTY IS OBLIGATED TO INDEMNIFY THE OTHER PARTY (OR AN INDEMNITEE OF SUCH OTHER PARTY) PURSUANT TO THIS ARTICLE 14 OR SECTION 12.8(J) AND ANY BREACH OF ARTICLE 11 (CONFIDENTIALITY), IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY (OR THE OTHER PARTY'S AFFILIATES OR SUBLICENSEES) IN CONNECTION WITH THIS AGREEMENT FOR LOST REVENUE, LOST PROFITS, LOST SAVINGS, LOSS OF USE, DAMAGE TO GOODWILL, OR ANY CONSEQUENTIAL, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR INDIRECT DAMAGES UNDER ANY THEORY, INCLUDING CONTRACT, NEGLIGENCE, OR STRICT LIABILITY, EVEN IF THAT PARTY HAS BEEN PLACED ON NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.

**ARTICLE 15**  
**MISCELLANEOUS**

**15.1** **Notices**. All notices and other communications given or made pursuant hereto shall be in writing and shall be deemed to have been duly given on the date delivered, if delivered personally, or on the next Business Day after being sent by reputable overnight courier (with delivery tracking provided, signature required and delivery prepaid), in each case, to the Parties at the following addresses, or on the date sent and confirmed by electronic transmission to the telecopier number specified below (or at such other address or telecopier number for a Party as shall be specified by notice given in accordance with this Section 15.1).

**(a)** If to Incyte:

Incyte Corporation  
1801 Augustine Cut Off  
Wilmington, DE 19803  
Attention: CEO  
Fax: [\*\*]

with a copy to:

Incyte Corporation  
1801 Augustine Cut Off  
Wilmington, DE 19803  
Attention: EVP & General Counsel  
Fax: [\*\*]

(b) If to MacroGenics:

MacroGenics, Inc.  
9704 Medical Center Drive  
Rockville, MD 20850  
Attention: CEO  
Fax: [\*\*]

with a copy to:

MacroGenics, Inc.  
9704 Medical Center Drive  
Rockville, MD 20850  
Attention: General Counsel  
Fax: [\*\*]

**15.2 Governing Law.** This Agreement and all disputes arising out of or related to this Agreement or any breach hereof shall be governed by and construed under the laws of the State of New York, without giving effect to any choice of law principles that would require the application of the laws of a different state.

**15.3 Change of Control.**

- (a) **Notice** . Each Party (or its successor) shall provide notice to the other Party of any Change of Control of the notifying Party within [\*\*] after the date upon which the Change of Control closes or otherwise becomes effective. For purposes of this Section 15.3(a), a public announcement of the closing or effectiveness of a Change of Control shall be deemed notice to the other Party of such Change of Control.
- (b) **MacroGenics** . In the event of a Change of Control of MacroGenics, MacroGenics and the applicable Acquirer shall have the right to conduct Clinical Studies that evaluate the Combination of the Licensed Compound with any Acquirer Pipeline Asset or MacroGenics Pipeline Asset (such study, an “ **Acquirer Combination Study** ”) only as set forth in the remainder of this Section 15.3(b). For clarity, in addition to the requirements and limitations of this Section 15.3(b), (x) any Acquirer Combination Study shall be subject to the requirements and limitations set forth herein with respect to MacroGenics Combination Studies (e.g., the limitations set forth in Section 4.3, and Article 5), (y) MacroGenics shall be responsible for any failure of the Acquirer to comply with the obligations set forth in this Section 15.3(b); and (z) except where this Agreement specifies terms and conditions that are specifically applicable to an Acquirer (e.g., Sections 5.5(c), 15.3(b), and 15.3(d)), all obligations of MacroGenics under this agreement shall apply to the Acquirer as if the Acquirer were MacroGenics hereunder.
- (i) MacroGenics (or the Acquirer, as applicable) shall notify Incyte of each Acquirer Combination Study to be Initiated following the date of the

Change of Control and until the earlier of [\*\*] after the Effective Date, or (y) [\*\*], shall provide Incyte with a copy of the protocol synopsis for the conduct of such proposed Acquirer Combination Study and, solely to the extent the components outlined in the protocol synopsis reviewed by Incyte are materially different from the corresponding components in the full protocol, such updated protocol synopsis, in each case, subject to reasonable redaction with respect to any MacroGenics Pipeline Asset Information (or commercially sensitive confidential information related to the Acquirer Pipeline Asset, as applicable). Incyte shall have the right to object to the conduct of such Acquirer Combination Study if Incyte reasonably believes in its sole determination that:

- (A) the proposed Acquirer Combination Study poses a [\*\*], following the procedures set forth in Section 4.3(b)(i)(3), but substituting “Acquirer Combination Study(ies)” for “MacroGenics Combination Study(ies)” and with Incyte (and not MacroGenics) holding the final decision-making authority with respect thereto pursuant to Section 4.3(b)(i)(3); provided that such veto right under this paragraph (A) shall expire [\*\*] after the Effective Date; or
  - (B) the design or conduct of any such Acquirer Combination Study (x) that does not satisfy the applicable dosage and schedule requirements of Section 4.3(b)(ii) (substituting for such purpose, “Acquirer Combination Study(ies)” for MacroGenics Combination Study(ies) in Section 4.3(b)(ii)), provided that Incyte (and not MacroGenics) shall have final decision-making authority with respect thereto pursuant to Section 4.3(b)(ii); or (y) for which the Acquirer Pipeline Asset, when combined with or compared to the Licensed Compound, is reasonably expected by Incyte, in its sole determination, to have a material negative impact on Incyte’s business (with Incyte’s objection rights under the foregoing clauses (B)(x) and (B)(y) expiring upon achievement of the first Licensed Compound Approval by either the FDA or EMA).
- (ii) If Incyte so objects under subsection (i), MacroGenics (or the Acquirer, as applicable) shall not Initiate such Acquirer Combination Study without the prior written consent of Incyte, it being understood that such objection right shall apply with respect to the Initiation of each Acquirer Combination Study for each applicable Pipeline Asset until the expiration of such right as set forth in Sections 15.3(b)(i)(A) and 15.3(b)(i)(B), as applicable.
  - (iii) If the Acquirer or its Affiliates owns or Controls, and has not discontinued the Development and Commercialization of, or divested, upon the consummation of the Change of Control, a clinical-stage or approved anti-PD-1 or anti-PD-L1 Monoclonal Antibody in the Field (such product, an “**Incyte Competing Product**”), then:

- (A) Acquirer shall and shall cause its Affiliates, within [\*\*]after such consummation, to: (x) adopt reasonable written procedures to prevent Acquirer’s employees or contractors ([\*\*], and [\*\*], it being understood that such employees are otherwise subject to the applicable confidentiality obligations under this Agreement) involved in the Development or Commercialization of such Incyte Competing Product from [\*\*] or [\*\*] to the Licensed Compound or any Licensed Product, for Development or Commercialization of the Incyte Competing Product; and (y) if the Incyte Competing Product is undergoing a pivotal Clinical Study or has received Regulatory Approval, then require such employees and contractors of Acquirer to [\*\*] and [\*\*] between MacroGenics and Incyte under this Agreement (including Joint Committee meetings) and [\*\*] to the Licensed Compound or any Licensed Product; and
- (B) on or before the date that is [\*\*] after the date upon which a Change of Control of MacroGenics closes or otherwise becomes effective, the Parties shall dissolve the JSC and CCC and thereafter Incyte shall perform all activities assigned by this Agreement to the JSC; provided that, the JDC shall remain in place for the coordination of any MacroGenics Combination Studies, the JMC shall remain in place for the coordination of Manufacturing activities, and the JIPC shall remain in place for the coordination of the prosecution and maintenance of the Licensed Patents.
- (c) **Incyte** . Notwithstanding anything to the contrary herein, in the event of a Change of Control of Incyte, if the Acquirer or its Affiliates owns or Controls, and has not discontinued the Development and Commercialization of, or divested, upon the consummation of the Change of Control, a clinical-stage or approved anti-PD-1 or anti-PD-L1 Monoclonal Antibody in the Field (such product, a “ **MacroGenics Competing Product** ”), the following terms and conditions shall apply:
- (i) Acquirer shall and shall cause its Affiliates, within [\*\*] after such consummation to adopt the protections, and Acquirer shall have the rights and obligations, set forth in Sections 15.3(b)(iii)(A) and (B) *mutatis mutandis* ; and
- (ii) Incyte’s right to object to the conduct of an Acquirer Combination Study pursuant to Section 15.3(b)(i)(B)(y) shall immediately terminate.
- (d) **Acquirer IP** . Notwithstanding any provisions of this Agreement to the contrary, in the event of a Change of Control of either Party, such Change of Control shall not provide the other Party with any rights or access to the intellectual property or technology of the acquired Party’s Acquirer or successor which was a Third Party prior to such event.

**15.4 Assignment**. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, except that a Party may make such an assignment or transfer without the other Party's consent to (a) an Affiliate or (b) subject to Section 15.3 above, an Acquirer. Any successor or assignee of rights and/or obligations permitted hereunder shall, in writing to the other Party, expressly assume performance of such rights and/or obligations. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 15.4 shall be null, void and of no legal effect.

**15.5 Designation of Affiliates**. Each Party may discharge any obligation and exercise any right hereunder through delegation of its obligations or rights to any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

**15.6 Relationship of the Parties**. It is expressly agreed that MacroGenics, on the one hand, and Incyte, on the other hand, are independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither MacroGenics nor Incyte shall have the authority to make any statements, representations or commitments of any kind, or to take any action which shall be binding on the other, without the prior written consent of the other Party to do so. All individuals employed by a Party shall be employees of that Party and not of the other Party and all costs and obligations incurred by reason of such employment shall be for the account and expense of such Party.

**15.7 Force Majeure**. Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by Force Majeure and the nonperforming Party promptly provides notice of such Force Majeure circumstances to the other Party. Such excuse shall be continued so long as the condition constituting Force Majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a Force Majeure affecting such Party. If a Force Majeure persists for more than [\*\*], then the Parties shall discuss in good faith the modification of the Parties' obligations under this Agreement in order to mitigate the delays caused by such Force Majeure. In the event a Party is prevented from performing its obligations under this Agreement due to Force Majeure for more than [\*\*] according to this Section 15.7, the other Party shall have the right to terminate this Agreement upon [\*\*] notice after the expiration of such period. A termination under this Section 15.7 by either Party shall be treated as a termination under Section 12.3 above and the corresponding provisions for termination under Section 12.3 shall apply except to the extent the affected Party is prevented from performing due to the Force Majeure.

**15.8 Entire Agreement; Amendments**. This Agreement, including the Exhibits and Schedules hereto, and together with the Ancillary Agreements, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties with respect to the subject matter hereof and supersedes, as of

the Execution Date, all prior and contemporaneous agreements and understandings between the Parties with respect to the subject matter hereof, including the Prior CDA. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party. In the event of any inconsistency between the body of this Agreement and either any Exhibits to this Agreement or any subsequent agreements ancillary to this Agreement, unless otherwise expressly stated to the contrary in such Exhibit or ancillary agreement, the terms contained in this Agreement shall control.

**15.9 Severability.** If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is timely taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make good faith efforts to replace any such invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

**15.10 English Language.** This Agreement shall be written in and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version hereof or thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

**15.11 Waiver and Non-Exclusion of Remedies.** Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

**15.12 Further Assurance.** Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further assignments, agreements, documents, and instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary including as the other Party may reasonably request in connection with this Agreement to carry out more effectively the provisions and purposes hereof.

**15.13 Headings.** The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.

**15.14 Standstill**

- (a) Incyte agrees that neither it nor any of its Affiliates (but excluding any Acquirer of Incyte or any Affiliates of such Acquirer following a Change of Control of Incyte), officers or directors acting at Incyte's direction, alone or as part of any 13D Group, shall, directly or indirectly, for a period of twenty-four (24) months from the Execution Date (the "**Standstill Period**"), without the prior written approval of MacroGenics' Board of Directors (or any committee thereof):
- (i) acquire, offer or propose to acquire or agree to acquire or cause to be acquired ownership (including, but not limited to, beneficial ownership as defined in Rule 13d-3 under the Securities and Exchange Act of 1934) more than three percent (3%) of the voting securities of MacroGenics, or any rights or options to acquire any such ownership (including from a Third Party);
  - (ii) make or participate, directly or indirectly, in any "solicitation" of "proxies" (as such terms are used in the proxy rules (Regulation 14A) of the Securities and Exchange Commission) to vote, or seek to advise or influence any person with respect to the voting of, any voting securities of MacroGenics;
  - (iii) form or join a "group" (within the meaning of Section 13(d)(3) of the Securities Exchange Act of 1934) ("**13D Group**") with respect to any voting securities of MacroGenics;
  - (iv) otherwise act, whether alone or in concert with others, to seek to propose to MacroGenics any merger, business combination, restructuring, recapitalization or similar transaction with respect to or with MacroGenics or otherwise act, whether alone or in concert with others, to seek to "control" (as such term is defined in Section 1.2), change the management or Board of Directors of MacroGenics, or nominate any person as a director of MacroGenics who is not nominated by a then incumbent director; or
  - (v) publicly announce its intentions to enter into any discussion, negotiations, arrangements or understandings with any Third Party with respect to, any of the foregoing.
- (b) If at any time during the Standstill Period, Incyte or, to its actual knowledge, any of its officers or directors are approached by any Third Party concerning Incyte's participation in a transaction of the type referred to in Sections 15.14(a)(i)-(v), Incyte shall, or shall use reasonable efforts to cause such officer or director (as applicable) to, promptly inform such Third Party that Incyte is bound by the provisions of this Section 15.14.
- (c) The restrictions set forth in Section 15.14(a) shall terminate immediately if: (i) a Person or 13D Group (not including Incyte or its Affiliates) (A) commences or publicly announces its intent to commence a tender or exchange offer for voting securities of MacroGenics representing more than twenty percent (20%) of the then-outstanding voting power of the voting securities of MacroGenics or (B)

publicly announces a bona fide proposal to enter into a transaction described in, or of a similar nature to those described in, clause (ii)(A) or (ii)(B) below and, prior to the termination, withdrawal or abandonment of such proposal by such Person or 13D Group (as evidenced by a subsequent public announcement or by communication to MacroGenics that is then either publicly announced or provided to Incyte), either (x) MacroGenics publicly announces its willingness to consider such proposal or alternative proposals for a transaction described in, or of a similar nature as those described in, clause (ii)(A) or (ii)(B) below, (y) the Board of Directors of MacroGenics determines to engage in negotiations with such Person or 13D Group or any other party other than Incyte or its Affiliates with respect to a transaction described in clause (ii)(A) or (ii)(B) below, or (z) such offer or proposal is not publicly rejected or recommended against by MacroGenics within ten (10) Business Days after such offer or proposal becomes public, or (ii) MacroGenics or its Affiliates initiates a process to consider or enter into a transaction described in clause (A) or (B) below, or enters into a letter of intent or definitive agreement with any Third Party regarding (A) any merger, consolidation, sale, reorganization, recapitalization or other business combination pursuant to which the outstanding shares of MacroGenics would be converted into cash or securities of a Person or a 13D Group not including Incyte or its Affiliates and the stockholders or equity holders of MacroGenics immediately prior to such transaction would own, immediately after consummation of such a transaction, less than a controlling portion of the outstanding voting securities of MacroGenics or the entity surviving such transaction; or (B) any transaction or series of transactions that would result, directly or indirectly, in the sale or transfer to a Third Party of (1) all or substantially all of MacroGenics' assets; or (2) a majority of MacroGenics' assets which relate to this Agreement.

- (d) Nothing in this Section 15.14 shall prohibit: (i) Incyte or its Affiliates or its or their Representatives from acquiring or offering to acquire any securities of MacroGenics in connection with any mutual fund, pension plan or employee benefit plan managed on behalf of employees or former employees of Incyte or its Affiliates; or (ii) an officer of Incyte from engaging in discussions with an officer of MacroGenics on a confidential, non-public basis regarding any of the transactions contemplated under this Section 15.14 that would not reasonably be expected to require Incyte or MacroGenics to make any public disclosure with respect thereto.

**15.15 Construction.** Whenever this Agreement refers to a number of days without using a term otherwise defined herein, such number refers to calendar days. Except where the context otherwise requires, (a) wherever used, the singular shall include the plural, the plural shall include the singular; (b) the use of any gender shall be applicable to all genders; (c) the terms "including," "include," "includes" or "for example" shall not limit the generality of any description preceding such term and, as used herein, shall have the same meaning as "including, but not limited to," or "including, without limitation"; (d) the words "herein", "hereof" and "hereunder", and words of similar import, refer to this Agreement in its entirety and not to any particular provision hereof; (e) the word "or" has the inclusive meaning that is typically associated with the phrase "and/or";

(f) the word “will” means “shall”; (g) if a period of time is specified and dates from a given day or Business Day, or the day or Business Day of an act or event, it is to be calculated exclusive of that day or Business Day; (h) “Dollar”, “USD” or “\$” means U.S. Dollars; (i) references to a particular Person include such Person’s successors and assigns to the extent not prohibited by this Agreement; (j) a capitalized term not defined herein but reflecting a different part of speech than a capitalized term which is defined herein shall be interpreted in a correlative manner; (k) “written” includes communications sent and received by facsimile or electronic mail; (l) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein) and (m) references herein to pharmaceutical products, therapies, ingredients, and the like, shall include biologics and biopharmaceutical products, therapies, ingredients, and the like, as applicable. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied for or against either Party. Whenever a provision of this Agreement requires an approval or consent by a Party to this Agreement within a specified time period and notification of such approval or consent is not delivered within such time period, then, unless otherwise specified, the Party whose approval or consent is required shall be conclusively deemed to have withheld its approval or consent. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof.

**15.16 Third Party Beneficiaries**. Except with respect to indemnification obligations pursuant to Article 14, for which MacroGenics Indemnitees and Incyte Indemnitees are third party beneficiaries, no other Persons, other than MacroGenics and Incyte (including their respective successors and permitted assigns), shall be entitled to enforce the performance of this Agreement. For the avoidance of doubt, Collaborators shall not constitute third party beneficiaries under this Agreement for any purpose whatsoever.

**15.17 Counterparts**. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by .pdf or other electronically transmitted signatures and such signatures shall be deemed to bind each Party as if they were the original signatures.

**SIGNATURE PAGE FOLLOWS**

**IN WITNESS WHEREOF** , the Parties have signed this Agreement as of the Execution Date.

**INCYTE CORPORATION**

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

**MACROGENICS, INC.**

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

*SIGNATURE PAGE TO GLOBAL COLLABORATION AND LICENSE AGREEMENT*

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## **EXHIBIT A**

### **Licensed Patents**

Patents and applications claiming the benefit of U.S. Provisional Application Nos: [\*\*], which cover the composition of matter, or the method of making or using, the sale or the importation of the Licensed Compound.

**EXHIBIT B-1**

**Incyte Global Development Plan**

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**CONFIDENTIAL**

Exhibit B-1 – 1

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**EXHIBIT B-2**

**MacroGenics Global Development Plan**

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**EXHIBIT C**

**Existing Third Party Licenses**

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## EXHIBIT D

### Form of Press Release



#### **For Immediate Release**

#### **Incyte and MacroGenics Announce Global Collaboration and Licensing Agreement for Anti-PD-1 Monoclonal Antibody MGA012**

- *Incyte gains exclusive, worldwide development and commercialization rights to MGA012 in all indications*
- *MacroGenics to receive an upfront cash payment of \$150 million plus potential milestone payments and royalties, and retains right to develop its pipeline assets in combination with MGA012*

**WILMINGTON, DE AND ROCKVILLE, MD – October XX, 2017** – Incyte Corporation (NASDAQ:INCY) and MacroGenics, Inc. (NASDAQ:MGNX) announced today that the companies have entered into an exclusive global collaboration and license agreement for MacroGenics' MGA012, an investigational monoclonal antibody that inhibits programmed cell death protein 1 (PD-1). Incyte has obtained exclusive worldwide rights for the development and commercialization of MGA012 in all indications, while MacroGenics retains the right to develop its pipeline assets in combination with MGA012.

"Anti-PD-1 therapy is becoming a mainstay of cancer treatment across multiple tumor types, and we believe the addition of MGA012 to our clinical pipeline is important to fulfilling our long-term development strategy in immunology. This collaboration with MacroGenics will allow us to rapidly explore the potential clinical benefit of developing MGA012 as a monotherapy and also combining anti-PD-1 therapy with several of our existing portfolio assets," said Steven Stein, M.D., Chief Medical Officer of Incyte.

"We believe Incyte is the ideal partner for MGA012, given its immuno-oncology portfolio and dedication to researching and developing innovative and transformative cancer therapies and we hope that the combined resources of both companies will be able to significantly expand and accelerate the current development efforts for this promising molecule," said Scott Koenig, M.D., Ph.D., President and Chief Executive Officer of MacroGenics.

"Furthermore, we look forward to exploring the combination of MGA012 with multiple molecules in our own portfolio, including DART molecules for redirected T-cell killing, antibodies with enhanced effector function and ADCs, potentially to provide improved patient benefit."

Enrollment in the dose escalation portion of the Phase 1 study of MGA012 has been completed and the molecule is currently being evaluated as monotherapy across four solid tumor types in the dose expansion portion of the study. Data from the dose escalation portion of the Phase 1 study have been accepted for poster presentation at the upcoming Society for Immunotherapy of Cancer (SITC) 32nd Annual Meeting in November 2017.

### **Terms of the Collaboration**

Upon closing, Incyte will pay MacroGenics an upfront payment of \$150 million. Incyte will receive worldwide rights to develop and commercialize MGA012 in all indications.

Per the terms of the collaboration, MacroGenics will also be eligible to receive up to \$420 million in potential development and regulatory milestones, and up to \$330 million in potential commercial milestones. If MGA012 is approved and commercialized, MacroGenics would be eligible to receive royalties, tiered from 15 percent to 24 percent, on future sales of MGA012 by Incyte.

Under the terms of the collaboration, Incyte will lead global development of MGA012. MacroGenics retains the right to develop its pipeline assets in combination with MGA012, with Incyte commercializing MGA012 and MacroGenics commercializing its asset(s), if any such potential combinations are approved.

In addition, MacroGenics retains the right to manufacture a portion of both companies' global clinical and commercial supply needs of MGA012. MacroGenics intends to utilize its commercial-scale GMP facility, which is expected to be fully operational in 2018.

The transaction is expected to close in the fourth quarter of 2017, subject to the early termination or expiration of any applicable waiting periods under the Hart-Scott Rodino Act and customary closing conditions.

### **About Incyte Corporation**

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit the Company's website at [www.incyte.com](http://www.incyte.com).

Follow @Incyte on Twitter at <https://twitter.com/Incyte>.

## **About MacroGenics, Inc.**

MacroGenics is a clinical-stage biopharmaceutical company focused on discovering and developing innovative monoclonal antibody-based therapeutics for the treatment of cancer, as well as autoimmune disorders and infectious diseases. MacroGenics generates its pipeline of product candidates primarily from its proprietary suite of next-generation antibody-based technology platforms. The combination of MacroGenics' technology platforms and protein engineering expertise has allowed MacroGenics to generate promising product candidates and enter into several strategic collaborations with global pharmaceutical and biotechnology companies. For more information, please see MacroGenics' website at [www.macrogenics.com](http://www.macrogenics.com). MacroGenics and the MacroGenics logo are trademarks or registered trademarks of MacroGenics, Inc.

## **Incyte Forward-Looking Statements**

Except for the historical information set forth herein, the matters set forth in this press release contain predictions, estimates and other forward-looking statements, including without limitation statements regarding: whether the planned transaction will close within the expected timeframe or ever; whether MGA012 will successfully advance through clinical studies or will ever be approved for use in humans anywhere or will be commercialized anywhere successfully or at all; whether MGA012 will be effective in the treatment of cancer or other indications; and whether and when any of the milestone payments or royalties under this collaboration will ever be paid by Incyte. These forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: obtaining approval for this planned collaboration; research and development efforts related to the collaboration programs; the possibility that results of clinical trials may be unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; other market or economic factors; unanticipated delays; each company's ability to compete against parties with greater financial or other resources; greater than expected expenses; and such other risks detailed from time to time in each company's reports filed with the Securities and Exchange Commission, including the Form 10-Q for the quarter ended June 30, 2017 filed by each company. Each party disclaims any intent or obligation to update these forward-looking statements.

## **MacroGenics' Cautionary Note on Forward-Looking Statements**

Any statements in this press release about future expectations, plans and prospects for MacroGenics, including statements about MacroGenics' strategy, future operations, clinical development of MacroGenics' therapeutic candidates, milestone or opt-in payments from MacroGenics' collaborators, MacroGenics' anticipated milestones and future expectations and plans and prospects for MacroGenics and other statements containing the words "subject to", "believe", "anticipate", "plan", "expect", "intend", "estimate", "project", "may",

"will", "should", "would", "could", "can", the negatives thereof, variations thereon and similar expressions, or by discussions of strategy constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties inherent in the initiation and enrollment of future clinical trials, expectations of expanding ongoing clinical trials, availability and timing of data from ongoing clinical trials, expectations for regulatory approvals, other matters that could affect the availability or commercial potential of MacroGenics' product candidates and other risks described in MacroGenics' filings with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent MacroGenics' views only as of the date hereof. MacroGenics anticipates that subsequent events and developments will cause MacroGenics' views to change. However, while MacroGenics may elect to update these forward-looking statements at some point in the future, MacroGenics specifically disclaims any obligation to do so, except as may be required by law. These forward-looking statements should not be relied upon as representing MacroGenics' views as of any date subsequent to the date hereof.

# # #

**Incyte Contacts:**

**Investors**

Michael Booth, DPhil  
+1 302 498 5914  
[mbooth@incyte.com](mailto:mbooth@incyte.com)

**Media**

Catalina Loveman  
+1 302 498 6171  
[cloveman@incyte.com](mailto:cloveman@incyte.com)

**MacroGenics Contacts:**

**Investors**

Jim Karrels  
1-301-251-5172  
[info@macrogenics.com](mailto:info@macrogenics.com)

**Media**

Karen Sharma  
1-781-235-3060  
[ksharma@macbiocom.com](mailto:ksharma@macbiocom.com)

**EXHIBIT E**

**Ongoing Clinical Study Activities**

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## **EXHIBIT G**

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Patents and patent applications claiming the benefit of [\*\*].

Patents and patent applications claiming the benefit of [\*\*].

Exhibit G – 1

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## EXHIBIT H

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Patents and patent applications claiming the benefit of [\*\*].

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Patents and patent applications claiming the benefit of [\*\*].

Exhibit H – 1

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## COMPUTATION OF RATIOS OF EARNINGS TO FIXED CHARGES

	Year Ended December 31,				
	2013	2014	2015	2016	2017
			(in thousands)		
Income (loss) before provision for income taxes	\$ (82,848)	\$ (48,547)	\$ 7,556	\$ 107,404	\$ (312,290)
Fixed charges	17,131	11,793	11,937	7,684	1,657
Total earnings and fixed charges	<u>\$ (65,717)</u>	<u>\$ (36,754)</u>	<u>\$ 19,493</u>	<u>\$ 115,088</u>	<u>\$ (310,633)</u>
Fixed charges	17,131	11,793	11,937	7,684	1,657
Ratio of earnings to fixed charges <sup>(1)(2)</sup>	NM	NM	1.6	15.0	NM

(1) The ratio of earnings to fixed charges is computed by dividing income (loss) before provision for income taxes plus fixed charges by fixed charges. Fixed charges consist of interest expense (including interest expense from capital leases) and the estimated portion of rental expense deemed by us to be representative of the interest factor of rental payments under operating leases. Earnings were insufficient to cover fixed charges by \$82.8 million, \$48.5 million and \$312.3 million for the years ended December 31, 2013, 2014 and 2017 respectively.

(2) NM—Not meaningful.

## SUBSIDIARIES

<u>Subsidiary</u>	<u>Jurisdiction of Incorporation</u>
Incyte Holdings Corporation	Delaware
Incyte Research Institute LLC	Delaware
Mighty Oak Insurance Company	Delaware
Incyte International Holdings S.à r.l.	Luxembourg
Incyte Biosciences International S.à r.l.	Switzerland
Incyte Biosciences Austria GmbH	Austria
Incyte Biosciences Denmark ApS	Denmark
Incyte Biosciences Finland Oy	Finland
Incyte Biosciences France	France
Incyte Biosciences Germany GmbH	Germany
Incyte Biosciences Italy S.R.L.	Italy
Incyte Biosciences Israel Ltd.	Israel
Incyte Biosciences Distribution B.V.	Netherlands
Incyte Biosciences Benelux B.V.	Netherlands
Incyte Biosciences Norway AS	Norway
Incyte Biosciences Iberia S.L.	Spain
Incyte Biosciences Nordic AB	Sweden
Incyte Biosciences UK Ltd	UK
Incyte Biosciences Technical Operations S.à r.l.	Switzerland
Incyte Biosciences Australia Pty Ltd	Australia
Incyte Biosciences Canada ULC	Canada
Incyte Biosciences Japan G.K.	Japan

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**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the following Registration Statements: (Form S-3 No. 333-209694) of Incyte Corporation, (Form S-8 Nos. 333-91556, 333-125995, and 333-160006) pertaining to the 1993 Directors' Stock Option Plan of Incyte Corporation, (Form S-8 No. 333-160005) pertaining to the 1991 Stock Plan of Incyte Corporation, (Form S-8 Nos. 333-174919 and 333-212102) pertaining to the 1997 Employee Stock Purchase Plan of Incyte Corporation, (Form S-8 Nos. 333-174918, 333-182218, 333-189424, 333-197907, and 333-212104) pertaining to the 2010 Stock Incentive Plan of Incyte Corporation, (Form S-8 No. 333-193333) pertaining to the 2014 Restricted Stock Unit Award Agreement between Incyte Corporation and Hervé Hoppenot, as applicable, of our reports dated February 15, 2018, with respect to the consolidated financial statements of Incyte Corporation and the effectiveness of internal control over financial reporting of Incyte Corporation, included in this Annual Report (Form 10-K) for the year ended December 31, 2017.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania  
February 15, 2018

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## CERTIFICATION

I, Hervé Hoppenot, certify that:

1. I have reviewed this annual report on Form 10-K of Incyte Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 15, 2018

/s/ Hervé Hoppenot

Hervé Hoppenot  
*Chief Executive Officer*

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## CERTIFICATION

I, David W. Gryska, certify that:

1. I have reviewed this annual report on Form 10-K of Incyte Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 15, 2018

/s/ David W. Gryska

David W. Gryska  
*Chief Financial Officer*

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**STATEMENT PURSUANT TO  
18 U.S.C. SECTION 1350**

With reference to the Annual Report of Incyte Corporation (the “Company”) on Form 10-K for the year ended December 31, 2017, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Hervé Hoppenot, Chief Executive Officer of the Company, certify, for the purposes of 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Hervé Hoppenot

Hervé Hoppenot  
*Chief Executive Officer*  
February 15, 2018

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**STATEMENT PURSUANT TO  
18 U.S.C. SECTION 1350**

With reference to the Annual Report of Incyte Corporation (the "Company") on Form 10-K for the year ended December 31, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David W. Gyska, Chief Financial Officer of the Company, certify, for the purposes of 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ David W. Gyska

David W. Gyska  
*Chief Financial Officer*  
February 15, 2018

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