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

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