INCYTE CORP
Form 10-Q
April 30, 2015
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2015

or

o 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: 0-27488

INCYTE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**94-3136539**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
1801 Augustine Cut-Off	
Wilmington, DE 19803	**19803**
(Address of principal executive offices)	(Zip Code)

(302) 498-6700

(Registrant s telephone number, including area code)

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. x Yes o 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). x Yes o No

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

Large accelerated filer x	Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

The number of outstanding shares of the registrant s Common Stock, $0.001 par value, was 179,042,841 as of April 23, 2015.

Table of Contents

INCYTE CORPORATION

INDEX

PART I: FINANCIAL INFORMATION		3
Item 1.	Financial Statements	3
	Condensed Consolidated Balance Sheets	3
	Condensed Consolidated Statements of Operations	4
	Condensed Consolidated Statements of Comprehensive Loss	5
	Condensed Consolidated Statements of Cash Flows	6
	Notes to Condensed Consolidated Financial Statements	7
Item 2.	Management s Discussion and Analysis of Financial Condition and Results of Operations	22
Item 3.	Quantitative and Qualitative Disclosures about Market Risk	37
Item 4.	Controls and Procedures	38
PART II: OTHER INFORMATION		39
Item 1A.	Risk Factors	39
Item 6.	Exhibits	56
	Signatures	57
	Exhibit Index	58

Table of Contents

PART I: FINANCIAL INFORMATION

Item 1. Financial Statements

INCYTE CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except number of shares and par value)

	March 31, 2015 (unaudited)	December 31, 2014*
ASSETS		
Current assets:		
Cash and cash equivalents	$ 421,822	$ 452,297
Marketable securities available-for-sale	163,602	147,966
Restricted investments	500	500
Accounts receivable	69,604	57,933
Inventory	2,414	358
Deferred income taxes	6,025	19,641
Prepaid expenses and other current assets	28,178	20,519
Total current assets	692,145	699,214
Restricted investments	13,875	14,000
Long term investment	39,829	
Inventory	17,021	19,078
Property and equipment, net	80,667	81,790
Other assets, net	19,087	15,987
Total assets	$ 862,624	$ 830,069
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Accounts payable	$ 26,586	$ 24,462
Accrued compensation	24,324	34,422
Interest payable	4,443	1,841
Accrued and other current liabilities	70,048	62,270
Deferred revenue collaborative agreements	12,857	12,880
Convertible senior notes	87,337	85,640
Total current liabilities	225,595	221,515
Convertible senior notes	610,210	603,478
Other liabilities	52,910	54,552
Deferred income taxes	6,025	19,641
Deferred revenue collaborative agreements	9,297	12,511
Total liabilities	904,037	911,697

Stockholders deficit:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; none issued or outstanding as of March 31, 2015 and December 31, 2014		
Common stock, $0.001 par value; 400,000,000 shares authorized; 173,386,941 and 170,876,619 shares issued and outstanding as of March 31, 2015 and December 31, 2014, respectively	173	171
Additional paid-in capital	1,760,033	1,701,904
Accumulated other comprehensive income	2,258	1,815
Accumulated deficit	(1,803,877)	(1,785,518)
Total stockholders deficit	(41,413)	(81,628)
Total liabilities and stockholders deficit	$ 862,624	$ 830,069

* The condensed consolidated balance sheet at December 31, 2014 has been derived from the audited financial statements at that date.

See accompanying notes.

Table of Contents

INCYTE CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

(unaudited)

	Three Months Ended March 31,	
	2015	**2014**
Revenues:		
Product revenues, net	$ 115,330	$ 69,651
Product royalty revenues	15,673	9,826
Contract revenues	28,214	10,214
Other revenues	58	101
Total revenues	159,275	89,792
Costs and expenses:		
Cost of product revenues	2,974	168
Research and development	118,365	75,585
Selling, general and administrative	44,871	36,974
Total costs and expenses	166,210	112,727
Loss from operations	(6,935)	(22,935)
Interest and other income, net	1,630	735
Interest expense	(12,687)	(11,443)
Debt exchange expense on senior note conversions		(265)
Loss before provision for income taxes	(17,992)	(33,908)
Provision for income taxes	367	49
Net loss	$ (18,359)	$ (33,957)
Basic and diluted net loss per share	$ (0.11)	$ (0.21)
Shares used in computing basic and diluted net loss per share	172,070	165,357

See accompanying notes.

Table of Contents

INCYTE CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

(unaudited)

	Three Months Ended March 31,	
	2015	**2014**
Net loss	$ (18,359)	$ (33,957)
Other comprehensive income:		
Unrealized gains on restricted investments and marketable securities, net of tax	443	47
Other comprehensive income	443	47
Comprehensive loss	$ (17,916)	$ (33,910)

See accompanying notes.

Table of Contents

INCYTE CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Three Months Ended March 31,	
	2015	**2014**
Cash flows from operating activities:		
Net loss	$ (18,359)	$ (33,957)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of debt discounts	11,835	9,623
Stock-based compensation	17,558	15,347
Debt exchange expense on senior note conversions		265
Excess tax provision (benefit) from stock based compensation	(3,833)	31
Changes in operating assets and liabilities:		
Accounts receivable	(11,671)	(11,020)
Prepaid expenses and other assets	(194)	(4,899)
Inventory	1	(506)
Accounts payable	2,124	(1,152)
Accrued and other liabilities	1,190	(2,208)
Deferred revenue collaborative agreements	(3,237)	(3,218)
Net cash used in operating activities	(4,586)	(31,694)
Cash flows from investing activities:		
Long term investment	(39,829)	
Capital expenditures	(3,553)	(2,663)
Purchases of marketable securities	(34,467)	(45,114)
Maturities of marketable securities	19,274	90
Net cash used in investing activities	(58,575)	(47,687)
Cash flows from financing activities:		
Release of restricted investments	125	
Proceeds from issuance of common stock under stock plans	29,180	44,833
Direct financing arrangement repayments	(452)	
Excess tax provision (benefit) from stock based compensation	3,833	(31)
Cash paid in connection with exchange of 4.75% convertible senior notes due 2015		(265)
Net cash provided by financing activities	32,686	44,537
Net decrease in cash and cash equivalents	(30,475)	(34,844)
Cash and cash equivalents at beginning of period	452,297	471,429
Cash and cash equivalents at end of period	$ 421,822	$ 436,585
Supplemental Schedule of Cash Flow Information		
Interest paid	$ 839	$
Incomes taxes paid	$ 13	$
Reclassification to additional paid in capital in connection with exchange of 4.75% convertible senior notes due 2015	$	$ 4,446

See accompanying notes.

Table of Contents

INCYTE CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2015

(Unaudited)

1. Organization and business

Incyte Corporation (Incyte, we, us, or our) is a biopharmaceutical company focused on developing and commercializing proprietary therapeutics, primarily for oncology. Our pipeline includes compounds in various stages, ranging from preclinical to late stage development, and a commercialized product, JAKAFI® (ruxolitinib). Our operations are treated as one operating segment.

2. Summary of significant accounting policies

Basis of presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. The condensed consolidated balance sheet as of March 31, 2015 and the condensed consolidated statements of operations, comprehensive loss and cash flows for the three months ended March 31, 2015 and 2014, are unaudited, but include all adjustments, consisting only of normal recurring adjustments, which we consider necessary for a fair presentation of the financial position, operating results and cash flows for the periods presented. The condensed consolidated balance sheet at December 31, 2014 has been derived from audited financial statements.

Although we believe that the disclosures in these financial statements are adequate to make the information presented not misleading, certain information and footnote information normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) have been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission.

Results for any interim period are not necessarily indicative of results for any future interim period or for the entire year. The accompanying financial statements should be read in conjunction with the financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2014.

Principles of Consolidation. The condensed consolidated financial statements include the accounts of Incyte Corporation and our wholly owned subsidiaries, including Incyte Holdings Corporation, Incyte International Holdings Sarl, and Incyte Europe Sarl. All inter-company accounts,

transactions, and profits have been eliminated in consolidation.

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, which approximates the results that would be obtained using actual currency rates on the dates of individual transactions. 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 the 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 condensed consolidated statements of operations. To date, both the translation gains or losses in other comprehensive income and the transaction gains or losses in interest and other income, net 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 notes and bills issued by the U.S. government and its agencies and corporate 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. Our receivables mainly relate to our product sales of JAKAFI and collaborative agreements with pharmaceutical companies. We have not

Table of Contents

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 U.S. 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. All marketable securities are classified as 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 deficit. We classify marketable securities that are available for use in current operations as current assets on the condensed 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 March 31, 2015 and December 31, 2014, 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 or market value with cost determined under the specific identification method and may consist of raw materials, work in process and finished goods. We began capitalizing inventory in mid-November 2011 once the U.S. Food and Drug Administration (FDA) approved JAKAFI as the related costs were expected to be recoverable through the commercialization of the product. Costs incurred prior to approval of JAKAFI have been recorded as research and development expense in our statements of operations. As a result, cost of product revenues for the next 18 to 21 months will reflect a lower average per unit cost of materials.

The 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. 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 condensed consolidated balance sheets when we expect inventory to be consumed for commercial use within the next twelve months.

Variable Interest Entities. We perform an initial and on-going evaluation of the entities with which we have variable interests, such as equity ownership, in order to identify entities that (i) 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 March 31, 2015, there were no entities in which we held a variable interest which we determined to be VIEs.

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 and all changes in fair value are reported in our results of operations.

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 (generally three to five years). 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.

Table of Contents

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 as adjustments to 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 condensed consolidated balance sheets and depreciated in a manner similar to other property and equipment.

Certain construction projects may be accounted for as direct financing arrangements, whereby we record, over the construction period, the full cost of the asset in property and equipment, net on the condensed consolidated balance sheets. A corresponding liability is also recorded, net of leasehold improvements paid for by us, and is amortized over the expected lease term through monthly rental payments using the effective interest method.

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. 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 included in other assets, net on the condensed 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 condensed consolidated balance sheets.

Net Loss Per Share. Our basic and diluted losses per share are calculated by dividing the net loss by the weighted average number of shares of common stock outstanding during all periods presented. Options to purchase stock 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 unrealized gains or losses on marketable securities and restricted cash and 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 are recognized once we meet all four revenue recognition criteria described above. In November 2011, we began shipping JAKAFI to our specialty pharmacy customers, which in turn dispense JAKAFI to patients in fulfillment of prescriptions.

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

Customer Credits: Our specialty pharmacy customers are offered various forms of consideration, including allowances, service fees and prompt payment discounts. We expect our specialty pharmacy 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.

Table of Contents

Rebates: Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program. Rebate amounts are based upon contractual agreements or legal requirements with public sector (e.g. Medicaid) 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 specialty pharmacy 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 contracted customers purchase directly from a specialty pharmacy, or an intermediary distributor. Contracted customers, which currently consist primarily of Public Health Service institutions, non-profit clinics, and Federal government entities purchasing via the Federal Supply Schedule, generally purchase the product at a discounted price. The specialty pharmacy or distributor, in turn, charges back to us the difference between the price initially paid by the specialty pharmacy or distributor and the discounted price paid to the specialty pharmacy or distributor by the customer. The accrual for chargebacks is based on the estimated contractual discounts on the inventory levels on hand in our distribution channel. If actual future chargebacks vary from 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 specialty pharmacy 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® 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. We recognize royalty revenues in the period the sales occur.

Cost of Product Revenues

Cost of product revenues includes all JAKAFI related costs that are recoverable through the commercialization of the product. Beginning in October 2014, we became obligated to pay tiered, low single digit royalties under our collaboration and license agreement to Novartis on all future sales of JAKAFI in the United States which are included in cost of product revenues.

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 March 31, 2015, all remaining potential milestones under our collaborative arrangements are considered substantive.

Table of Contents

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 three months ended March 31, 2015 and 2014, 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 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

Table of Contents

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 and clinical trial 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, which are generally subject to cliff vesting, are recognized as compensation expense over the requisite service period using the straight line 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 $17.6 million and $15.3 million of stock compensation expense on our condensed consolidated statements of operations for the three months ended March 31, 2015 and 2014, respectively.

Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-15, Presentation of Financial Statements Going Concern , to provide guidance on management s responsibility in evaluating whether there is substantial doubt about a company s ability to continue as a going concern and about related footnote disclosures. For each reporting period, management will be required to evaluate whether there are conditions or events that raise substantial doubt about a company s ability to continue as a going concern within one year from the date the financial statements are issued. This guidance is effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. We do not believe the pending adoption of ASU No. 2014-15 will have a material impact on our condensed consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers, which provides a five step approach to be applied to all contracts with customers. ASU No. 2014-09 also requires expanded disclosures about revenue recognition. On April 1, 2015, the FASB proposed to extend the effective date of ASU No. 2014-09 from reporting periods beginning after December 15, 2016 to reporting periods beginning after December 15, 2017. Early adoption is permitted for reporting periods beginning after December 15, 2016. Once the proposal is formally issued, the public will have 30 days to comment, after which the proposal will be decided upon. We are currently analyzing the impact of ASU No. 2014-09 on our results of operations and, at this time, we are unable to determine the impact on the new standard, if any, on our

condensed consolidated financial statements.

3. Fair value of financial instruments

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. 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.

Table of Contents

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.

Our marketable securities consist of investments in U.S. government agencies, corporate debt securities and non-agency mortgage-backed securities that are classified as available-for-sale.

At March 31, 2015 and December 31, 2014, our Level 2 corporate debt securities and mortgage-backed securities are valued using readily available pricing sources which utilize market observable inputs, including the current interest rate and other characteristics for similar types of instruments.

The following fair value hierarchy table presents information about each major category of our financial assets and liabilities measured at fair value on a recurring basis as of March 31, 2015 (in thousands):

	Fair Value Measurement at Reporting Date Using:			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of March 31, 2015
Cash and cash equivalents	$ 421,822	$	$	$ 421,822
Corporate debt securities		160,180		160,180
Long term investment (Note 7)	39,829			39,829
Mortgage-backed securities		3,422		3,422
Total assets	$ 461,651	$ 163,602	$	$ 625,253

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, 2014 (in thousands):

	Fair Value Measurement at Reporting Date Using:			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of December 31, 2014
Cash and cash equivalents	$ 452,297	$	$	$ 452,297
Corporate debt securities		144,402		144,402
Mortgage-backed securities		3,564		3,564
Total assets	$ 452,297	$ 147,966	$	$ 600,263

The following is a summary of our marketable security portfolio as of March 31, 2015 and December 31, 2014, respectively.

	Amortized Cost	Net Unrealized Gains	Net Unrealized Losses	Estimated Fair Value
		(in thousands)		
March 31, 2015				
Corporate debt securities	$ 160,008	$ 172	$	$ 160,180
Mortgage backed securities	1,330	2,092		3,422
	$ 161,338	$ 2,264	$	$ 163,602
December 31, 2014				
Corporate debt securities	$ 144,684	$	$ (282)	$ 144,402
Mortgage backed securities	1,461	2,103		3,564
	$ 146,145	$ 2,103	$ (282)	$ 147,966

Our corporate debt securities generally have contractual maturity dates of between 12 to 18 months. Because of the potential for prepayment on mortgage-backed securities, they are not categorized by contractual maturity.

Table of Contents

4. Concentration of Credit Risk

In December 2009, we entered into a license, development and commercialization agreement with Eli Lilly and Company (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 Contract Revenues for the Three Months Ended, March 31,	
	2015	2014
Collaboration Partner A	89%	68%
Collaboration Partner B	11%	32%

Collaboration Partner A and Collaboration Partner B comprised in the aggregate 23% and 26% of the accounts receivable balance as of March 31, 2015 and December 31, 2014, respectively.

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

	Percentage of Total Net Product Revenues for the Three Months Ended, March 31,	
	2015	2014
Customer A	28%	29%
Customer B	20%	21%
Customer C	13%	11%
Customer D	8%	9%

We are exposed to risks associated with extending credit to specialty pharmacy customers related to the sale of products. Customer A, Customer B, Customer C and Customer D comprised in the aggregate 69% and 54% of the accounts receivable balance as of March 31, 2015 and December 31, 2014, respectively.

5. Inventory

Our inventory balance consists of the following:

	March 31, 2015	December 31, 2014
	(in thousands)	
Raw materials	$ 500	$ 591
Work-in-process	16,521	18,487
Finished goods	2,414	358
	19,435	19,436
Inventories current	2,414	358
Inventories non-current	$ 17,021	$ 19,078

Inventories, stated at the lower of cost or market, consist of raw materials, work in process and finished goods. At March 31, 2015, $2.4 million of inventory was classified as current on the condensed consolidated balance sheet as we expect this inventory to be consumed for commercial use within the next twelve months. At March 31, 2015, $17.0 million of inventory was classified as non-current on the condensed consolidated balance sheet as we did not expect this inventory to be consumed for commercial use within the next twelve months. We obtain a number of inventory components from single source suppliers due to technology, availability, price, quality or other considerations. The loss of a single source supplier, the deterioration of its relationship with a single source supplier, or any unilateral violation of the contractual terms under which we are supplied components by a single source supplier could adversely affect our total revenues and gross margins.

The 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. 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.

Table of Contents

6. Property and Equipment

Property and equipment consists of the following:

	March 31, 2015	December 31, 2014
	(in thousands)	
Office equipment	$ 6,223	$ 6,090
Laboratory equipment	27,053	26,800
Computer equipment	19,775	18,648
Building and leasehold improvements	64,862	64,926
	117,913	116,464
Less accumulated depreciation and amortization	(37,246)	(34,674)
	$ 80,667	$ 81,790

In 2013, we entered into a lease agreement for a new corporate headquarters, which consists of approximately 190,000 square feet of laboratory and office space located in Wilmington, Delaware. The term of this lease is 15 years from the date of commencement. The construction of the facility was completed and the lease commenced on October 1, 2014 with a monthly lease rate of $0.5 million for the first 10 years of the lease and with the monthly lease rate increasing annually during the last five years of lease.

We are accounting for the lease as a direct financing arrangement whereby over the construction period, we recorded the value of the facility (consisting of the estimated fair value of the existing shell, plus construction costs incurred) as a capital asset, with a corresponding lease liability, net of build out costs paid for by us during the construction period. The lease liability will be amortized over the term of the lease using the effective interest method. In addition, we have posted a $15.0 million letter of credit for the facility lease for the benefit of the landlord, which is collateralized by a restricted investments account for the same amount. This amount was recorded as restricted investments on the condensed consolidated balance sheets and will be reduced over a period of time during the duration of the lease. The letter of credit could be subject to accelerated reductions if we meet certain pre-defined financial targets. Restricted investments on the condensed consolidated balance sheets at March 31, 2015 and December 31, 2014 were $14.4 million and $14.5 million, respectively.

7. 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 c-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. As of March 31, 2015, we have recognized in the aggregate $97.0 million for the achievement of development milestones and $160.0 million for the achievement of regulatory milestones.

During the three months ended March 31, 2015, under this agreement, we recognized and received 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. In 2014, we recognized and received a $60.0 million regulatory milestone related to reimbursement of JAKAVI (ruxolitinib) in Europe, recognized and received 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 and received a $25.0 million development milestone payment under this agreement based on the formal initiation by Novartis of a Phase II clinical trial evaluating capmatinib. In 2012, we recognized and received a $40.0 million regulatory milestone payment under this agreement for the

Table of Contents

achievement of a predefined milestone for the European Union regulatory approval of JAKAVI. In 2011, we recognized and received a $15.0 million development milestone payment under this agreement 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 payment for the approval of JAKAFI in the United States. We determined the 2015, 2014, 2013, 2012 and 2011 milestones to be 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 JAKAVI net sales outside of the United States. Since the achievement of the $60.0 million regulatory milestone related to reimbursement of JAKAVI in Europe, 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 three months ended March 31, 2015, such royalties payable to Novartis on net sales within the United States totaled $2.5 million and are reflected in cost of product revenues on the condensed consolidated statement 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 now 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 (1) the expiration of the last valid claim of the licensed patent rights covering the licensed product in the relevant country, (2) the expiration of regulatory exclusivity for the licensed product in such country and (3) 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.

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 will be recorded net against the related research and development expenses. At March 31, 2015 and December 31, 2014, $0.5 million and $0.3 million, respectively, of reimbursable costs were included in accounts receivable on the condensed consolidated balance sheets. Research and development expenses for the three months ended March 31, 2015 and 2014 were net of $0.5 million and $1.1 million, respectively, of costs reimbursed by Novartis.

Contract revenue under the Novartis agreement was $25.0 million and $7.0 million for the three months ended March 31, 2015 and 2014, respectively. In addition, for the three months ended March 31, 2015 and 2014, respectively, we recorded $15.7 million and $9.8 million of product royalty revenues related to Novartis net sales of JAKAVI outside of the United States. At March 31, 2015 and December 31, 2014, $15.8 million and $14.8 million, respectively, of product royalties were included in accounts receivable on the condensed consolidated balance sheets.

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 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. As of March 31, 2015, we have recognized and received in the aggregate $99.0 million for the achievement of development milestones.

In 2012, we recognized a $50.0 million development milestone under this agreement for the achievement of a predefined milestone for the initiation of the rheumatoid arthritis Phase III program for baricitinib. In 2010, we recognized and received a $30.0 million development milestone payment 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 payment for the Phase IIb clinical trial initiation of baricitinib for the treatment of rheumatoid arthritis. We determined the 2012 and 2010 milestones to be substantive as their achievement required substantive efforts by us and was at risk until the milestones were ultimately achieved. We also could receive tiered, double-digit royalty payments on future global net sales with rates ranging up to 20% if the product is successfully commercialized.

We retained options to co-develop our JAK 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. We

Table of Contents

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. We also retained an option to co-promote products in the United States. 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. 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 $11.6 million and $14.0 million for the three months ended March 31, 2015 and 2014, 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 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 (1) the expiration of the last valid claim of the licensed patent rights covering the licensed product in the relevant country, (2) the expiration of regulatory exclusivity for the licensed product in such country and (3) 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.

Contract revenue under the Lilly agreement was $3.2 million for the three months ended March 31, 2015 and 2014.

Agenus

In January 2015, we entered into a License, Development and Commercialization Agreement with Agenus Inc. and its wholly owned subsidiary, 4 Antibody AG, 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 proprietary Retrocyte Display antibody discovery platform. 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 (HSR Act).

Under the terms of this 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. These 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 will be responsible for all costs associated with discovery, preclinical activities, clinical development and commercialization activities. The programs relating to GITR and OX40 are profit share programs and the programs relating to LAG-3 and TIM-3 are royalty bearing programs. For each royalty bearing product, Agenus will be eligible to receive up to $155 million in future contingent development, regulatory and commercialization milestones as well as tiered royalties on global net sales ranging from 6% to 12%. For each profit share product, Agenus will be eligible to receive up to $20 million in future contingent development milestones. Additionally, Agenus retains co-promotion participation rights in the United States on any profit share product. For each royalty bearing product, Agenus has reserved the right to elect to co fund 30% of development costs for a commensurate increase in royalties. The agreement may be terminated by us for convenience and may also be terminated under certain other circumstances, including material breach.

In January 2015, we also entered into a Stock Purchase Agreement with Agenus Inc. pursuant to which we agreed to purchase, subject to expiration of the waiting period under the HSR Act, approximately 7.76 million shares of Agenus Inc. common stock for an aggregate purchase price of $35.0 million in cash, or approximately $4.51 per share. We completed the purchase of the shares on February 18, 2015. On February 18, 2015 the closing price of Agenus Inc. common shares on The NASDAQ Stock Market was $5.13 per share and, therefore, the value of the 7.76 million shares acquired by us was $39.8 million. We have agreed not to dispose of any of the shares of common stock for a period of 12 months and Agenus Inc. has agreed to certain registration rights with respect to the shares of common stock.

Upon closing of the Agenus transaction on February 18, 2015, we paid total consideration of $60.0 million to Agenus Inc. 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

Table of Contents

the condensed consolidated balance sheets and $20.2 million was allocated to research and development expense on the condensed consolidated statement of operations.

At the February 18, 2015 closing date and at March 31, 2015, 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. We own approximately 11% of the outstanding shares of Agenus Inc. common stock and conclude that we have the ability to exercise significant influence, but not control, over Agenus Inc. based primarily on our ownership interest, 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 three months ended March 31, 2015, there was no gain or loss recorded as the market price of Agenus Inc. s common stock at March 31, 2015 was consistent with the fair value on the acquisition date of the investment.

Research and development expenses for the three months ended March 31, 2015, also included $1.8 million of development costs incurred pursuant to the Agenus arrangement. Such costs were included in accrued and other liabilities on the condensed consolidated balance sheets as of March 31, 2015.

8. Stock compensation

We recorded $17.6 million and $15.3 million of stock compensation expense on our condensed consolidated statements of operations for the three months ended March 31, 2015 and 2014, respectively. Stock compensation expense included within our condensed consolidated statements of operations included research and development expense of $10.3 million and $8.3 million for the three months ended March 31, 2015 and 2014, respectively. Stock compensation expense included within our condensed consolidated statements of operations also included selling, general and administrative expense of $7.3 million and $7.0 million for the three months ended March 31, 2015 and 2014, respectively.

We utilized the Black-Scholes valuation model for estimating the fair value of the stock compensation granted, with the following weighted-average assumptions:

	Employee Stock Options For the Three Months Ended March 31,		Employee Stock Purchase Plan For the Three Months Ended March 31,	
	2015	2014	2015	2014
Average risk-free interest rates	1.35%	1.18%	0.56%	0.44%
Average expected life (in years)	5.05	4.47	0.25	0.25
Volatility	50%	50%	38%	52%
Weighted-average fair value (in dollars)	32.59	26.52	9.56	8.65

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.

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, 2014	5,399,816	14,655,043	$ 21.96
Options granted	(1,622,520)	1,622,520	$ 74.03
Options exercised		(2,478,752)	$ 15.91
Options cancelled	74,169	(74,169)	$ 42.21
Balance at March 31, 2015	3,851,465	13,724,642	$ 29.10

Table of Contents

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, 2014	1,001,523	398,477	
RSUs granted	(175,338)	175,338	$ 74.08
PSUs granted			
RSUs cancelled	5,074	(5,074)	$ 64.74
PSUs cancelled			
Balance at March 31, 2015	831,259	568,741	

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. We granted a total of 175,338 RSUs during the three months ended March 31, 2015 which will cliff vest in three years and will be recognized as stock compensation expense over this period. 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 March 31, 2015, a total of 66,666 RSUs granted to Mr. Hoppenot vested and were released leaving 333,334 RSUs outstanding.

At March 31, 2015, we have only recognized stock compensation expense relating to performance conditions of the outstanding PSUs that are deemed probable of achievement at that date. For PSUs containing performance conditions which have not been deemed probable of achievement at March 31, 2015, no stock compensation expense has been recognized for these awards. The actual number of shares of our common stock into which each PSU may convert are subject to a multiplier of up to 125% based on the level at which the performance conditions are achieved.

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 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.

Total compensation cost of options granted but not yet vested, as of March 31, 2015, was $58.1 million, which is expected to be recognized over the weighted average period of 3.0 years. Total compensation cost of RSUs granted but not yet vested, as of March 31, 2015, was $31.8 million, which is expected to be recognized over the weighted average period of 3.0 years. Total compensation cost of PSUs granted but not yet vested, as of March 31, 2015, was $0.7 million, which is expected to be recognized over the weighted average period of 3.0 years, should the underlying performance conditions be deemed probable of achievement.

9. Debt

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

Debt	Interest Rates March 31, 2015	Maturities	Carrying Amount March 31, 2015	Carrying Amount December 31, 2014
4.75% Convertible Senior Notes due 2015	4.75%	2015	$ 87,337	$ 85,640
0.375% Convertible Senior Notes due 2018	0.375%	2018	318,292	314,752
1.25% Convertible Senior Notes due 2020	1.25%	2020	291,918	288,726
			697,547	689,118
Less current portion			87,337	85,640
			$ 610,210	$ 603,478

Table of Contents

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

	March 31, 2015		December 31, 2014	
	Carrying Amount	Fair Value	Carrying Amount	Fair Value
4.75% Convertible Senior Notes due 2015	$ 87,337	$ 947,148	$ 85,640	$ 755,143
0.375% Convertible Senior Notes due 2018	318,292	682,500	314,752	560,156
1.25% Convertible Senior Notes due 2020	291,918	695,861	288,726	577,736
	$ 697,547	$ 2,325,509	$ 689,118	$ 1,893,035

The fair values of the 4.75% Convertible Senior Notes due 2015 (the 2015 Notes), 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.

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 April 1, 2015, the 2018 Notes and 2020 Notes became convertible through at least June 30, 2015, based on the meeting the conversion criteria related to the sale price of our common stock during the calendar quarter ended March 31, 2015 as described in (1) above. Management s intent is to settle any conversions of 2018 Notes or 2020 Notes during this period in shares of our common stock and, therefore, the 2018 Notes and 2020 Notes are reflected in long term liabilities on the condensed consolidated balance sheet at March 31, 2015.

During April 2015, certain holders of the 2015 Notes converted a total of $46.9 million in aggregate principal amount of the 2015 Notes for the shares of our common stock into which the 2015 Notes were convertible, aggregating 5.3 million shares.

10. Income taxes

In January 2015, we licensed certain intellectual property rights related to our non-partnered clinical programs to our wholly-owned subsidiary in Switzerland. Although the license of intellectual property rights did not result in any gain or loss in the condensed consolidated statements of operations, the transaction generated a taxable gain in the U.S, and we are utilizing available federal and state net operating loss carryforwards to offset the majority of this gain. Any taxes incurred related to intercompany transactions are treated as prepaid tax in our condensed consolidated balance sheets and amortized to income tax expense over the life of the intellectual property. Any cash taxes anticipated to be paid related to this intercompany transaction are immaterial.

Table of Contents

11. Net loss per share

For all periods presented, both basic and diluted net loss per common share are computed by dividing the net loss by the number of weighted average common shares outstanding during the period. Stock options and potential common shares issuable upon conversion of the 2015 Notes, 2018 Notes and 2020 Notes were excluded from the computation of diluted net loss per share, as their share effect was anti-dilutive for all periods presented.

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

	Three Months Ended March 31,	
	2015	**2014**
Outstanding stock awards	14,626,717	18,027,392
Common shares issuable upon conversion of 4.75% Convertible Senior Notes due 2015	10,353,076	10,441,728
Common shares issuable upon conversion of 0.375% Convertible Senior Notes due 2018	7,245,263	7,245,263
Common shares issuable upon conversion of 1.25% Convertible Senior Notes due 2020	7,245,263	7,245,263
Total potential common shares excluded from diluted net loss per share computation	39,470,319	42,959,646

Table of Contents

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations as of and for the three months ended March 31, 2015 should be read in conjunction with the unaudited condensed consolidated financial statements and notes to those statements included elsewhere in this Quarterly Report on Form 10-Q and our audited consolidated financial statements as of and for the year ended December 31, 2014 included in our Annual Report on Form 10-K for the year ended December 31, 2014 previously filed with the SEC.

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);*

- *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;*

- *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;*
- *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;*

Table of Contents

- *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;*

- *our ability to maintain at anticipated levels, reimbursement for JAKAFI 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 JAKAFI, which could result in a short supply of JAKAFI, increased costs, and withdrawal of regulatory approval;*

- *our ability to maintain regulatory approvals to market JAKAFI;*

- *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 JAKAFI 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 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;*

- *our ability to compete against third parties with greater resources than ours;*

Table of Contents

- *risks relating to changes in pricing and reimbursements in the markets in which we may compete;*

- *competition to develop and commercialize similar drug products;*

- *our ability to obtain 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 substantial leverage;*

- *our ability to obtain additional capital when needed;*

- *fluctuations in net cash provided and used by operating, financing and investing activities;*

- *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 Quarterly Report on Form 10-Q.

Overview

Incyte is a biopharmaceutical company focused on the discovery, development and commercialization of proprietary therapeutics to treat serious unmet medical needs, primarily in oncology. 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.

In April 2015, we announced our intention to establish the new headquarters of Incyte Europe Sarl (Incyte Europe) in Geneva, Switzerland. We intend to use Incyte Europe as the base from which we will conduct our European clinical development operations.

JAKAFI is marketed in the United States through our own specialty sales force and commercial team. 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, solid tumors, rheumatoid arthritis, psoriasis 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 in the bone marrow. These diseases include myelofibrosis (MF), polycythemia vera (PV) and essential thrombocythemia.

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 and was approved by the FDA in November 2011 as a treatment for patients with intermediate or high-risk MF, which includes primary MF, post-polycythemia

Table of Contents

vera MF and post-essential thrombocythemia MF. 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 percent to 90 percent 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.

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. Current standard treatment for PV is phlebotomy (the removal of blood from the body) plus aspirin. 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.

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 also now in PV. The FDA has granted JAKAFI orphan drug status for MF, PV and essential thrombocythemia.

In August 2012, the European Commission approved ruxolitinib as JAKAVI for the treatment of disease-related splenomegaly or symptoms in adult patients with primary MF (also known as chronic idiopathic MF), post-polycythemia vera MF or post-essential thrombocythemia MF. In January 2015, the Committee for Medicinal Products for Human Use of the European Medicines Agency adopted a positive opinion for JAKAVI for the treatment of adult patients with polycythemia vera who are resistant to or intolerant of hydroxyurea, and approval was granted by the European Commission in March 2015.

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 through late 2027, excluding additional potential patent term extensions. We believe ruxolitinib may have potential as a treatment for other cancers.

Full results from the Phase II proof-of-concept RECAP trial of ruxolitinib in patients with refractory metastatic pancreatic cancer were presented in June 2014 and suggest a demonstrable survival benefit in a pre-specified subgroup of patients with elevated C-reactive protein (CRP). The Company and the FDA have agreed on a Special Protocol Assessment (SPA) for a registration trial for advanced or metastatic pancreatic cancer. Under the SPA, the Phase III JANUS 1 trial can be limited to patients with elevated CRP and there is no requirement to develop a companion diagnostic. The global Phase III program includes a second nearly identical Phase III trial, JANUS 2, and both trials are ongoing. The FDA has granted orphan drug status for ruxolitinib for the treatment of pancreatic cancer.

Elevated CRP has negative prognostic significance in many tumor types, and we believe that JAK inhibition may represent a new treatment approach for other solid tumors. To test this hypothesis, we have initiated three blinded proof-of-concept Phase II trials evaluating ruxolitinib in non-small cell lung cancer, breast cancer and colorectal cancer. The primary endpoint for each trial will be overall survival.

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.

We could receive tiered, double-digit royalty payments on future global sales of products subject to the agreement with rates ranging up to 20 percent if the products are successfully commercialized. This collaboration also contains an option for us to co-develop compounds for any inflammatory and autoimmune disease, whereby we fund 30 percent of development costs from Phase IIb through regulatory approval for that indication in exchange for tiered royalties ranging up to the high twenties on potential future sales. We exercised our co-development option for the development of baricitinib in rheumatoid arthritis in 2010. The Phase III program of baricitinib in patients with rheumatoid arthritis is ongoing, and in December 2014, we announced with Lilly that the first of the Phase III trials met the primary endpoint. In February 2015, we announced with Lilly that the second of the Phase III trials also met the primary endpoint. Baricitinib is also in Phase II trials for patients with moderate-to-severe psoriasis and patients with diabetic nephropathy. We have decided not to exercise our co-development option for psoriasis, and the timeframe for exercising our co-development option for diabetic nephropathy has not yet occurred.

We have a portfolio of wholly-owned JAK1 inhibitors. Our lead JAK1 inhibitor, INCB39110, has completed proof-of-concept studies in patients with psoriasis, rheumatoid arthritis and myelofibrosis. While the results of the psoriasis and rheumatoid arthritis studies were positive, for strategic reasons, we are pursuing oncologic indications with INCB39110. We believe that selective JAK1 inhibition has the potential to minimize the myelosuppression associated with JAK2 inhibition, thus potentially enabling the combination of JAK1 selective inhibitors with myelosuppressive chemotherapy. The clinical program to evaluate

Table of Contents

INCB39110 in solid tumors includes an ongoing open-label safety study in combination with gemcitabine and nab-paclitaxel. We have completed the Phase I dose-escalation portion of the trial, and additional first-line pancreatic cancer patients are being recruited into the dose-expansion cohort. INCB39110 is also in two blinded proof-of-concept Phase II trials in non-small cell lung cancer. Both trials are now underway, and both trials are designed with overall survival as the primary endpoint. We have another JAK1 inhibitor, INCB52793, which has recently initiated a Phase I/II trial in advanced malignancies.

We have an oral IDO1 inhibitor, epacadostat (previously INCB24360) which belongs to a new class of agents known as immuno-oncology agents. IDO1 is an enzyme whose increased levels in multiple solid tumor types are associated with decreased survival. IDO1 inhibition shifts the immune system from an immunosuppressive state to an activated state, allowing the body to mount a more effective anti-tumor immune response. While preclinical data suggest that IDO1 inhibition can provide anti-tumor effects as monotherapy, based on the significant synergy exhibited in combination with checkpoint inhibitors as well as emerging clinical data, we believe that the optimal development strategy for our IDO1 inhibitor is in combination with other immuno-oncology therapies. During 2014 we signed clinical trial agreements with Merck, Roche / Genentech, AstraZeneca / MedImmune and Bristol-Myers Squibb to evaluate epacadostat with their respective PD-1 and PD-L1 agents in Phase I/II trials, and all four of these trials are now in progress. The tumor types under investigation under these agreements include non-small cell lung cancer, metastatic melanoma, head and neck cancer, colorectal cancer, ovarian cancer, diffuse large B-cell lymphoma and pancreatic cancer.

We have two PI3K-delta inhibitors in clinical development, INCB40093 and INCB50465. The PI3K-delta pathway mediates oncogenic signaling in B cell malignancies. INCB40093 is being studied as both monotherapy and in combination with our JAK1 inhibitor, INCB39110, in patients with B-lymphoid malignancies.An open-label, dose-escalation study of INCB50465 in subjects with previously treated B-cell malignancies has also been initiated.

We have a c-MET inhibitor, capmatinib, which is licensed to Novartis. c-MET is a clinically validated receptor kinase cancer target. Abnormal c-MET activation in cancer correlates with poor prognosis. Dysregulation of the c-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 c-MET pathway is seen in many types of cancers, including kidney, liver, stomach, breast and brain. Several small molecule c-MET kinase inhibitors have demonstrated clinical efficacy in a number of cancers; however, these molecules have limited potency and are relatively non-selective, which could lead to off-target toxicities. We believe that capmatinib has the requisite properties to overcome these limitations, including greater selectivity, improved potency and more effective inhibition of c-MET. 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 hepatocellular carcinoma, non-small cell lung cancer, and other solid tumors and may have potential utility as a combination agent.

We have recently added two new compounds to our clinical development portfolio. INCB54828 is a selective inhibitor of the FGFR1, FGFR2 and FGFR3 kinases that has demonstrated potency and selectivity in preclinical studies across multiple solid tumor types. The FGFR family of receptor tyrosine kinases can act as oncogenic drivers in several solid and liquid tumor types. INCB54329 is a bromodomain (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 genes in all of human cancer. INCB54329 has shown broad single agent activity in preclinical models of leukemia, lymphoma, multiple myeloma and in some solid tumor settings; INCB54329 can synergize with inhibitors of JAK/STAT signaling, PI3K/AKT signaling and PIM signaling. Clinical trials of INCB54828 are now underway, and we plan to begin clinical trials of INCB54329 in the second quarter of this year.

We have a number of programs in preclinical development, and we intend to continue our investment in drug discovery to expand our pipeline.

Table of Contents

Our current pipeline includes the following compounds:

Target/Drug Compound	Indication	Collaborator (1)	Status
ONCOLOGY			
JAK1 and JAK2			
JAKAFI	Myelofibrosis(2)	Novartis	FDA Approved Marketed
JAKAFI	Polycythemia Vera(3)	Novartis	FDA Approved Marketed
ruxolitinib	Pancreatic Cancer	Novartis (opt-in option)	Phase III
ruxolitinib	Breast Cancer	Novartis (opt-in option)	Phase II
ruxolitinib	Non-Small Cell Lung Cancer	Novartis (opt-in option)	Phase II
ruxolitinib	Colorectal Cancer	Novartis (opt-in option)	Phase II
JAK1			
INCB39110	Pancreatic Cancer	None	Phase II
INCB39110	Non-Small Cell Lung Cancer	None	Phase II
INCB39110	Non-Small Cell Lung Cancer	None	Phase II
INCB52793	Advanced malignancies	None	Phase I/II
PI3K-delta			
INCB40093	B-lymphoid Malignancies	None	Phase I/II
INCB50465	B-lymphoid Malignancies	None	Phase I/II
JAK1+PI3K-delta			
INCB39110+INCB40093	B-lymphoid Malignancies	None	Phase I/II
IDO1			
epacadostat	Metastatic Melanoma	None	Phase II
epacadostat	Non-Small Cell Lung Cancer	Merck	Phase I/II
epacadostat	Non-Small Cell Lung Cancer	Roche / Genentech	Phase I/II
epacadostat	Multiple tumor types	AstraZeneca / MedImmune	Phase I/II
epacadostat	Multiple tumor types	Bristol-Myers Squibb	Phase I/II
c-MET			
capmatinib	Solid Tumors	Novartis	Phase I/II
capmatinib	Hepatocellular Carcinoma	Novartis	Phase II
capmatinib	Non-Small Cell Lung Cancer	Novartis	Phase II
FGFR			
INCB54828	Solid Tumors	None	Phase I/II
BRD			
INCB54329	Hematology / Oncology	None	(4)
INFLAMMATION			
JAK1 and JAK2			
baricitinib	Rheumatoid Arthritis	Lilly	Phase III
baricitinib	Psoriasis	Lilly	Phase IIb
baricitinib	Diabetic Nephropathy	Lilly	Phase II

(1) For information about certain of our agreements with collaborators and other third parties, please see *Business Relationships* below and Note 7, *License Agreements* to our condensed consolidated financial statements included in this report.

(2) JAKAFI is approved for treatment of people with intermediate or high-risk myelofibrosis (MF), including primary MF, post polycythemia vera MF, and post essential thrombocythemia MF.

(3) JAKAFI is approved for treatment of people with polycythemia vera (PV) who have had an inadequate response to or are intolerant of hydroxyurea.

(4) Phase I/II clinical trial not yet initiated.

Table of Contents

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 relationships and collaborations that expand our pipeline and provide us with certain rights to existing and potential new products and technologies. For more information regarding certain of these relationships, including their ongoing financial and accounting impact on our business, please read Note 7, *License Agreements* to our condensed consolidated financial statements included in this report.

- ***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 including pancreatic cancer, breast cancer, non-small cell lung cancer, and colorectal cancer. Novartis also received worldwide exclusive development and commercialization rights to our c-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. Several JAKAFI clinical trials in patients with myelofibrosis are ongoing, including long-term extension studies, alternative dosing studies, joint global trials with Novartis and trials in patients with low platelet counts.

- ***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 our JAK inhibitor baricitinib, and certain back-up compounds for inflammatory and autoimmune diseases. We retained options to co-develop and co-promote our JAK inhibitors for the treatment of Diabetic Nephropathy, we retained options to co-promote our JAK inhibitors for the treatment of Psoriasis, and we elected to co-develop our JAK inhibitors for the treatment of Rheumatoid Arthritis and retained co-promotion options.

- ***Merck & Co.*** - In 2014, we entered into a clinical trial agreement with Merck to evaluate epacadostat with their anti-PD-1immunotherapy, Keytruda (pembrolizumab), for the treatment of non-small cell lung cancer, metastic melanoma, head and neck cancer, colorectal cancer, ovarian cancer, diffuse large B-cell lymphoma and pancreatic cancer. The trial is in progress and is currently in Phase I/II.

- ***Roche / Genentech*** - In 2014, we entered into a clinical trial agreement with Roche / Genentech to evaluate epacadostat with their anti-PD-L1 immunotherapy, MPDL3280A, for the treatment of non-small cell lung cancer, metastic melanoma, head and neck cancer, colorectal cancer, ovarian cancer, diffuse large B-cell lymphoma and pancreatic cancer. The trial is in progress and is currently in Phase I/II.

- ***AstraZeneca / MedImmune*** - In 2014, we entered into a clinical trial agreement with AstraZeneca / MedImmune to evaluate epacadostat with their anti-PD-L1 immunotherapy, MEDI4736, for the treatment of non-small cell lung cancer, metastic melanoma, head and neck cancer, colorectal cancer, ovarian cancer, diffuse large B-cell lymphoma and pancreatic cancer. The trial is in progress and is currently in Phase I/II.

- ***Bristol-Myers Squibb*** - In 2014, we entered into a clinical trial agreement with Bristol-Myers Squibb to evaluate epacadostat with their anti-PD-1 immunotherapy, Opdivo (nivolumab), for the treatment of non-small cell lung cancer, metastic melanoma, head and neck cancer, colorectal cancer, ovarian cancer, diffuse large B-cell lymphoma and pancreatic cancer. The trial is in progress and is currently in Phase I/II.

- ***Agenus*** - In 2015, we announced a global license, development and commercialization agreement with Agenus Inc. focused on novel immuno-therapeutics using Agenus proprietary Retrocyte Display antibody discovery platform. The alliance will initially focus on the development of checkpoint modulator antibodies directed against GITR, OX40, LAG-3 and TIM-3.

Table of Contents

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 on-going 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 condensed consolidated financial statements:

- Revenue recognition;
- Research and development costs;
- Stock compensation;
- Investments;
- Inventory; and
- Convertible debt accounting

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 are recognized once we meet all four revenue recognition criteria described above. In November 2011, we began shipping JAKAFI to our specialty pharmacy customers, which in turn dispense JAKAFI to patients in fulfillment of prescriptions.

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

Customer Credits: Our specialty pharmacy customers are offered various forms of consideration, including allowances, service fees and prompt payment discounts. We expect our specialty pharmacy 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: Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program. Rebate amounts are based upon contractual agreements or legal requirements with public sector (e.g. Medicaid) 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 specialty pharmacy 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 contracted customers purchase directly from a specialty pharmacy, or an intermediary distributor. Contracted customers, which currently consist primarily of Public Health Service institutions, non-profit clinics, and Federal government entities purchasing via the Federal Supply Schedule, generally purchase the product at a discounted price. The specialty pharmacy or distributor, in turn, charges back to us the difference between the price initially paid by

Table of Contents

the specialty pharmacy or distributor and the discounted price paid to the specialty pharmacy or distributor by the customer. The accrual for chargebacks is based on the estimated contractual discounts on the inventory levels on hand in our distribution channel. If actual future chargebacks vary from 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 specialty pharmacy 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. 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 prior period which would affect royalty revenue in the period of adjustment.

Cost of Product Revenues

Cost of product revenues includes all JAKAFI related costs that are recoverable through the commercialization of the product. Beginning in October 2014, we became obligated to pay tiered, low single digit royalties to Novartis on all future sales of JAKAFI in the United States, which are included in cost of product revenues.

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 March 31, 2015, 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 three months ended March 31, 2015 and 2014, 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.

Table of Contents

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.

Table of Contents

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 on the dates of grant. 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, which are generally subject to cliff vesting, are recognized as compensation expense over the requisite service period using the straight line 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 $17.6 million and $15.3 million of stock compensation expense for the three months ended March 31, 2015 and 2014, respectively.

Investments. We carry our investments at their respective fair values. We periodically evaluate the fair values of our investments to determine whether any declines in the fair value of investments represent an other-than-temporary impairment. This evaluation consists of a review of several factors, including the length of time and extent that a security has been in an unrealized loss position, the existence of an event that would impair the issuer s future repayment potential, the near term prospects for recovery of the market value of a security and if we intend to sell or if it is more likely than not that we will be required to sell the security before recovery of its amortized cost basis. If management determines that such an impairment exists, we would recognize an impairment charge. Because we may determine that market or business conditions may lead us to sell our marketable securities prior to maturity, we classify our marketable securities as available-for-sale. Investments in securities that are classified as available-for-sale and have readily determinable fair values are measured at fair market value in the balance sheets, and unrealized holding gains and losses for these investments are reported as a separate component of stockholders equity until realized. We classify marketable securities that are available for use in current operations as current assets on the condensed consolidated balance sheets.

Inventory. Inventories are determined at the lower of cost or market value with cost determined under the specific identification method and may consist of raw materials, work in process and finished goods. 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 approval of JAKAFI have been recorded as research and development expense in our statements of operations. As a result, cost of product revenues for the next 18 to 21 months will reflect a lower average per unit cost of materials.

The 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. 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 condensed consolidated balance sheets when we expect inventory to be consumed for commercial use within the next twelve months.

Convertible Debt Accounting. We perform an assessment of all embedded features of a debt instrument to determine if (1) such features should be bifurcated and separately accounted for, and (2) 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 condensed consolidated balance sheets, and re-measured to fair value at each reporting period. Any changes in fair value are recorded in the condensed 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.

Table of Contents

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 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 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: (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 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 April 1, 2015, the 2018 Notes and 2020 Notes became convertible through at least June 30, 2015, based on meeting the conversion criteria related to the sale price of our common stock during the calendar quarter ended March 31, 2015 as described above. Management s intent is to settle any conversions of 2018 Notes or 2020 Notes in common shares and, therefore, the 2018 and 2020 Notes are reflected in long term liabilities on the condensed consolidated balance sheet as of March 31, 2015.

Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-15, Presentation of Financial Statements Going Concern , to provide guidance on management s responsibility in evaluating whether there is substantial doubt about a company s ability to continue as a going concern and about related footnote disclosures. For each reporting period, management will be required to evaluate whether there are conditions or events that raise substantial doubt about a company s ability to continue as a going concern within one

year from the date the financial statements are issued. This guidance is effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. We do not believe the pending adoption of ASU No. 2014-15 will have a material impact on our condensed consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers, which provides a five step approach to be applied to all contracts with customers. ASU No. 2014-09 also requires expanded disclosures about revenue recognition. On April 1, 2015, the FASB proposed to extend the effective date of ASU No. 2014-09 from reporting periods beginning after December 15, 2016 to reporting periods beginning after December 15, 2017. Early adoption is permitted for reporting periods beginning after December 15, 2016. Once the proposal is formally issued, the public will have 30 days to comment, after which the proposal will be decided upon. We are currently analyzing the impact of ASU No. 2014-09 on our results of operations and, at this time, we are unable to determine the impact on the new standard, if any, on our condensed consolidated financial statements.

Table of Contents

Results of Operations

We recorded a net loss of $18.4 million and basic and diluted net loss per share of $0.11 for the three months ended March 31, 2015, as compared to a net loss of $34.0 million and basic and diluted net loss per share of $0.21 in the corresponding period in 2014.

Revenues.

	For the three months ended, March 31,	
	2015	2014
	(in millions)	
Product revenues, net	$ 115.3	$ 69.7
Product royalty revenues	15.7	9.8
Contract revenues	28.2	10.2
Other revenues	0.1	0.1
Total revenues	$ 159.3	$ 89.8

Our product revenues, net from JAKAFI for the three months ended March 31, 2015 and 2014, were $115.3 million and $69.7 million, respectively. This increase was comprised of a volume increase of $35.3 million and a price increase of $10.3 million. Product revenues from the sale of JAKAFI 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 three months ended March 31, 2015:

Three Months Ended March 31, 2015	Discounts and Distribution Fees	Government Rebates and Chargebacks	Co-Pay Assistance and Other Discounts	Product Returns	Total
Balance at January 1, 2015	$ 2,057	$ 7,906	$ 119	$ 399	$ 10,481
Allowances for current period sales	3,638	13,483	625	266	18,012
Allowances for prior period sales	(156)	(358)			(514)
Credits/payments for current period sales	(1,853)	(3,633)	(540)	(101)	(6,127)
Credits/payments for prior period sales	(1,505)	(3,387)	(61)	(72)	(5,025)
Balance at March 31, 2015	$ 2,181	$ 14,011	$ 143	$ 492	$ 16,827

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 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 net product royalty revenues for the three months ended March 31, 2015 and 2014, were $15.7 million and $9.8 million, respectively.

Our contract revenues were $28.2 million and $10.2 million for the three months ended March 31, 2015 and 2014, respectively. For the three months ended March 31, 2015 and 2014, 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 Novartis earned during the periods. The upfront fees related to the Lilly agreement consisted of a $90.0 million upfront payment received in 2010. During the three months ended March 31, 2015, under the Novartis agreement, we recognized 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. During the three months ended March 31, 2014, under the Novartis agreement, we recognized a $7.0 million

Table of Contents

development milestone based on the formal initiation by Novartis of a Phase II clinical trial evaluating capmatinib in non-small cell lung cancer.

Cost of Product Revenues

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 March 31, 2015, inventory with $2.0 million of product costs incurred prior to FDA approval had not yet been sold. We expect to sell the pre- commercialization inventory over the next 18 to 21 months; however, the time period over which this inventory is consumed will depend on a number of factors, including the amount of future JAKAFI sales, and the ability to utilize inventory prior to its expiration date. As a result, cost of product revenues for the next 18 to 21 months will reflect a lower average per unit cost of materials. Commencing in October 2014, we became obligated to pay tiered, low single digit royalties to Novartis on all sales of JAKAFI in the United States, which is included in cost of product revenues.

Cost of product revenues was $3.0 million and $0.2 million for the three months ended March 31, 2015 and 2014, respectively. The increase in cost of product revenues for the three months ended March 31, 2015 as compared to the same period in 2014 is due to increased JAKAFI sales and our obligation that commenced in October 2014 to pay royalties to Novartis on all JAKAFI sales in the United States. We expect future cost of product revenues to range in the mid-single digits as a percentage of net product sales subsequent to the utilization of all of the remaining pre-launch inventory.

Operating Expenses.

Research and development expenses.

	For the three months ended, March 31,	
	2015	2014
	(in millions)	
Salary and benefits related	$ 26.2	$ 21.7
Stock compensation	10.2	8.3
Clinical research and outside services	71.8	38.5
Occupancy and all other costs	10.2	7.1
Total research and development expenses	$ 118.4	$ 75.6

We currently account for research and development costs by natural expense line and not costs by project. Salary and benefits related expense increased from the three months ended March 31, 2014 to the three months ended March 31, 2015 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 the three months ended March 31, 2014 to the three months ended March 31, 2015 was primarily the result of increased development costs to advance our clinical pipeline and the $20.2 million charge related to the upfront payment made to Agenus pursuant to our license, development and commercialization agreement, as well as an additional

$1.8 million of research and development costs incurred under the arrangement through March 31, 2015. Research and development expenses for the three months ended March 31, 2015 and 2014 were net of $1.2 million and $1.1 million, respectively, of costs reimbursed by our collaborative partners. Research and development expenses may fluctuate from period to period depending upon the stage of certain projects and the level of pre-clinical and clinical trial related activities. 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. 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 $11.6 million and $14.0 million for the three months ended March 31, 2015 and 2014, 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

Table of Contents

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.

Selling, general and administrative expenses.

	For the three months ended, March 31,	
	2015	2014
	(in millions)	
Salary and benefits related	$ 14.2	$ 12.8
Stock compensation	7.3	7.0
Other contract services and outside costs	23.4	17.2
Total selling, general and administrative expenses	$ 44.9	$ 37.0

Salary and benefits related expense increased from the three months ended March 31, 2014 to the three months ended March 31, 2015 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 for the commercial launch in uncontrolled polycythemia vera which occurred in December 2014. 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.

Other income (expense)

Interest and other income, net. Interest and other income, net, for the three months ended March 31, 2015 and 2014 was $1.6 million and $0.7 million, respectively.

Interest Expense. Interest expense for the three months ended March 31, 2015 and 2014 was $12.7 million and $11.4 million, respectively. Included in interest expense for the three months ended March 31, 2015 and 2014, were $9.2 million and $8.8 million, respectively, 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.

Debt exchange expense on senior note conversions. Debt exchange expense on senior note conversions for the three months ended March 31, 2014 was $0.3 million and related to the exchange of $4.9 million in aggregate principal amount of our 2015 Notes for the underlying shares of common stock and cash.

Liquidity and Capital Resources

We had net losses from inception in 1991 through 1996 and in 1999 through March 31, 2015. Because of those losses, we had an accumulated deficit of $1.8 billion as of March 31, 2015. 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 March 31, 2015, we had available cash, cash equivalents and marketable securities of $585.4 million. 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 agency and non-agency mortgage-backed securities. Available cash is invested in accordance with our investment policy s primary objectives of liquidity, safety of principal and diversity of investments.

Net cash used in operating activities was $4.6 million for the three months ended March 31, 2015, compared to $31.7 million used in operating activities for the three months ended March 31, 2014. The $27.1 million decrease was due primarily to our lower net loss.

Our investing activities, other than purchases, sales and maturities of marketable securities, have consisted predominantly of capital expenditures and sales and purchases of long term investments. Net cash used in investing activities was $58.6 million for the three months ended March 31, 2015, which represented purchases of marketable securities of $34.5 million, capital expenditures of $3.6 million, and long term investment in Agenus of $39.8 million offset in part by maturities of marketable securities of $19.3 million. Net cash used in investing activities was $47.7 million for the three months ended March 31, 2014, which represented purchases of marketable securities of $45.1 million and capital expenditures of $2.7 million offset by maturities of marketable securities of $0.1 million. In the future, net cash used by investing activities may fluctuate significantly from period to period due to

Table of Contents

the timing of strategic equity investments, acquisitions and capital expenditures and maturities/sales and purchases of marketable securities.

Net cash provided by financing activities was $32.7 million and $44.5 million for the three months ended March 31, 2015 and 2014, respectively, primarily representing proceeds from the issuance of common stock under our stock plans and employee stock purchase plan.

The following summarizes our significant contractual obligations as of March 31, 2015 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
Contractual Obligations:					
Principal on convertible senior debt	$ 840.8	$ 90.8	$	$ 375.0	$ 375.0
Interest on convertible senior debt	38.1	10.4	12.2	10.8	4.7
Non-cancelable lease obligations:					
Related to corporate headquarters	87.3	6.9	12.1	12.0	56.3
Total contractual obligations	$ 966.2	$ 108.1	$ 24.3	$ 397.8	$ 436.0

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 up front fees, milestone payments, and royalties on sales of future products.

We believe that 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; our receipt of any milestone or other payments under any collaborative agreements we may enter into, including the agreements with Novartis and Lilly; the extent to which commercialization of JAKAFI is successful; expenditures in connection with potential exchanges of our outstanding convertible senior notes; and expenditures in connection with strategic relationships and license agreements, including our agreement with Agenus, 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.

Until we can generate a sufficient amount of product revenues to finance our cash requirements, which we may never do, we expect to finance future cash needs 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. We do not know whether additional funding will be available on acceptable terms, if at all. If we are not able to secure additional funding when needed, we may have to scale back our operations, delay or 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.

Off Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our investments in marketable securities, which are composed primarily of U.S. government agency and non-agency mortgage-backed securities and corporate debt 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 rate interest rates increase. As of March 31, 2015, marketable securities were $163.6 million. Due to the nature of these investments, if market interest rates were to increase immediately and uniformly by 10% from levels as of March 31, 2015, the decline in fair value would not be material.

Table of Contents

Item 4. 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 Quarterly Report on Form 10-Q, 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 changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) for the three months ended March 31, 2015, that materially affected or are reasonably likely to materially affect our internal control over financial reporting.

Table of Contents

PART II: OTHER INFORMATION

Item 1A. Risk Factors

RISKS RELATING TO OUR LEAD PRODUCT JAKAFI

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 product to be 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. 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 JAKAVI 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 JAKAFI 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 JAKAFI on a profitable basis or our profitability may be reduced if we are required to sell JAKAFI at lower than anticipated prices or reimbursement is unavailable or limited in scope or amount. JAKAFI is expensive and almost all patients will require some form of third party coverage to afford its 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 JAKAFI to the patient. In the United States, there have been, and we expect there will continue to be, efforts to control and reduce healthcare costs. Government and other third-party payors are challenging the prices charged for healthcare products and increasingly limiting and attempting to limit both coverage and level of reimbursement for prescription drugs. If these entities refuse to provide coverage and reimbursement with respect to JAKAFI, determine to provide a lower level of coverage and reimbursement than anticipated, or reduce previously approved

Table of Contents

levels of coverage and reimbursement, then our pricing or reimbursement for JAKAFI 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 group purchasing organizations 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 group purchasing organizations could adversely affect our operations and financial condition.

We sell JAKAFI primarily to specialty pharmacies and group purchasing organizations, which in turn dispense JAKAFI to patients in fulfillment of prescriptions. We do not promote JAKAFI to specialty pharmacies and group purchasing organizations, 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 group purchasing organizations, 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 group purchasing organizations 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 cause higher product costs, 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 group purchasing organization. The loss of any large specialty pharmacy or group purchasing organization as part of our distribution network, a significant reduction in sales we make to specialty pharmacies or group purchasing organizations, 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 JAKAFI.

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 maintain our own capabilities or enter into and maintain any marketing, distribution or third-party logistics agreements with third-party providers on acceptable terms, if at all. 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 JAKAFI. 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 JAKAFI.

Our reliance on other parties to manufacture JAKAFI could result in a short supply of JAKAFI, increased costs, and withdrawal of regulatory approval.

We do not currently operate manufacturing facilities for commercial production of JAKAFI. Accordingly, we will be subject to the risks described below under Other Risks Relating to Our Business 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.

If we fail to comply with applicable laws and regulations, we could lose our approval to market JAKAFI or be subject to other governmental enforcement activity.

We cannot guarantee that we will be able to maintain regulatory approval to market JAKAFI in the United States. If we do not maintain our regulatory approval to market 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. 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.

Our commercialization of JAKAFI is subject to post-regulatory approval product surveillance, and JAKAFI 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 JAKAFI, and JAKAFI may be recalled or may be subject to reformulation, additional studies, changes in labeling, warnings to the public and negative publicity.

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

Table of Contents

- administrative and judicial sanctions, including warning letters;
- fines and other civil penalties;
- withdrawal of regulatory approval to market JAKAFI;
- 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 JAKAFI harms patients, or is perceived to harm patients even when such harm is unrelated to JAKAFI, our regulatory approval could be revoked or otherwise negatively impacted or we could be subject to costly and damaging product liability claims.

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

- lessen the frequency with which physicians decide to prescribe JAKAFI;

- encourage physicians to stop prescribing JAKAFI to their patients who previously had been prescribed JAKAFI;

- cause serious harm to patients that may give rise to product liability claims against us; and

- result in our need to withdraw or recall JAKAFI from the marketplace.

If JAKAFI is 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 JAKAFI may also be discovered in connection with unapproved, or off-label, uses of JAKAFI. We are prohibited by law from promoting or in any way supporting or encouraging the promotion of JAKAFI 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.

Patients who have been enrolled in our clinical trials or who may use JAKAFI 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 JAKAFI. 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 JAKAFI, 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 JAKAFI, 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 JAKAFI receives or maintains, or delay the regulatory approval process for our collaborator Novartis in other countries.

Table of Contents

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

If we market JAKAFI in a manner that violates various federal and state health care related 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 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 JAKAFI from generic products could potentially harm our business and result in a decrease in our revenue.

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. JAKAFI was approved pursuant to a New Drug Application, or NDA, by the FDA on November 16, 2011. The four-year period after which a generic manufacturer may file an ANDA and challenge the patents related to JAKAFI will expire on November 16, 2015. Since the Hatch-Waxman Act provides significant incentives to generic manufacturers to challenge U.S. patents on successful innovative pharmaceutical products, generic manufacturers may target JAKAFI and challenge our related U.S. patent rights as early as the fourth quarter of 2015. 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 have a material adverse effect on our operating results and business.

Table of Contents

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 and 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 the activities listed above and may not be successful in discovering, developing, or commercializing drug products. Discovery and development of drug candidates are expensive 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, 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 III clinical trials for the treatment of advanced or metastatic pancreatic cancer, as well as in other 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 September 2011, we announced that we had discontinued development of our lead sheddase inhibitor, INCB7839, for the treatment of breast cancer. If a product is developed, but is not marketed, we may have spent significant amounts of time and money on it, which could adversely affect our operating results and financial condition.

Table of Contents

Although we obtained a special protocol assessment agreement for ruxolitinib for advanced or metastatic pancreatic cancer, a special protocol assessment agreement does not guarantee any particular outcome from regulatory review, including any regulatory approval.

We have obtained a special protocol assessment, or SPA, agreement with the FDA for a registration trial, which is one of two Phase III trials in the development plan, for ruxolitinib for the treatment of advanced or metastatic pancreatic cancer in a subgroup of patients with elevated CRP. The SPA process allows for FDA evaluation of a clinical trial protocol intended to form the primary basis of an efficacy claim in support of an NDA, and provides a product sponsor with an agreement confirming that the design and size of a trial will be appropriate to form the primary basis of an efficacy claim for an NDA if the trial is performed according to the SPA. Even if we believe that the data from a clinical trial are supportive, an SPA is not a guarantee of approval, and we cannot be certain that the design of, or data collected from, a trial will be adequate to demonstrate safety and efficacy, or otherwise be sufficient to support regulatory approval. There can be no assurance that the terms of an SPA will ultimately be binding on the FDA, and the FDA is not obligated to approve an NDA, if any, even if the clinical outcome is positive. The FDA retains significant latitude and discretion in interpreting the terms of an SPA and the data and results from a clinical trial, and can require trial design changes or additional studies if issues arise essential to determining safety or efficacy. Data may subsequently become available that causes the FDA to reconsider the previously agreed upon scope of review and the FDA may have subsequent safety or efficacy concerns that override an SPA, and we can give no assurance that as clinical trials proceed or as part of an NDA review process, if any, the FDA will determine that a previously approved SPA is still valid.

Additionally, an SPA may be changed only with the written agreement of the FDA, and any further changes we may propose to the protocol will remain subject to the FDA s approval. The FDA may not agree to any such amendment and, even if they agree, they may request other amendments to the trial design that could require additional cost and time, as well as increase the degree of difficulty in reaching clinical endpoints. As a result, even with an SPA, we cannot be certain that the trial results will be found to be adequate to support an efficacy claim and product approval.

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 c-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.

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 such parties compounds or biologics. We are evaluating strategic relationships with respect to several of our other programs and may enter into an agreement with respect to one or more of these programs in the future. However, because

Table of Contents

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.

In order for any of these collaboration or license arrangements to be successful, we must first identify potential collaborators or licensees whose capabilities complement and integrate well with ours. We may rely on these arrangements for not only financial resources, but also for expertise or economies of scale that we expect to need in the future relating to clinical trials, manufacturing, sales and marketing, and for licenses to technology rights. However, it is likely that we will 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, 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. 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 that fit within our focus on oncology, such as our collaboration with Agenus. 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 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 by the termination of a drug candidate and termination and winding down of the related license agreement. 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, 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;

Table of Contents

- 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.

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

In order to commercialize drug products in the United States, our drug candidates will have to obtain regulatory approval from the FDA. Satisfaction of regulatory requirements typically takes many years. To obtain regulatory approval, we 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 to undertake clinical trials of any drug candidates in addition to our compounds currently in clinical trials.

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 by many factors, including:

- the high degree of risk 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 industry, including biotechnology companies, have suffered significant setbacks in

Table of Contents

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 conduct additional trials of any of our drug candidates, which would result in delays.

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. 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. Failure to obtain regulatory approval would delay or prevent us from commercializing products.

Outside the United States, our 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.

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 or by developing their products more efficiently. 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.

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. We currently hire third parties to manufacture the raw materials, active pharmaceutical ingredient, or API, and finished drug product of JAKAFI 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. For JAKAFI and most of our drug candidates, we hire third parties to manufacture the raw materials, another third party to manufacture the API and another to make the finished drug product and 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 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. 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. Also, required raw materials may only be available from a limited number of suppliers and, in the case of JAKAFI, are currently supplied by a single source. As noted above, generally, we have a single source or a limited number of suppliers that are qualified to supply each of the API and finished product of JAKAFI and our other drug candidates. 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

Table of Contents

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.

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, as well as compliance with strictly enforced federal, state and foreign regulations.

In order to obtain approval of our products by the FDA and foreign regulatory agencies, we need to complete testing on both the API and on the finished product in the packaging we propose for commercial sales. This includes testing of stability, identification of impurities and testing of other product specifications by validated test methods. In addition, we will be required to consistently produce the API in commercial quantities and of specified quality on a repeated basis and document our ability to do so. This requirement is referred to as process validation.

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.

Under our collaboration with Agenus, Agenus has primary responsibility for manufacturing activities, including selecting and monitoring third-party manufacturers. 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 Foreign Corrupt Practices Act and similar anti-bribery or anti-corruption laws, or violations related to environmental matters. Violations of governmental regulation 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. 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.

Health care reform measures could impact the pricing and profitability of pharmaceuticals, and adversely affect the commercial viability of our 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 recent healthcare reform legislation.

Our ability to commercialize our drug candidates 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.

Table of Contents

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 recently enacted, including changes to the methods for, and amounts of, Medicare reimbursement. These 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 drug candidates. Some of these changes and proposed changes could result in reduced reimbursement rates, which could reduce the price that we or any of our collaborators or licensees receive for any products, if commercialized, in the future, and which would adversely affect our business strategy, operations and financial results. Further federal and state proposals and health care reforms are possible, which could limit the prices that can be charged for any of our drug candidates and may further limit the commercial viability of our drug candidates. In certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. If reimbursement for our products, if commercialized, is unavailable, 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 drug candidates, 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 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 drug candidates by the medical community may be limited without adequate reimbursement for our products. Cost control initiatives may decrease coverage and payment levels for our drug candidates and, in turn, the price that we will be able to charge for any product, if commercialized. Our drug candidates 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 drug candidates.

The continuing efforts of 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.

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. Our lease contains provisions that provide for its early termination upon the occurrence of certain events of default. 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, or early termination of our lease 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,

Table of Contents

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.

Risks associated with expanding our operations to Europe could adversely affect our business.

We plan to expand our operations and conduct certain development activities in Europe. 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, 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;

- 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 enforcing contracts and 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;

- 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;

Any of these risks, 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 Our Lead Product JAKAFI If the use of JAKAFI harms patients, or is perceived to harm patients even when such harm is unrelated to JAKAFI, our regulatory approval 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. 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.

Table of Contents

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 expect to incur losses in the future and we may not achieve or maintain profitability in the future.

We had net losses from inception in 1991 through 1996 and in 1999 through March 31, 2015. Because of those losses, we had an accumulated deficit of $1.8 billion as of March 31, 2015. We intend to continue to spend significant amounts on our efforts to discover and develop drugs. As a result, we could continue to incur losses in 2015 and 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 JAKAFI, 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, we expect that we will continue to incur losses if our drug products do not generate significant revenues. If we achieve profitability, we may not be able to sustain or increase profitability.

We will 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;
- our ability to maintain and establish new corporate relationships and research collaborations;

Table of Contents

- 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 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.

We have a large amount of debt and our debt service obligations may prevent us from taking actions that we would otherwise consider to be in our best interests.

As of March 31, 2015, the aggregate principal amount of our total consolidated debt was $840.8 million and our stockholders deficit was $41.4 million. Our substantial leverage could have significant negative consequences for our future operations, including:

- increasing our vulnerability to general adverse economic and industry conditions;

- limiting our ability to obtain additional financing for working capital, capital and research and development expenditures, and general corporate purposes;

- requiring the dedication of a substantial portion of our expected cash flow or our existing cash to service our indebtedness, thereby reducing the amount of our cash available for other purposes, including working capital, capital expenditures and research and development expenditures;

- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; or

- placing us at a possible competitive disadvantage compared to less leveraged competitors and competitors that have better access to capital resources.

We may not generate sufficient cash flow from our operations in the future to enable us to meet our anticipated fixed charges, including our obligations with respect to our outstanding convertible senior notes. As of March 31, 2015, $90.8 million aggregate principal amount of our 4.75% convertible senior notes due 2015 was outstanding and due in October 2015. The remaining interest payments for our 4.75% convertible senior notes through 2015, assuming that none of these notes are converted, repurchased or exchanged, will total $4.3 million. As of March 31, 2015, $375.0 million aggregate principal amount of our 0.375% convertible senior notes due 2018 was outstanding and due in November 2018. Annual interest payments for our 0.375% convertible senior notes through 2018, assuming that none of these notes are converted, repurchased or exchanged, are $1.4 million. As of March 31, 2015, $375.0 million aggregate principal amount of our 1.25% convertible senior notes due 2020 was outstanding and due in November 2020. Annual interest payments for our 1.25% convertible senior notes through 2020, assuming that none of these notes are converted, repurchased or exchanged, are $4.7 million. If we are unable to generate cash from our operations or raise additional cash through financings sufficient to meet the remaining obligations under our convertible senior notes, we will need to use existing cash or liquidate marketable securities in order to fund these obligations, which may delay or curtail our research, development and commercialization programs.

Table of Contents

Our marketable securities and long term investments are subject to certain 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. Recently similar types of investments and money market funds have experienced losses in value or liquidity issues which 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.

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

Our current revenues are derived from JAKAFI product sales, JAKAVI 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 three months ended March 31, 2015 and the year ended December 31, 2014 from JAKAFI product revenues, JAKAVI 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.

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

Table of Contents

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.

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.

Table of Contents

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.

Table of Contents

Item 6. Exhibits

Exhibit Number	Description of Document
10.1	License, Development and Commercialization Agreement, dated as of January 9, 2015, by and between the Company, Incyte Europe Sarl (a wholly owned subsidiary of the Company), Agenus Inc. and 4-Antibody AG.
10.2	Stock Purchase Agreement, dated as of January 9, 2015, between the Company and Agenus Inc.
10.3#	Amendment, dated as of April 13, 2015, to Employment Agreement between the Company and Hervé Hoppenot, dated as of January 11, 2014
31.1	Rule 13a-14(a) Certification of Chief Executive Officer
31.2	Rule 13a-14(a) Certification of Chief Financial Officer
32.1*	Statement of the Chief Executive Officer under Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350)
32.2*	Statement of the Chief Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350)
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
101.DEF**	XBRL Taxonomy Definition Linkbase Document

# Indicates management contract or compensatory plan or arrangement.

* In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 34-47986, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-Q and will not be deemed filed for purposes 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.

** In accordance with Rule 406T of Regulation S-T, the information furnished in these exhibits will not be deemed filed for purposes of Section 18 of the Exchange Act. Such exhibits will not be deemed to be incorporated by reference into any filing under the Securities Act or Exchange Act.

Confidential treatment has been requested with respect to certain portions of this agreement.

Table of Contents

SIGNATURES

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

INCYTE CORPORATION

Dated: April 30, 2015	By:	/s/ HERVÉ HOPPENOT Hervé Hoppenot Chief Executive Officer (Principal Executive Officer)
Dated: April 30, 2015	By:	/s/ DAVID W. GRYSKA David W. Gryska Chief Financial Officer (Principal Financial Officer)

Table of Contents

INCYTE CORPORATION

EXHIBIT INDEX

Exhibit Number	Description of Document
10.1	License, Development and Commercialization Agreement, dated as of January 9, 2015, by and between the Company, Incyte Europe Sarl (a wholly owned subsidiary of the Company), Agenus Inc. and 4-Antibody AG.
10.2	Stock Purchase Agreement, dated as of January 9, 2015, between the Company and Agenus Inc.
10.3#	Amendment, dated as of April 13, 2015, to Employment Agreement between the Company and Hervé Hoppenot, dated as of January 11, 2014
31.1	Rule 13a-14(a) Certification of Chief Executive Officer
31.2	Rule 13a-14(a) Certification of Chief Financial Officer
32.1*	Statement of the Chief Executive Officer under Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350)
32.2*	Statement of the Chief Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350)
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
101.DEF**	XBRL Taxonomy Definition Linkbase Document

# Indicates management contract or compensatory plan or arrangement.

* In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 34-47986, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-Q and will not be deemed filed for purposes 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.

** In accordance with Rule 406T of Regulation S-T, the information furnished in these exhibits will not be deemed filed for purposes of Section 18 of the Exchange Act. Such exhibits will not be deemed to be incorporated by reference into any filing under the Securities Act or Exchange Act.

Confidential treatment has been requested with respect to certain portions of this agreement.