EXELIXIS, INC.
Form 10-Q
November 03, 2016
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q
(Mark One)
ý QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2016
or
¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the transition period from to
Commission File Number: 000-30235
EXELIXIS, INC.
(Exact name of registrant as specified in its charter)

Delaware	04-3257395
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

210 East Grand Ave.
South San Francisco, CA 94080
(650) 837-7000
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)
Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days). Yes ý 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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý 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 ý	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No ý
As of October 26, 2016, there were 286,455,917 shares of the registrant's common stock outstanding.

Table of Contents

EXELIXIS, INC.
QUARTERLY REPORT ON FORM 10-Q
INDEX

Table of Contents

PART I - FINANCIAL INFORMATION
Item 1. Financial Statements
EXELIXIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	September 30, 2016 (unaudited)	December 31, 2015*
ASSETS		
Current assets:		
Cash and cash equivalents	$ 111,219	$141,634
Short-term investments	208,462	25,426
Trade and other receivables	91,207	5,183
Inventory	3,292	2,616
Prepaid expenses and other current assets	7,148	3,806
Total current assets	421,328	178,665
Long-term investments	55,817	83,600
Long-term restricted cash and investments	4,150	2,650
Property and equipment, net	1,737	1,434
Goodwill	63,684	63,684
Other long-term assets	1,774	2,309
Total assets	$ 548,490	$332,342
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 3,965	$6,401
Accrued collaboration liability	18,710	10,938
Accrued compensation and benefits	15,986	3,629
Accrued clinical trial liabilities	14,887	18,071
Current portion of convertible notes	29,365	—
Current portion of term loan payable	80,000	—
Current portion of deferred revenue	18,939	—
Other accrued liabilities	19,791	13,212
Total current liabilities	201,643	52,251
Long-term portion of convertible notes	81,493	337,937
Long-term portion of term loan payable	—	80,000
Long-term portion of deferred revenue	232,573	—
Other long-term liabilities	759	2,960
Total liabilities	516,468	473,148
Commitments		
Stockholders' equity (deficit):		
Preferred stock	—	—
Common stock, $0.001 par value; 400,000,000 shares authorized; issued and outstanding: 286,123,166 and 227,960,943 shares at September 30, 2016 and December 31, 2015, respectively	286	228
Additional paid-in capital	2,050,086	1,772,123
Accumulated other comprehensive loss	(80)	(232)
Accumulated deficit	(2,018,270)	(1,912,925)
Total stockholders' equity (deficit)	32,022	(140,806)
Total liabilities and stockholders' equity (deficit)	$ 548,490	$332,342

* The condensed consolidated balance sheet as of December 31, 2015 has been derived from the audited financial statements as of that date.

The accompanying notes are an integral part of these condensed consolidated financial statements.

Table of Contents

EXELIXIS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenues:				
Net product revenues	$42,742	$6,854	$83,459	$24,234
Royalty, license and contract revenues	19,452	3,000	30,414	3,000
Total revenues	62,194	9,854	113,873	27,234
Operating expenses:				
Cost of goods sold	2,455	1,420	4,700	2,872
Research and development	20,256	26,091	72,166	72,879
Selling, general and administrative	32,463	17,842	103,143	40,162
Restructuring (recovery) charge	(244)	282	871	1,142
Total operating expenses	54,930	45,635	180,880	117,055
Income (loss) from operations	7,264	(35,781)	(67,007)	(89,821)
Other income (expense), net:				
Interest income and other, net	3,059	276	4,010	146
Interest expense	(7,834)	(10,037)	(28,575)	(30,501)
Loss on extinguishment of debt	(13,773)	—	(13,773)	—
Total other income (expense), net	(18,548)	(9,761)	(38,338)	(30,355)
Net loss	$(11,284)	$(45,542)	$(105,345)	$(120,176)
Net loss per share, basic and diluted	$(0.04)	$(0.21)	$(0.44)	$(0.59)
Shares used in computing basic and diluted net loss per share	256,319	217,587	238,024	203,153

The accompanying notes are an integral part of these condensed consolidated financial statements.

EXELIXIS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net loss	$(11,284)	$(45,542)	$(105,345)	$(120,176)
Other comprehensive income (loss) (1)	(209)	133	152	80
Comprehensive loss	$(11,493)	$(45,409)	$(105,193)	$(120,096)

(1) Other comprehensive income (loss) consisted solely of unrealized gains or losses, net on available for sale securities arising during the periods presented. There were no reclassification adjustments to net loss resulting from realized gains or losses on the sale of securities and there was no income tax expense related to other comprehensive income during those periods.

The accompanying notes are an integral part of these condensed consolidated financial statements.

Table of Contents

EXELIXIS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	$(105,345)	$(120,176)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	754	1,063
Stock-based compensation expense	18,346	15,420
Accretion of debt discount and debt issuance costs	8,295	14,274
Accrual of interest paid in kind	5,939	1,890
Gain on sale of equity investment	(2,494)	(95)
Loss on extinguishment of debt	13,773	—
Change in the fair value of warrants	—	549
Other	(1,381)	1,338
Changes in assets and liabilities:		
Trade and other receivables	(85,923)	1,034
Inventory	(676)	259
Prepaid expenses and other current assets	(3,342)	(1,940)
Other long term assets	535	1,832
Accounts payable, accrued compensation and benefits, and other accrued liabilities	18,816	(14,293)
Accrued collaboration liability	7,772	8,400
Clinical trial liabilities	(3,184)	(11,757)
Deferred revenue	251,512	(2,583)
Other long-term liabilities	(815)	(1,367)
Net cash provided by (used in) operating activities	122,582	(106,152)
Cash flows from investing activities:		
Purchases of property and equipment	(1,116)	(114)
Proceeds from sale of property and equipment	92	1,300
Proceeds from sale of equity investments	2,494	95
Proceeds from maturities of restricted cash and investments	2,650	16,754
Purchase of restricted cash and investments	(4,150)	(2,616)
Proceeds from sale of investments	2,266	—
Proceeds from maturities of investments	100,635	130,341
Purchases of investments	(258,509)	(119,692)
Net cash (used in) provided by investing activities	(155,638)	26,068
Cash flows from financing activities:		
Proceeds from issuance of common stock, net	—	145,651
Proceeds from exercise of stock options	9,296	3,787
Proceeds from employee stock purchase plan	479	274
Principal payments on debt	—	(4,381)
Payments on conversion of convertible notes	(7,134)	—
Net cash provided by financing activities	2,641	145,331
Net (decrease) increase in cash and cash equivalents	(30,415)	65,247
Cash and cash equivalents at beginning of period	141,634	80,395
Cash and cash equivalents at end of period	$111,219	$145,642

Supplemental cash flow disclosure - non-cash financing activity:		
Issuance of common stock in settlement of convertible notes	$285,308	$—

The accompanying notes are an integral part of these condensed consolidated financial statements.

Table of Contents

EXELIXIS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

NOTE 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization

Exelixis, Inc. ("Exelixis," "we," "our" or "us") is a biopharmaceutical company committed to the discovery, development and commercialization of new medicines that will improve care and outcomes for people with cancer. Since its founding in 1994, three products discovered at Exelixis have progressed through clinical development, received regulatory approval, and entered the commercial marketplace. This portfolio includes two products derived from cabozantinib, an inhibitor of multiple tyrosine kinases including MET, AXL, and VEGF receptors. They are CABOMETYX™ tablets for the treatment of advanced kidney cancer and COMETRIQ® capsules for the treatment of certain forms of thyroid cancer, each approved both in the United States and European Union. The third product is COTELLIC®, a product derived from cobimetinib, a selective inhibitor of MEK, marketed under a collaboration with Roche and Genentech (a member of the Roche Group) that has been approved in combination with ZELBORAF® (vemurafenib) to treat advanced melanoma in several major territories, including the United States and European Union.

Basis of Consolidation

The condensed consolidated financial statements include the accounts of Exelixis and those of our wholly-owned subsidiaries. These entities' functional currency is the U.S. dollar. All intercompany balances and transactions have been eliminated.

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 pursuant to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission ("SEC"). Accordingly, they do not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements. In our opinion, all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation of the results of operations and cash flows for the periods presented have been included.

We adopted a 52- or 53-week fiscal year that generally ends on the Friday closest to December 31st. Fiscal year 2016 will end on December 30, 2016, and fiscal year 2015, ended on January 1, 2016. For convenience, references in this report as of and for the fiscal periods ended September 30, 2016, and October 2, 2015, and as of and for the fiscal years ended December 30, 2016 and January 1, 2016, are indicated as being as of and for the periods ended September 30, 2016, September 30, 2015, and the years ended December 31, 2016, and December 31, 2015, respectively. Operating results for the nine months ended September 30, 2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016 or for any future period. These financial statements and notes should be read in conjunction with the consolidated financial statements and notes thereto for the year ended December 31, 2015, included in our Annual Report on Form 10-K filed with the SEC on February 29, 2016.

Correction of an Immaterial Error

During the third quarter of 2016, we identified errors in the Consolidated Balance Sheets and Consolidated Statements of Operations, Comprehensive Loss and Cash Flows for 2015, 2014, 2013, and 2012, and in the unaudited interim Condensed Consolidated Balance Sheets and Condensed Consolidated Statements of Operations, Comprehensive Loss and Cash Flows for all prior interim fiscal periods from September 30, 2012 through June 30, 2016. Specifically, in 2012 we incorrectly calculated 1) the allocation between Additional paid-in capital and Convertible notes of the $287.5 million aggregate principal amount from our 4.25% Convertible Subordinated Notes due 2019 ("2019 Notes"); and 2) the amortization of the debt discount associated with the 2019 Notes during 2012 and all subsequent periods. Having evaluated the materiality of these errors from a quantitative and qualitative perspective, management has concluded that although the accumulation of these errors was significant to the three and nine months ended September 30, 2016, the correction of these errors would not be material to any individual prior period, and did not have an effect on the trend of financial results, taking into account the requirements of the SEC Staff Accounting Bulletin No. 99, Materiality and Staff Accounting Bulletin No. 108, Considering the Effects of Prior Year

Misstatements when Quantifying Misstatements in Current Year Financial Statements. Because management has concluded that these errors are not material, we will correct

Table of Contents

them prospectively when the consolidated balance sheets, statements of operations, comprehensive loss and cash flows for such periods are included in future filings.

Following are the amounts (in thousands, except per share amounts) that should have been reported for the affected line items of the statements of operations, statements of comprehensive loss and statements of cash flows:

	Three months ended September 30, 2015	Nine months ended September 30, 2015	Year ended December 31,			
			2015	2014	2013	2012
Statements of Operations:						
Interest expense, overstated by $2,022, $5,920, $7,993, $7,245, $6,568, $2,310 for the three and nine months ended September 30, 2015 and the years ended December 31, 2015, 2014, 2013 and 2012, respectively	$(10,037)	$(30,501)	$(40,680)	$(41,362)	$(38,779)	$(24,778)
Total other income (expense), net, overstated by $2,022, $5,920, $7,993, $7,245, $6,568, $2,310 for the three and nine months ended September 30, 2015 and the years ended December 31, 2015, 2014, 2013 and 2012, respectively	$(9,761)	$(30,355)	$(40,268)	$(37,021)	$(37,556)	$(22,792)
Net loss, overstated by $2,022, $5,920, $7,993, $7,245, $6,568, $2,310 for the three and nine months ended September 30, 2015 and the years ended December 31, 2015, 2014, 2013 and 2012, respectively	$(45,542)	$(120,176)	$(161,744)	$(261,297)	$(238,192)	$(145,335)
Net loss per share, basic and diluted, overstated by $0.01, $0.03, $0.04, $0.04, $0.04, $0.01 for the three and nine months ended September 30, 2015 and the years ended December 31, 2015, 2014, 2013 and 2012, respectively	$(0.21)	$(0.59)	$(0.77)	$(1.34)	$(1.29)	$(0.91)
Statements of Comprehensive Loss:						
Comprehensive loss, overstated by $2,022, $5,920, $7,993, $7,245, $6,568, $2,310 for the three and nine months ended September 30, 2015 and the years ended December 31, 2015, 2014, 2013 and 2012, respectively	$(45,409)	$(120,096)	$(161,855)	$(261,564)	$(237,954)	$(145,289)
Statements of Cash Flows[(1)]:						
Net loss, overstated by $5,920, $7,993, $7,245, $6,568, $2,310 for the nine months ended September 30, 2015 and the years ended December 31, 2015, 2014, 2013 and 2012, respectively	Not reported	$(120,176)	$(161,744)	$(261,297)	$(238,192)	$(145,335)
Accretion of debt discount and debt issuance costs, overstated by $5,920, $7,993, $7,245, $6,568, $2,310 for the nine months ended September 30, 2015 and the years ended December 31, 2015, 2014,	Not reported	$14,274	$17,041	$22,289	$19,722	$12,442

2013 and 2012, respectively

(1) The error did not impact our net cash provided by or used in operating activities, financing activities or investing activities for any of the periods presented.

Table of Contents

Following are the amounts (in thousands) that should have been reported for the affected line items of the balance sheets and statements of stockholders' (deficit) equity:

	December 31, 2015	2014	2013	2012
Balance Sheets:				
Long-term portion of convertible notes, understated by $36,502, $44,494, $51,739, $58,307 as of December 31, 2015, 2014, 2013 and 2012, respectively	$337,937	$223,629	$301,550	$291,828
Liabilities, understated by $36,502, $44,494, $51,739, $58,307 as of December 31, 2015, 2014, 2013 and 2012, respectively	$473,148	$482,592	$483,452	$476,015
Additional paid-in capital, overstated by $60,618 as of all dates presented	$1,772,123	$1,591,782	$1,504,052	$1,489,727
Accumulated deficit, overstated by $24,116, $16,124, $8,879, $2,310 as of December 31, 2015, 2014, 2013 and 2012, respectively	$(1,912,925)	$(1,751,180)	$(1,489,883)	$(1,251,692)
Stockholders' (deficit) equity, misstated by $36,502, $44,494, $51,739, $58,307 as of December 31, 2015, 2014, 2013 and 2012, respectively	$(140,806)	$(159,323)	$14,499	$238,127
Statements of Stockholders' (Deficit) Equity:				
Net loss, overstated by $7,993, $7,245, $6,568, $2,310 for the years ended December 31, 2015, 2014, 2013 and 2012, respectively	$(161,744)	$(261,297)	$(238,192)	$(145,335)
Additional paid-in capital, overstated by $60,618 as of all dates presented	$1,772,123	$1,591,782	$1,504,052	$1,489,727
Accumulated deficit, overstated by $24,116, $16,124, $8,879, $2,310 as of December 31, 2015, 2014, 2013 and 2012, respectively	$(1,912,925)	$(1,751,180)	$(1,489,883)	$(1,251,692)
Stockholders' (deficit) equity, misstated by $36,502, $44,494, $51,739, $58,307 as of December 31, 2015, 2014, 2013 and 2012, respectively	$(140,806)	$(159,323)	$14,499	$238,127

These errors did not affect any other caption or total in our unaudited condensed or annual consolidated financial statements.

Segment Information

We operate as a single reportable segment.

Use of Estimates

The preparation of our consolidated financial statements is in conformity with accounting principles generally accepted in the United States that requires management to make judgments, estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosures. On an ongoing basis, management evaluates its estimates including, but not limited to, those related to revenue recognition, including for deductions from revenues (such as rebates, chargebacks, sales returns and sales allowances) and the period of performance, identification of deliverables and evaluation of milestones with respect to our collaborations, recoverability of inventory, certain accrued liabilities including clinical trial and collaboration liability accruals, the valuation of the debt and equity components of our convertible debt and share-based compensation. We base our estimates on historical experience and on various other market-specific and other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ materially from those estimates.

Limited Sources of Revenues and the Need to Raise Additional Capital

We have incurred net losses since inception through September 30, 2016, with the exception of the 2011 fiscal year. For the nine months ended September 30, 2016, we incurred a net loss of $105.3 million and as of September 30, 2016, we had an accumulated deficit of $2.0 billion. These losses have had an adverse effect on our stockholders' equity and working

Table of Contents

capital. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses or when we will become profitable. Excluding fiscal 2011, our research and development expenditures and selling, general and administrative expenses have exceeded our revenues for each fiscal year, and we expect to spend significant additional amounts to fund the continued development and commercialization of cabozantinib. In addition, we are evaluating the expansion of our pipeline through drug discovery and corporate development activities. As a result, we expect to continue to incur substantial operating expenses and, consequently, we will need to generate significant additional revenues to achieve future profitability.

Other than sales of CABOMETYX and COMETRIQ, which have totaled $157.7 million in net product revenues since the first commercial launch in January 2013, we have derived substantially all of our revenues since inception from collaborative research and development agreements, which depend on royalties, license fees, the achievement of milestones, and research funding we earn from any products developed from the collaborative research.

The amount of our net losses will depend, in part, on: the level of sales of CABOMETYX and COMETRIQ in the United States; achievement of clinical, regulatory and commercial milestones and the amount of royalties, if any, from sales of CABOMETYX and COMETRIQ under our collaboration with Ipsen Pharma SAS (“Ipsen”); our share of the net profits and losses for the commercialization of COTELLIC in the U.S. under our collaboration with Genentech (a member of the Roche group); the amount of royalties from COTELLIC sales outside the U.S. under our collaboration with Genentech; other license and contract revenues; and, the level of our expenses, including commercialization activities for cabozantinib and any pipeline expansion efforts.

As of September 30, 2016, we had $379.6 million in cash and investments, which included $293.8 million available for operations, $81.6 million of compensating balance investments that we are required to maintain on deposit with Silicon Valley Bank, and $4.2 million of long-term restricted investments. We anticipate that our current cash and cash equivalents, and short-term investments available for operations, and product revenues, will enable us to maintain our operations for a period of at least 12 months following the filing date of this report. Our capital requirements will depend on many factors, and we may need to use available capital resources and raise additional capital significantly earlier than we currently anticipate.

Revenue Recognition

We recognize revenue from product sales and from license fees, milestones, contingent payments and royalties earned on research, collaboration and license arrangements.

See “Note 1 - Organization and Summary of Significant Accounting Policies” to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2015 for a description of our revenue recognition policies for product sales discounts and allowances, license and contract revenues under our collaboration agreement with Genentech and our Patient Assistance Program.

Net Product Revenues

We recognize revenue when it is both realized or realizable and earned, meaning persuasive evidence of an arrangement exists, delivery has occurred, title has transferred, the price is fixed or determinable, there are no remaining customer acceptance requirements, and collectability of the resulting receivable is reasonably assured. For product sales in the United States, this generally occurs upon delivery of the product to a specialty pharmacy or distributor. For product sales to our distribution partner, Swedish Orphan Biovitrum (“Sobi”), this generally occurs when Sobi has accepted the product. For product sales to our collaboration partner Ipsen, this generally occurs upon delivery.

In the United States, we sell our products, CABOMETYX and COMETRIQ, to specialty pharmacies and distributors that benefit from customer incentives and have a right of return under certain circumstances. Prior to 2015, COMETRIQ had limited sales history and we could not reliably estimate expected future returns, discounts and rebates of the product at the time the product was sold to a single specialty pharmacy, therefore we recognized revenue when the specialty pharmacy provided the product to a patient based on the fulfillment of a prescription. This is frequently referred to as the “sell-through” revenue recognition model. In January 2015, we established that we had sufficient historical experience and data to reasonably estimate expected future returns of COMETRIQ and the discounts and rebates due to payors at the time of shipment to the specialty pharmacy. Accordingly, beginning in January 2015 we began to recognize revenue upon delivery to the specialty pharmacy. This approach is frequently

referred to as the “sell-in” revenue recognition model. In connection with the change in the timing of recognition of U.S. COMETRIQ sales, we recorded a one-time adjustment to recognize revenue that had previously been deferred under the “sell-through” revenue recognition model, resulting in the additional recognition of gross product revenues of $2.6 million for the nine months ended September 30, 2015; there were no such additional amounts recorded during the comparable period in 2016.

Table of Contents

In determining discounts and allowances for the initial launch and sale of CABOMETYX, in addition to using payer data received from the specialty pharmacies and distributors that sell CABOMETYX and historical data for COMETRIQ, we also utilized claims data from third party sources for competitor products for the treatment of advanced renal cell carcinoma ("RCC"). Based in part on the availability of this third party data, we made the determination that we had sufficient experience and data to reasonably estimate expected future returns and the discounts and allowances due to payers at the time of shipment to the specialty pharmacy or distributor, and therefore record revenue for the product using the "sell-in" revenue recognition model. Net product revenues during the nine months ended September 30, 2016 were impacted by the build of channel inventory related to the initial launch period for CABOMETYX.

We also utilize the "sell-in" revenue recognition model for product sales to Sobi for all periods presented. Once Sobi has accepted the product, the product is generally no longer subject to return; therefore, we record revenue at the time Sobi has accepted the product. As described further in "Note 2 - Research and Collaboration Agreements", under the terms of our collaboration and license agreement with Ipsen for the commercialization and further development of cabozantinib, we provided Sobi with a notice of termination of our commercialization agreement for COMETRIQ which will become effective November 1, 2016. We expect to repurchase the remaining product on hand from Sobi following the termination. As of September 30, 2016, we recorded allowances for expected future returns totaling $0.4 million; there were no such allowances recorded as of December 31, 2015 or September 30, 2015.

For product sales to Ipsen, which began during the three months ended September 30, 2016, we utilize the "sell-in" revenue recognition model. Once title has transferred to Ipsen, the product is generally no longer subject to return; therefore, we record revenue at the time product is delivered.

Royalty, License and Contract Revenues

We enter into corporate collaboration and license agreements under which we may obtain upfront license fees, research funding, and contingent, milestone and royalty payments. These arrangements have multiple elements and our deliverables may include intellectual property rights, distribution rights, delivery of manufactured product, and participation on joint steering, commercial and development committees. In order to account for these arrangements, we identify the deliverables and evaluate whether the delivered elements have value to our collaboration partner on a stand-alone basis and represent separate units of accounting. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver future goods or services, a right or license to use an asset, or another performance obligation. If we determine that multiple deliverables exist, the consideration is allocated to one or more units of accounting based upon the best estimate of the selling price of each deliverable. The selling price used for each deliverable will be based on vendor-specific objective evidence, if available, third-party evidence if vendor-specific objective evidence is not available, or estimated selling price if neither vendor-specific or third-party evidence is available. A delivered item or items that do not qualify as a separate unit of accounting within the arrangement shall be combined with the other applicable undelivered items within the arrangement. The allocation of arrangement consideration and the recognition of revenue then shall be determined for those combined deliverables as a single unit of accounting. For a combined unit of accounting, non-refundable upfront fees are recognized in a manner consistent with the final deliverable, which has generally been ratably over the period of continued involvement. Amounts received in advance of performance are recorded as deferred revenue. Upfront fees are classified as license revenues in our consolidated statements of operations.

We consider sales-based contingent payments to be royalty revenue which is generally recognized at the date the contingency is achieved. Royalties are recorded based on sales amounts reported to us for the preceding quarter.

For certain contingent payments under collaboration and license arrangements, we recognize revenue using the milestone method. Under the milestone method a payment that is contingent upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is an event: (i) that can be achieved based in whole or in part on either our performance or on the occurrence of a specific outcome resulting from our performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to us. The determination that a milestone is substantive requires estimation and judgment and is made at the inception of the arrangement. Milestones are considered substantive when the consideration earned from the achievement of the

milestone is: (i) commensurate with either our performance to achieve the milestone or the enhancement of value of the item delivered as a result of a specific outcome resulting from our performance to achieve the milestone, (ii) relates solely to past performance and (iii) reasonable relative to all deliverables and payment terms in the arrangement. In making the determination as to whether a milestone is substantive or not, we consider all facts and circumstances relevant to the arrangement, including factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether any portion of the milestone consideration is related to future performance or deliverables.

Table of Contents

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Updates ("ASU") No. 2014-09, Revenue from Contracts with Customers, ("ASU 2014-09"). ASU 2014-09 will replace most existing revenue recognition guidance when it becomes effective and permits the use of either the retrospective or cumulative effect transition method. In August 2015, the FASB issued an update to defer the effective date of this update by one year. ASU 2014-09, as amended, becomes effective for us in the first quarter of fiscal year 2018, but allows us to adopt the standard one year earlier if we so choose. We currently plan to adopt this accounting standard in the first quarter of fiscal year 2018. We have not yet selected a transition method and are evaluating the effect that ASU 2014-09 will have on our Consolidated Financial Statements and related disclosures.

In April 2015, the FASB issued Accounting Standards Update No. 2015-05, Customer's Accounting for Fees Paid in a Cloud Computing Arrangement, ("ASU 2015-05"). ASU 2015-05 provides guidance to customers about whether a cloud computing arrangement includes a software license. If a cloud computing arrangement includes a software license, then the customer should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the customer should account for the arrangement as a service contract. ASU 2015-05 was effective for all interim and annual reporting periods beginning after December 15, 2015 and therefore we adopted ASU 2015-05 in the three months ended March 31, 2016 on a prospective basis. The adoption of ASU 2015-05 did not have a material impact on our Condensed Consolidated Statements of Operations during the period of adoption and is not expected to have a material effect on our Consolidated Financial Statements in future periods.

In July 2015, the FASB issued ASU No. 2015-11, Inventory: Simplifying the Measurement of Inventory ("ASU No. 2015-11"). ASU No. 2015-11 requires inventory measurement at the lower of cost and net realizable value. ASU No. 2015-11 are effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. Early adoption is permitted by all entities as of the beginning of an interim or annual reporting period. We are in the process of assessing the impact, if any, of ASU No. 2015-11 on our condensed consolidated financial statements.

In March 2016, the FASB issued Accounting Standards Update No. 2016-09, Improvements to Employee Share-Based Payment Accounting, ("ASU 2016-09"). ASU 2016-09 is aimed at the simplification of several aspects of the accounting for employee share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for all interim and annual reporting periods beginning after December 15, 2016. Early adoption is permitted. We do not expect the adoption of ASU 2016-09 to have a material impact on our Consolidated Financial Statements.

In August 2016, the FASB issued Accounting Standards Update No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments, ("ASU 2016-15"). ASU 2016-15 addresses eight specific cash flow issues including debt prepayment or debt extinguishment costs, settlement of zero-coupon debt instruments or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing and contingent consideration payments made after a business combination. We do not expect the adoption of ASU 2016-15 to have a material impact on our Consolidated Statements of Cash Flows.

NOTE 2: RESEARCH AND COLLABORATION AGREEMENTS

Ipsen Collaboration

On February 29, 2016, we entered into a collaboration and license agreement (the "Agreement") with Ipsen for the commercialization and further development of cabozantinib. Pursuant to the terms of the Agreement, Ipsen will have exclusive commercialization rights for current and potential future cabozantinib indications outside of the United States, Canada and Japan. We have also agreed to collaborate with Ipsen on the development of cabozantinib for current and potential future indications.

In consideration for the exclusive license and other rights contained in the Agreement, Ipsen paid us an upfront nonrefundable payment of $200.0 million in March 2016. As a result of the approval of cabozantinib by the European Medicines Agency ("EMA") in second-line RCC in September 2016, we achieved a $60.0 million milestone which we expect to receive in November 2016. We will be eligible to receive additional development and regulatory milestones, totaling up to $240.0 million, including milestone payments of $10.0 million and $40.0 million upon the filing and the

approval of cabozantinib in second-line hepatocellular carcinoma, and additional milestones for other future indications. We will also be eligible to receive two $10.0 million milestone payments upon the launch of the product in the first two of the following countries: Germany, France, Italy, Spain and the United Kingdom. The Agreement also provides that we will be eligible to receive contingent payments of up to $525.0 million associated with the achievement of specified levels of Ipsen sales to end

Table of Contents

users. We will also receive royalties on net sales of cabozantinib outside of the United States, Canada and Japan. We will receive a 2% royalty on the initial $50.0 million of net sales, and a 12% royalty on the next $100.0 million of net sales. After the initial $150.0 million of sales, we will receive a tiered royalty of 22% to 26% on annual net sales; these tiers will reset each calendar year. We are primarily responsible for funding cabozantinib related development costs for existing trials; global development costs for potential future trials will be shared between the parties, with Ipsen to reimburse us for 35% of such costs. Pursuant to the terms of the Agreement, we will remain responsible for the manufacture and supply of cabozantinib for all development and commercialization activities under the Agreement. As part of the Agreement, we entered into a supply agreement which provides that through the end of the second quarter of 2018, we will supply finished, labeled product to Ipsen for distribution in the territories outside of the United States, Canada and Japan. From the end of the second quarter of 2018 forward, we will continue to manufacture CABOMETYX tablets, while Ipsen will be responsible for packaging and labeling the product in territories where it has been approved outside of the United States, Canada and Japan, as applicable.

The Agreement contains multiple elements, and the deliverables under the Agreement consist of intellectual property licenses, delivery of products and/or materials containing cabozantinib to Ipsen for all development and commercial activities, research and development services, and participation on the joint steering and development committees (as defined in the Agreement) with Ipsen. These deliverables are non-contingent in nature. The Company determined that these deliverables do not have stand-alone value, because each one of them has value only if the Company meets its obligation to provide Ipsen with cabozantinib, which the Company deems to be the predominant deliverable under the Agreement. The Company also determined that the level of effort required of the Company to meet its obligations under the Agreement is not expected to vary significantly over the life of the Agreement. Accordingly, the Company combined these deliverables into a single unit of accounting and allocated the entire arrangement consideration to that combined unit of accounting. As a result, the upfront payment of $200.0 million, received in the first quarter of 2016 is being recognized ratably over the effective term of the Agreement, which continues through early 2030, the current estimated patent expiration of cabozantinib in the European Union. At the time we entered into the agreement, we also determined that the $60.0 million milestone we achieved upon the approval of cabozantinib by the EMA in second-line RCC was not substantive due to the relatively low degree of uncertainty and relatively low amount of effort required on our part to achieve the milestone as of the date of the Agreement; the $60.0 million was deferred as of the date of the EMA’s approval of cabozantinib in second-line RCC in September 2016, which we expect to receive in November 2016, and is being recognized ratably over the remaining term of the Agreement. We determined that the remaining development and regulatory milestones are substantive and will be recognized as revenue in the periods in which they are achieved. We consider the contingent payments due to us upon the achievement of specified sales volumes to be similar to royalty payments. Subsequent to February 29, 2016, we transferred the intellectual property rights to Ipsen, and participated in s regulatory filing activities and planning for the production, delivery and distribution of manufactured product. As a result of these activities, we began to recognize of the upfront payment under the Agreement. During the three and nine months ended September 30, 2016, we have recognized $3.8 million and $8.6 million, respectively, in license revenue under the Agreement. As of September 30, 2016, short-term and long-term deferred revenue relating to the Agreement was $18.9 million and $232.6 million, respectively.

In connection with the establishment of the Agreement with Ipsen, we provided Sobi with a notice of termination of our distribution and commercialization agreement for COMETRIQ. Effective November 1, 2016, Ipsen will become responsible for the distribution and commercialization of COMETRIQ for the approved medullary thyroid cancer indication in territories previously supported by Sobi. Pursuant to our commercialization agreement with Sobi we are required to pay a termination fee. As of September 30, 2016, we had a $2.7 million accrual for the estimated termination fee to be paid to Sobi and the related expense, which was recorded during the three months ended March 31, 2016, is included in Selling, general and administrative expenses in the accompanying Condensed Consolidated Statements of Operations for the nine months ended September 30, 2016. Additionally, pursuant to our commercialization agreement with Sobi, we expect to repurchase unsold product from Sobi and have recorded a returns allowance of $0.4 million as of September 30, 2016, the related charge for which is included as a reduction to Net product revenues in the accompanying Condensed Consolidated Statements of Operations.

Genentech Collaboration

In December 2006, we out-licensed the development and commercialization of cobimetinib to Genentech (a member of the Roche group) pursuant to a worldwide collaboration agreement. We discovered cobimetinib internally and advanced the compound to investigational new drug ("IND") status.

Genentech paid upfront and milestone payments of $25.0 million in December 2006 and $15.0 million in January 2007 upon signing of the collaboration agreement and with the submission of the IND application for cobimetinib. Under the terms of the agreement, we were responsible for developing cobimetinib through the determination of the maximum-tolerated dose in a phase 1 clinical trial, and Genentech had the option to co-develop cobimetinib, which Genentech could exercise after receipt of certain phase 1 data from us. In March 2008, Genentech exercised its option to co-develop cobimetinib. In March

Table of Contents

2009, we granted to Genentech an exclusive worldwide revenue-bearing license to cobimetinib, at which point Genentech became responsible for completing the phase 1 clinical trial and subsequent clinical development.

The U.S. Food and Drug Administration ("FDA") approved cobimetinib in the United States under the brand name COTELLIC on November 10, 2015. It is indicated in combination with vemurafenib as a treatment for patients with BRAF V600E or V600K mutation-positive advanced melanoma. COTELLIC in combination with vemurafenib has also been approved in multiple other territories including the European Union and Canada.

Under the terms of our collaboration agreement with Genentech for cobimetinib, we are entitled to a share of U.S. profits and losses in connection with the commercialization of cobimetinib. The profit and loss share has multiple tiers: we are entitled to 50% of profits and losses from the first $200.0 million of U.S. actual sales, decreasing to 30% of profits and losses from U.S. actual sales in excess of $400.0 million. We are entitled to low double-digit royalties on ex-U.S. net sales. In November 2013, we exercised an option under the collaboration agreement to co-promote in the United States. Following the approval of COTELLIC in the United States in November 2015, we began fielding 25% of the sales force promoting COTELLIC in combination with vemurafenib as a treatment for patients with BRAF V600E or V600K mutation-positive advanced melanoma.

We recorded net losses of $2.9 million and $14.8 million under the collaboration agreement during the three and nine months ended September 30, 2016, respectively, as compared to $4.3 million and $11.8 million for the comparable periods in 2015; those costs are included in Selling, general and administrative expenses on the accompanying Condensed Consolidated Statements of Operations. A majority of the liability for those costs which consists of commercialization expenses that Genentech has allocated to the collaboration, but are in dispute, is identified as Accrued collaboration liability on the accompanying Condensed Consolidated Balance Sheets. On June 3, 2016, we filed a Demand for Arbitration before JAMS in San Francisco, California asserting claims against Genentech related to its clinical development, pricing and commercialization of COTELLIC, and cost and revenue allocations in connection with COTELLIC's commercialization in the United States.

Our arbitration demand asserts that Genentech has breached the parties' contract for, amongst other breaches, failing to meet its diligence and good faith obligations. The demand seeks various forms of declaratory, monetary, and equitable relief, including without limitation that the cost and revenue allocations for COTELLIC be shared equitably consistent with the collaboration agreement's terms, along with attorneys' fees and costs of the arbitration. Genentech has asserted a counterclaim for breach of contract, which seeks monetary damages and interest related to the cost allocations under the collaboration agreement.

We also recognized license revenues of $0.7 million and $1.8 million for royalties on ex-U.S. net sales of COTELLIC during the three and nine months ended September 30, 2016, respectively, based on sales amounts reported by Genentech for the preceding quarter. We recognized no such royalties during the comparable periods in 2015.

Other Collaborations

During the three and nine months ended September 30, 2016, we recognized $15.0 million in contract revenues from a milestone payment earned from Daiichi Sankyo related to its worldwide license of our compounds that modulate mineralocorticoid receptor ("MR"), including CS-3150 (an isomer of XL550). During the nine months ended September 30, 2016 and the three and nine months ended September 30, 2015, we recognized $5.0 million, $3.0 million and $3.0 million, respectively, in contract revenues from milestone payments earned from Merck related to its worldwide license of our phosphoinositide-3 kinase-delta program.

See "Note 2 - Research and Collaboration Agreements" to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2015 for a description of our existing collaboration agreements.

NOTE 3: RESTRUCTURINGS

Between March 2010 and May 2013, we implemented five restructurings (which we refer to collectively as the "2010 Restructurings") to manage costs and as a consequence of our decision in 2010 to focus our proprietary resources and development efforts on the development and commercialization of cabozantinib. In September 2014, as a consequence of the failure of COMET-1, one of our two phase 3 pivotal trials of cabozantinib in metastatic castration-resistant prostate cancer, we initiated a restructuring (which we refer to as the "2014 Restructuring") to enable us to focus our financial resources on the phase 3 pivotal trials of cabozantinib in advanced RCC and advanced hepatocellular

carcinoma. See “Note 3 - Restructurings” to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2015 for additional information about the restructurings.

For the nine months ended September 30, 2016 and 2015, we recorded a restructuring charge of $0.9 million and $1.1 million, respectively, for the restructurings. Both periods included the effect of the passage of time on our discounted cash flow computations (“accretion expense”) for the exit, in prior periods, of certain of our South San Francisco buildings. During the nine months ended September 30, 2016, the restructuring charge included $0.8 million in charges related to a tenant’s default on an existing sublease which was partially offset by a $0.1 million recovery related to a new sublease executed in July 2016. The restructuring charge for the nine months ended September 30, 2015 included $1.5 million in additional charges due to the

Table of Contents

partial termination of one of our building leases and additional facility-related charges related to the decommissioning and exit of certain buildings which was partially offset by $0.9 million in recoveries recorded in connection with the sale of excess equipment and other assets.

The total outstanding restructuring liability is included in the current and long-term portion of restructuring on the accompanying Condensed Consolidated Balance Sheets. The changes of these liabilities during the nine months ended September 30, 2016, which related primarily to facilities, are summarized in the following table (in thousands):

	2010 Restructurings	2014 Restructuring	Total
Restructuring liability as of December 31, 2015	$ 4,087	$ 503	$4,590
Restructuring charge	862	9	871
Proceeds from sale of assets	—	34	34
Cash payments, net	(3,774)	(437)	(4,211)
Other items	975	(34)	941
Restructuring liability as of September 30, 2016	$ 2,150	$ 75	$2,225

We expect to pay accrued facility charges of $2.2 million, net of cash received from our subtenants, through the end of the lease terms of the buildings, all of which end in May 2017. We expect to incur additional restructuring charges of approximately $0.1 million relating to the effect of accretion expense through to the end of the lease terms of the buildings.

NOTE 4: CASH AND INVESTMENTS

All of our cash equivalents and investments are classified as available-for-sale. The following tables summarize cash and cash equivalents, investments, and restricted cash and investments by balance sheet line item as of September 30, 2016 and December 31, 2015 (in thousands):

	September 30, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents	$111,219	$ —	$ —	$111,219
Short-term investments	208,412	70	(20)	208,462
Long-term investments	55,840	28	(51)	55,817
Long-term restricted cash and investments	4,150	—	—	4,150
Total cash and investments	$379,621	$ 98	$ (71)	$379,648

	December 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents	$141,634	$ —	$ —	$141,634
Short-term investments	25,484	5	(63)	25,426
Long-term investments	83,665	2	(67)	83,600
Long-term restricted cash and investments	2,650	—	—	2,650
Total cash and investments	$253,433	$ 7	$ (130)	$253,310

Under our loan and security agreement with Silicon Valley Bank, we are required to maintain compensating balances on deposit in one or more investment accounts with Silicon Valley Bank or one of its affiliates. The total collateral balances were $81.6 million as of both September 30, 2016 and December 31, 2015 and are reflected in our Condensed Consolidated Balance Sheets in short-term investments as of September 30, 2016 and long-term investments as of December 31, 2015; the change in classification from long-term to short-term was the result of a corresponding change in the classification for our term loan payable to Silicon Valley Bank which matures in May 2017. See “Note 7 - Debt” to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2015, for more information regarding the collateral balance requirements under our Silicon Valley Bank loan and security agreement.

14

Table of Contents

The following tables summarize our cash equivalents and investments by security type as of September 30, 2016 and December 31, 2015. The amounts presented exclude cash, but include investments classified as cash equivalents (in thousands):

	September 30, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$47,148	$ —	$ —	$47,148
Commercial paper	133,309	—	—	133,309
Corporate bonds	124,346	44	(67)	124,323
U.S. Treasury and government sponsored enterprises	61,228	54	(4)	61,278
Total investments	$366,031	$ 98	$ (71)	$366,058

	December 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$72,000	$ —	$ —	$72,000
Commercial paper	78,155	—	—	78,155
Corporate bonds	72,205	4	(118)	72,091
U.S. Treasury and government sponsored enterprises	28,434	1	(12)	28,423
Marketable equity security	16	2	—	18
Total investments	$250,810	$ 7	$ (130)	$250,687

All of our investments are subject to a quarterly impairment review. During the nine months ended September 30, 2016 and 2015, we did not record any other-than-temporary impairment charges on our available-for-sale securities. As of September 30, 2016, there were 37 investments in an unrealized loss position with gross unrealized losses of $71,000 and an aggregate fair value of $67.3 million. The investments in an unrealized loss position comprise corporate and government sponsored enterprise bonds. The unrealized losses were not attributed to credit risk, but rather associated with the changes in interest rates. Based on the scheduled maturities of our investments, we concluded that the unrealized losses in our investment securities are not other-than-temporary, as it is more likely than not that we will hold these investments for a period of time sufficient for a recovery of our cost basis.

The following table summarizes the fair value of securities classified as available-for-sale by contractual maturity as of September 30, 2016 (in thousands):

	Mature within One Year	After One Year through Two Years	Fair Value
Money market funds	$47,148	$—	$47,148
Commercial paper	133,309	—	133,309
Corporate bonds	74,661	49,662	124,323
U.S. Treasury and government sponsored enterprises	55,123	6,155	61,278
Total investments	$310,241	$55,817	$366,058

Cash is excluded from the table above.

Table of Contents

NOTE 5. INVENTORY

Inventory consists of the following (in thousands):

	September 30, 2016	December 31, 2015
Raw materials	$ 890	$ 1,037
Work in process	2,540	2,251
Finished goods	582	583
Total	4,012	3,871
Less: non-current portion included in Other assets	(720)	(1,255)
Inventory	$ 3,292	$ 2,616

We generally relieve inventory on a first-expiry, first-out basis. A portion of the manufacturing costs for inventory was incurred prior to regulatory approval of CABOMETYX and COMETRIQ and, therefore, were expensed as research and development costs when those costs were incurred, rather than capitalized as inventory. Write-downs related to excess and expiring inventory are charged to cost of goods sold. Such write-downs were $0.4 million for both the three and nine months ended September 30, 2016 as compared to $1.1 million and $0.9 million for the comparable periods in 2015. The non-current portion of inventory recorded as other assets consists of raw materials and a portion of the active pharmaceutical ingredient which is included in work in process.

NOTE 6. DEBT

The amortized carrying amount of our debt consists of the following (in thousands):

	September 30, 2016	December 31, 2015
Convertible Senior Subordinated Notes due 2019 (“2019 Notes”)	$ 1,865	$ 235,210
Secured Convertible Notes due 2018 (“Deerfield Notes”)	108,993	102,727
Term loan payable	80,000	80,000
Total debt	190,858	417,937
Less: current portion	(109,365)	—
Long-term debt	$ 81,493	$ 417,937

Prior period balances in this Note reflect revisions due to a correction of an immaterial error with regards to the 2019 Notes. The immaterial error resulted in an overstatement of the discount on the 2019 Notes and therefore understated the amortized carrying amount of the 2019 Notes and overstated the related interest expense. See “Note 1 - Organization and Summary of Significant Accounting Policies - Correction of an Immaterial Error” for additional information on the correction of the immaterial error.

See “Note 7 - Debt” to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2015, for additional information on the terms of our debt, including a description of the conversion features of the 2019 Notes and the Deerfield Notes.

2019 Notes

In August 2012, we issued and sold $287.5 million aggregate principal amount of the 2019 Notes, for net proceeds of $277.7 million, all of which remained outstanding at December 31, 2015. The 2019 Notes bear interest at a rate of 4.25% per annum, payable semi-annually in arrears on February 15 and August 15 of each year. On August 9, 2016 and August 19, 2016 we entered into separate, privately negotiated exchange agreements with certain holders of the 2019 Notes. Under the terms of the exchange agreements, the holders agreed to convert an aggregate principal amount of $239.4 million of 2019 Notes held by them in exchange for an aggregate of 45,064,456 shares of the Company’s common stock. In addition, the holders received inducements of $6.0 million which included an aggregate cash payment of $2.4 million and the forgiveness of the repayment of interest payments of $3.6 million. Further, under the terms of the indenture for the 2019 Notes, upon conversion the holders that entered into exchange agreements on August 9, 2016 were required to repay $3.6 million in interest payments that the holders of record on August 1, 2016 received on or about August 15, 2016. Under the terms of the exchange agreements, we forgave the repayment of such interest. We have included those interest payments as financing activities in our Condensed Consolidated Statement of Cash Flows. Inducements are included in the loss on extinguishment of debt.

16

Table of Contents

Following the completion of the exchange transactions, on August 24, 2016, we provided public notice of the redemption of $48.1 million of the 2019 Notes, representing all remaining notes outstanding. Following a required redemption period, which ended on November 2, 2016, holders of the 2019 Notes had the option to convert their notes into shares of our common stock, plus cash in lieu of any fractional share, at a conversion rate of 188.2353 shares of common stock per $1,000 principal amount of the remaining 2019 Notes at any time before close of business on October 31, 2016. Subsequent to the announcement of the redemption of all remaining 2019 Notes outstanding, on various dates in August and September of 2016, $45.9 million of additional aggregate principal amount of 2019 Notes were converted by the holders into an aggregate of 8,640,455 shares of the Company's common stock.

The combined issuance of 53,704,911 shares of the Company's common stock pursuant to the conversions resulted in an increase to common stock and additional paid-in capital of $589.2 million. We recognized an additional loss on extinguishment of debt of $7.3 million, representing the difference between the total settlement consideration transferred to the holders that was attributed to the liability component of the 2019 Notes, based on the fair value of that component at the time of conversion, and the net carrying value of the liability. The remaining settlement consideration transferred was allocated to the reacquisition of the embedded conversion option and recognized as a $340.5 million reduction of additional paid-in capital. Transaction costs incurred with third parties related to the settlement of the 2019 Notes were allocated between the liability and equity components and resulted in an additional $0.5 million of loss on extinguishment of debt and a $0.7 million reduction of additional paid-in capital.

As of September 30, 2016, $2.2 million aggregate principal amount the 2019 Notes remained outstanding. Unless converted earlier, those notes will be redeemed on November 2, 2016 in cash for 100% of the principal amount thereof, plus accrued and unpaid interest.

The following is a summary of the liability component of the 2019 Notes (in thousands):

	September 30, 2016	December 31, 2015
Net carrying amount of the liability component	$ 1,865	$ 235,210
Unamortized discount of the liability component	327	52,290
Face amount of the 2019 Notes	$ 2,192	$ 287,500

The following is a summary of the interest expense for the 2019 Notes (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Stated coupon interest	$1,683	$3,054	$7,793	$9,164
Amortization of debt discount and debt issuance costs	1,763	2,929	7,968	8,585
Total interest expense	$3,446	$5,983	$15,761	$17,749

The balance of unamortized fees and costs was $26,000 and $4.2 million as of September 30, 2016 and December 31, 2015, respectively, which is recorded as a reduction of the carrying amount of the 2019 Notes on the accompanying Condensed Consolidated Balance Sheets.

Deerfield Notes

As of September 30, 2016 and December 31, 2015, the outstanding principal balance on the Deerfield Notes was $109.8 million and $103.8 million, respectively, which, subject to certain limitations, is payable in cash or in stock at our discretion. Beginning on July 2, 2015, the outstanding principal amount of the Deerfield Notes bears interest at the rate of 7.5% per annum to be paid in cash, quarterly in arrears, and 7.5% per annum to be paid in kind, quarterly in arrears, for a total interest rate of 15% per annum. Through July 1, 2015, the outstanding principal amount of the Deerfield Notes bore interest in the annual amount of $6.0 million, payable quarterly in arrears.

Table of Contents

The following is a summary of the interest expense for the Deerfield Notes (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Stated coupon interest paid in cash	$2,031	$1,891	$5,939	$4,866
Amortization of debt discount, debt issuance costs and accrual of interest paid in kind	2,152	1,959	6,266	7,279
Total interest expense	$4,183	$3,850	$12,205	$12,145

The balance of unamortized fees and costs was $0.5 million and $0.7 million as of September 30, 2016 and December 31, 2015, respectively, which is recorded as a reduction of the carrying amount of the Deerfield Notes on the accompanying Condensed Consolidated Balance Sheets. Effective March 4, 2015, upon notification of our election to extend the maturity date to July 1, 2018, we began to amortize the remaining unamortized discount, fees and costs through July 1, 2018 using the effective interest method and an effective interest rate of 15.3%.

We were required to make an additional mandatory prepayment on the Deerfield Notes in January 2015 and 2016 equal to 15% of certain revenues from collaborative arrangements, which we refer to as Development/Commercialization Revenue, received during the prior fiscal year, subject to a maximum prepayment amount of $27.5 million. We made no such mandatory prepayments due to the fact that we received no such revenues during the fiscal year ended December 31, 2014 and Deerfield elected not to receive the mandatory prepayment in January 2016 related to development/commercialization revenue received during the year ended December 31, 2015. As a result of the extension of the maturity date of the Deerfield Notes to July 1, 2018, our obligation to make annual mandatory prepayments equal to 15% of Development/Commercialization Revenue received by us during the prior fiscal year will continue to apply in January 2017 and January 2018. However, we will only be obligated to make any such annual mandatory prepayment if the note holders provide notice to us of their election to receive the prepayment. Pursuant to this requirement, we may be required make a mandatory prepayment of $27.5 million in January 2017 as a result of the upfront payment of $200.0 million upfront nonrefundable payment received in March 2016 in consideration for the exclusive license and other rights contained in the collaboration and license agreement with Ipsen and the $5.0 million milestone payment from Merck we received in the first quarter of 2016 related to its worldwide license of our phosphoinositide-3 kinase-delta program. That portion of the Deerfield Notes is included in current liabilities. The definition of “Development/Commercialization Revenue” expressly excludes any sale or distribution of drug or pharmaceutical products in the ordinary course of our business, and any proceeds from any Intellectual Property Sale, but would include our share of the net profits from the commercialization of cobimetinib in the U.S. and the receipt of royalties from cobimetinib sales outside the U.S., if any.

NOTE 7. FAIR VALUE MEASUREMENTS

Financial Assets Measured on a Recurring Basis

The following table sets forth the fair value of our financial assets that were measured and recorded on a recurring basis as of September 30, 2016 and December 31, 2015. We did not have any Level 3 investments as of September 30, 2016 or December 31, 2015. The amounts presented exclude cash, but include investments classified as cash equivalents (in thousands):

	September 30, 2016		
	Level 1	Level 2	Total
Money market funds	$47,148	$—	$47,148
Commercial paper	—	133,309	133,309
Corporate bonds	—	124,323	124,323
U.S. Treasury and government sponsored enterprises	—	61,278	61,278
Total financial assets	$47,148	$318,910	$366,058

Table of Contents

	December 31, 2015		
	Level 1	Level 2	Total
Money market funds	$72,000	$—	$72,000
Commercial paper	—	78,155	78,155
Corporate bonds	—	72,091	72,091
U.S. Treasury and government sponsored enterprises	—	28,423	28,423
Marketable equity securities	18	—	18
Total financial assets	$72,018	$178,669	$250,687

The estimated fair value of our financial instruments that are carried at amortized cost is as follows (in thousands):

	September 30, 2016		December 31, 2015	
	Carrying Amount	Fair Value	Carrying Amount	Fair Value
2019 Notes	$1,865	$5,277	$235,210	$336,260
Deerfield Notes	$108,993	$110,806	$102,727	$101,096
Term loan payable	$80,000	$79,828	$80,000	$79,815

The carrying amounts of cash, trade and other receivables, accounts payable, accrued clinical trial liabilities, accrued compensation and benefits, accrued collaboration liability, and other accrued liabilities approximate their fair values and are excluded from the tables above.

The following methods and assumptions were used to estimate the fair value of each class of financial instrument:

- When available, we value investments based on quoted prices for those financial instruments, which is a Level 1 input. Our remaining investments are valued using third-party pricing sources, which use observable market prices, interest rates and yield curves observable at commonly quoted intervals of similar assets as observable inputs for pricing, which is a Level 2 input.
- On August 24, 2016, we announced the redemption of $48.1 million of the 2019 Notes, representing all remaining 2019 Notes outstanding. As of September 30, 2016, the 2019 Notes were convertible into shares of our common stock, plus cash in lieu of any fractional share, at a conversion rate of 188.2353 shares of common stock per $1,000 principal amount of the 2019 Notes at any time before close of business on October 31, 2016. Following our issuance of the notice of redemption of the 2019 Notes, the third-party pricing source we historically used to value the 2019 Notes was no longer available. Based on the terms of the redemption and the related conversion feature, we estimated that the value of the shares issuable pursuant to a conversion by the holder approximates the fair value of the 2019 Notes, which represents a Level 3 input.
- We estimate the fair value of our other debt instruments, where possible, using the net present value of the payments. For the term loan, we use an interest rate that is consistent with money-market rates that would have been earned on our non-interest-bearing compensating balances as our discount rate, which is a Level 2 input. For the Deerfield Notes, we used a discount rate of 15%, which we estimate as our current borrowing rate for similar debt as of September 30, 2016, which is a Level 3 input.

Financial Assets, Liabilities and Equity Measured on a Nonrecurring Basis

In connection with the conversions for our 2019 Note during the three months ended September 30, 2016, we were required to determine the fair value of the settlement consideration received by the holders and the fair value of the liability component of the 2019 Notes, as of the various settlement dates of the conversions. The following methods and assumptions were used to estimate the fair value of those financial instruments:

- The settlement consideration comprises, in part, shares of our Common Stock. The fair value of our Common Stock was determined based on the closing market price of our Common Stock on the various settlement dates of the conversions, which are level 1 inputs;
- The carrying value of the remaining settlement consideration, which includes cash and the forgiveness of the repayment of certain prior interest payments, approximates fair value;
- We estimated the fair value of the liability component of the 2019 Notes using the net present value of estimated future cash flows through maturity. We used a discount rate of 9.50%, which we estimate as our current borrowing

rate for straight debt as of September 30, 2016, which is a Level 3 input.

NOTE 8. STOCK-BASED COMPENSATION

We recorded and allocated employee stock-based compensation expense for our equity incentive plans and our 2000 Employee Stock Purchase Plan ("ESPP") as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Research and development expense	$1,165	$6,676	$7,894	$8,049
Selling, general and administrative expense	2,438	5,350	10,452	7,371
Total employee stock-based compensation expense	$3,603	$12,026	$18,346	$15,420

We use the Black-Scholes Merton option pricing model to value our stock options. The weighted average grant-date fair value of our stock options and ESPP purchases was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Stock options	$8.59	$3.92	$4.31	$2.51
ESPP	$1.51	$1.26	$1.65	$0.97

The fair value of employee stock option awards and ESPP purchases was estimated using the following assumptions:

	Stock Options			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Risk-free interest rate	1.07 %	1.18 %	1.09 %	1.20 %
Dividend yield	— %	— %	— %	— %
Volatility	76 %	88 %	76 %	93 %
Expected life	4.5 years	4.6 years	4.4 years	4.5 years

	Employee Stock Purchase Plan			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Risk-free interest rate	0.37 %	0.06 %	0.39 %	0.09 %
Dividend yield	— %	— %	— %	— %
Volatility	63 %	107 %	66 %	101 %
Expected life	6 months	6 months	6 months	6 months

The expected life computation is based on historical exercise patterns and post-vesting termination behavior. We considered implied volatility as well as our historical volatility in developing our estimate of expected volatility.

A summary of all stock option activity for the nine months ended September 30, 2016 is presented below (dollars in thousands, except per share amounts):

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Options outstanding at December 31, 2015	27,425,854	$ 4.22		
Granted	3,771,250	$ 7.35		
Exercised	(3,360,248)	$ 2.81		
Forfeited	(307,601)	$ 4.67		

Expired	(80,516)	$ 10.49		
Options outstanding at September 30, 2016	27,448,739	$ 4.80	4.58 years	$ 221,332
Exercisable at September 30, 2016	20,042,258	$ 4.19	4.02 years	$ 172,458

As of September 30, 2016, a total of 574,885 shares were available for grant under our stock option plans.

Table of Contents

As of September 30, 2016, we had $22.9 million of unrecognized compensation expense related to employee stock options that is expected to be recognized over a weighted-average period of 3.01 years.

On March 7, 2016, as a result of the FDA acceptance of our New Drug Application "NDA" submission and on April 28, 2016, as a result of the FDA's approval of our NDA submission, the Compensation Committee of the Board of Directors of Exelixis convened to determine we had met certain performance objectives related to performance-based stock options granted to employees in 2014 and 2015. As a result of these determinations, 5,870,303 performance-based stock options vested during the nine months ended September 30, 2016 and we recorded an additional $4.1 million in stock-based compensation expense during the period related to those options. During 2015, we recorded $3.3 million in employee stock-based compensation expense related to those options.

A summary of all restricted stock unit ("RSU") activity for the nine months ended September 30, 2016 is presented below (dollars in thousands, except per share amounts):

	Shares	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Awards outstanding at December 31, 2015	1,002,188	$ 5.16		
Awarded	3,038,386	$ 7.38		
Vested and released	(1,390,654)	$ 5.55		
Forfeited	(30,309)	$ 4.77		
Awards outstanding at September 30, 2016	2,619,611	$ 8.21	1.97 years	$ 33,505

As of September 30, 2016, we had $13.9 million of unrecognized compensation expense related to employee RSUs that is expected to be recognized over a weighted-average period of 3.30 years.

During the nine months ended September 30, 2016, we made a bonus payment to our employees in the form of 1,072,833 shares of fully-vested restricted stock units which had a grant date fair value of $4.5 million.

NOTE 9. NET LOSS PER SHARE

The following table sets forth a reconciliation of basic and diluted net loss per share (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Numerator:				
Net loss	$(11,284)	$(45,542)	$(105,345)	$(120,176)
Denominator:				
Shares used in computing basic and diluted net loss per share	256,319	217,587	238,024	203,153
Net loss per share, basic and diluted	$(0.04)	$(0.21)	$(0.44)	$(0.59)

The following table sets forth potentially dilutive shares of common stock that are not included in the computation of diluted net loss per share because to do so would be anti-dilutive (in thousands):

	September 30	
	2016	2015
Convertible Senior Subordinated Notes due 2019	413	54,118
Secured Convertible Notes due 2018	33,890	33,890
Outstanding stock options, unvested RSUs and ESPP contributions	30,474	31,331
Warrants	1,000	1,000
Total potentially dilutive shares	65,777	120,339

The warrants are participating securities and the warrant holders do not have a contractual obligation to share in our losses.

Table of Contents

NOTE 10. CONCENTRATIONS OF CREDIT RISK

Financial instruments that potentially subject us to concentrations of credit risk are primarily trade and other receivables and investments. Investments consist of money market funds, taxable commercial paper, corporate bonds with high credit quality, U.S. Treasury and government sponsored enterprises, and municipal bonds. All investments are maintained with financial institutions that management believes are creditworthy.

Trade and other receivables are unsecured and are concentrated in the pharmaceutical and biotechnology industries. Accordingly, we may be exposed to credit risk generally associated with pharmaceutical and biotechnology companies. We have incurred no bad debt expense since inception. As of September 30, 2016, 38%, 17%, 12% and 10% of our trade receivables are with Diplomat Specialty Pharmacy, Caremark L.L.C., Accredo Health, Incorporated and affiliates of McKesson Corporation, respectively. All of these customers pay promptly. As of September 30, 2016, we had also had other receivables for milestone payments totaling $60.0 million due from Ipsen and $15.0 million due from Daiichi Sankyo. We received the full amount due from Daiichi Sankyo subsequent to September 30, 2016 and expect to receive the payment from Ipsen in mid-November 2016 in accordance with the terms of our collaboration and license agreement with Ipsen.

All of our long-lived assets are located in the United States.

We have operations primarily in the United States, while some of our collaboration partners have headquarters outside of the United States and some of our clinical trials for cabozantinib are also conducted outside of the United States. The following table shows the percentage of revenues earned in the United States and Europe:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Percentage of revenues earned in the United States	98%	96%	98%	90%
Percentage of revenues earned in Europe	2%	4%	2%	10%

The following table sets forth the percentage of revenues recognized by customer that represent 10% or more of total revenues:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Product sales:				
Diplomat Specialty Pharmacy	31%	66%	41%	79%
Sobi	2%	4%	2%	10%
Collaboration agreements:				
Merck	—%	30%	4%	11%
Daiichi Sankyo	24%	—%	13%	—%

Table of Contents

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

The following discussion and analysis contains forward-looking statements. These statements are based on Exelixis, Inc.'s ("Exelixis," "we," "our" or "us") current expectations, assumptions, estimates and projections about our business and our industry, and involve known and unknown risks, uncertainties and other factors that may cause our or our industry's results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied in, or contemplated by, the forward-looking statements. Words such as "expect," "potential," "will," "goal," "would," "intend," "continues," "objective," "anticipate," "may be," "initia "could," "plan," "trend," or the negative of such terms or other similar expressions identify forward-looking statements. Our actual results and the timing of events may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such a difference include those discussed in Part II, Item 1A of this Form 10-Q, as well as those discussed elsewhere in this report.

This discussion and analysis should be read in conjunction with our financial statements and accompanying notes included in this report and the financial statements and accompanying notes thereto included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, filed with the Securities and Exchange Commission, or SEC, on February 29, 2016. Operating results are not necessarily indicative of results that may occur in future periods. We undertake no obligation to update any forward-looking statement to reflect events after the date of this report.

Overview

Exelixis, Inc. is a biopharmaceutical company committed to the discovery, development and commercialization of new medicines that will improve care and outcomes for people with cancer. Since its founding in 1994, three products discovered at Exelixis have progressed through clinical development, received regulatory approval, and entered the commercial marketplace. This portfolio includes two products derived from cabozantinib, an inhibitor of multiple tyrosine kinases including MET, AXL, and VEGF receptors. They are CABOMETYX™ tablets for the treatment of advanced kidney cancer and COMETRIQ® capsules for the treatment of certain forms of thyroid cancer, each approved both in the United States and the European Union. The third product is COTELLIC®, a product derived from cobimetinib, a selective inhibitor of MEK, marketed under a collaboration with Roche and Genentech (a member of the Roche Group) that has been approved in combination with ZELBORAF® (vemurafenib) to treat advanced melanoma in several major territories, including the United States and European Union.

The approval of CABOMETYX by the United States Food and Drug Administration, or FDA, as a treatment for patients with advanced renal cell carcinoma, or RCC, who have received prior anti-angiogenic therapy was a significant milestone for us because of the substantial commercial opportunity that the advanced RCC market represents in the United States. From a financial perspective, the early strength of the launch has made the realization of our goal to drive the business to become cash flow positive is increasingly achievable, while operationally, cabozantinib's significant commercial potential has enabled us to attract top talent and build commercial and medical affairs organizations of considerable size and strength. Having fully integrated these functions within our corporate structure, we are better equipped to support the growth of cabozantinib. Our commercial team markets the availability of CABOMETYX consistent with its FDA-approved labeling and maximizes accessibility for the patient populations for which it is indicated for treatment. Separately, our medical affairs organization engages and collaborates with clinicians and medical institutions towards a complete understanding of how cabozantinib may best be deployed in the fight against cancer. Looking to the future, the growth of our product revenue stream, as well as anticipated partnership royalty and contract revenue, and vigilant expense management, has provided us with the opportunity to begin to evaluate the expansion of our pipeline through reinvestment in drug discovery, in-licensing opportunities, and other corporate development activities.

The approval of CABOMETYX was based on results of our phase 3 pivotal trial METEOR (Metastatic RCC Phase 3 Study Evaluating Cabozantinib vs. Everolimus), which met its primary endpoint of improving progression-free survival, or PFS. The median PFS was 7.4 months for the cabozantinib arm versus 3.8 months for the everolimus arm, and the hazard ratio [HR] was 0.58 (95% confidence interval [CI] 0.45-0.74, $p<0.0001$), corresponding to a 42% reduction in the rate of disease progression or death for cabozantinib compared to everolimus. CABOMETYX also significantly improved the objective response rate, or ORR, and demonstrated a statistically significant and clinically meaningful increase in overall survival, or OS. Compared with everolimus, CABOMETYX was associated with a

34% reduction in the rate of death and median OS was 21.4 months for patients receiving CABOMETYX versus 16.5 months for those receiving everolimus (HR=0.66, 95% CI 0.53-0.83, P=0.0003). CABOMETYX, which was granted Fast Track and Breakthrough Therapy designations by the FDA, is the first therapy to demonstrate in a phase 3 trial for patients with advanced RCC, robust and clinically meaningful improvements in all three key efficacy parameters - OS, PFS and ORR. A review of adverse events, or AEs, demonstrated that the frequency of AEs of any grade regardless of causality was approximately balanced between study arms, and the rate of treatment discontinuation due to adverse events was 10% for each of the cabozantinib and everolimus arms.

On February 29, 2016, we entered into a collaboration and license agreement with Ipsen Pharma SAS, or Ipsen, focused on the further development of cabozantinib and the exclusive commercialization of current and potential future cabozantinib indications outside of the United States, Canada and Japan, if and when additional regulatory approvals are secured in those territories. A key reason we chose Ipsen as a partner was because Ipsen is established and engaged in the global distribution of oncology medicines. With the European Commission's, or EC, approval of CABOMETYX tablets for the treatment of adult patients with advanced RCC following prior vascular endothelial growth factor (VEGF)-targeted therapy on September 9, 2016, we and our partner Ipsen are poised to capitalize on the sizable European commercial opportunity. At the same time, we are engaged in an effort to determine the most effective means to obtain cabozantinib's approval and launch in Japan and Canada, either by partnering in those territories or potentially launching the product ourselves.

Beyond the FDA-approved indications of cabozantinib for second-line RCC and progressive, metastatic medullary thyroid carcinoma, or MTC, we are engaged in a broad development program composed of over 45 ongoing or planned clinical trials in additional tumor types, many of which are conducted through our Cooperative Research and Development Agreement, or CRADA, with the National Cancer Institute's Cancer Therapy Evaluation Program, or NCI-CTEP, or our investigator sponsored trial program. The most notable studies at this time are our company-sponsored phase 3 trial of cabozantinib in advanced hepatocellular carcinoma, or HCC, called CELESTIAL (Cabozantinib Phase 3 Controlled Study In Hepatocellular Carcinoma) and CABOSUN, a randomized phase 2 trial comparing cabozantinib to sunitinib in the first-line treatment of intermediate- or poor-risk RCC patients. In September 2016, following the first planned interim analysis for CELESTIAL, the trial's Independent Data Monitoring Committee, or IDMC, determined that the study should continue without modifications per the study protocol. We anticipate top-line results from CELESTIAL in 2017. The CABOSUN trial is being conducted by The Alliance for Clinical Trials in Oncology, or The Alliance, through our CRADA with NCI-CTEP. In May 2016, The Alliance informed us that CABOSUN met its primary endpoint demonstrating a statistically significant and clinically meaningful improvement of PFS compared with sunitinib. Based on these results, we plan to submit a Supplemental New Drug Application, or sNDA, for cabozantinib as a treatment for first-line advanced RCC. Additionally, results from a phase 1b trial of cabozantinib plus nivolumab alone, or in combination with ipilimumab, in patients with genitourinary tumors being conducted under our collaboration with NCI-CTEP, continue to support further investigation of cabozantinib in combination with immunotherapies to treat genitourinary and other tumors.

In addition to these advances connected with cabozantinib, significant progress continues to be made with respect to the clinical development, regulatory status and commercial potential of certain other partnered compounds. In the aggregate, these partnered compounds could be of significant value to us if their development programs progress successfully. For example, cobimetinib, a compound we out-licensed in 2006 to Genentech, was approved by the FDA on November 10, 2015, under the brand name COTELLIC, in combination with vemurafenib as a treatment for patients with BRAF V600E or V600K mutation-positive advanced melanoma. It was launched in the United States soon thereafter and in the United States we contribute 25% of the sales force to the commercialization effort. COTELLIC in combination with vemurafenib has also been approved and launched by Genentech in multiple other territories, including the European Union, Canada, Australia and Brazil. Cobimetinib is also being evaluated in a broad development program comprising a Phase 3 trial of cobimetinib in combination with atezolizumab in patients with colorectal carcinoma, as well as several earlier stage clinical trials investigating cobimetinib in combination with a variety of agents in multiple tumor types. Owing to disagreements over clinical development, pricing and commercialization of COTELLIC, and cost and revenue allocations arising from COTELLIC's commercialization in the United States, on June 3, 2016, we filed a demand for arbitration against Genentech, and shortly thereafter, Genentech filed a counterclaim against us. For additional information on our arbitration with Genentech please see, "- Part II - Other Information - Legal Proceedings."

Collaborations

We have established collaborations with Ipsen for cabozantinib, Genentech (a member of the Roche group) for cobimetinib, and other collaborations with leading pharmaceutical companies including Bristol-Myers Squibb Company, or Bristol-Myers Squibb, Sanofi, Merck (known as MSD outside of the United States and Canada), and Daiichi Sankyo Company Limited, or Daiichi Sankyo, for compounds and programs in our portfolio. Excluding our collaboration agreement with Ipsen for cabozantinib and our co-promotion agreement with Genentech, we have fully out-licensed compounds or programs to a partner for further development and commercialization under these collaborations and have no further development cost obligations under our collaborations. Under each of our collaborations, we are entitled to receive milestones and royalties or, in the case of cobimetinib, a share of profits (or losses) from commercialization.

Cabozantinib Collaboration

On February 29, 2016, we entered into a collaboration and license agreement, or the Agreement, with Ipsen for the commercialization and further development of cabozantinib. Pursuant to the terms of the Agreement, Ipsen will have exclusive commercialization rights for current and potential future cabozantinib indications outside of the United States, Canada and

Table of Contents

Japan. We have also agreed to collaborate with Ipsen on the development of cabozantinib for current and potential future indications.

In consideration for the exclusive license and other rights contained in the Agreement, Ipsen paid us an upfront nonrefundable payment of $200.0 million in March 2016. As a result of the approval of cabozantinib by the European Medicines Agency, or EMA, in second-line RCC in September 2016, we achieved a $60.0 million milestone which we expect to receive in November 2016. We are also eligible to receive additional development and regulatory milestones, totaling up to $240.0 million, including, milestone payments of $10.0 million and $40.0 million upon the filing and the approval of cabozantinib in second-line HCC with the EMA, and additional milestones for other future indications. We will also be eligible to receive two $10.0 million milestone payments upon the launch of the product in the first two of the following countries: Germany, France, Italy, Spain and the United Kingdom. The Agreement also provides that we will be eligible to receive contingent payments of up to $525.0 million associated with the achievement of specified levels of Ipsen sales to end users. We will also receive royalties on net sales of cabozantinib outside of the United States, Canada and Japan. We will receive a 2% royalty on the initial $50.0 million of net sales, and a 12% royalty on the next $100.0 million of net sales. After the initial $150.0 million of sales, we will receive a tiered royalty of 22% to 26% on annual net sales; these tiers will reset each calendar year. We are primarily responsible for funding cabozantinib related development costs for existing trials; global development costs for potential future trials will be shared between the parties, with Ipsen to reimburse us for 35% of such costs. Pursuant to the terms of the Agreement, we will remain responsible for the manufacture and supply of cabozantinib for all development and commercialization activities under the Agreement. As part of the Agreement, we entered into a supply agreement which provides that through the end of the second quarter of 2018, we will supply finished, labeled product to Ipsen for distribution in the territories outside of the United States, Canada and Japan. From the end of the second quarter of 2018 forward, we will continue to manufacture CABOMETYX tablets, while Ipsen will be responsible for packaging and labeling the product in territories where it has been approved outside of the United States, Canada and Japan, as applicable.

Cobimetinib Collaboration

Cobimetinib in combination with vemurafenib has been approved in multiple territories, including the United States, European Union and Canada as a treatment for patients with advanced melanoma harboring a BRAF V600E or V600K mutation, and is marketed as COTELLIC. Results from coBRIM, the phase 3 pivotal trial conducted by Genentech evaluating cobimetinib in combination with vemurafenib in previously untreated patients with unresectable locally advanced or metastatic melanoma harboring a BRAF V600E or V600K mutation served as the basis for such regulatory approvals.

In addition to the coBRIM trial, additional clinical trials are ongoing studying the combination of cobimetinib with a variety of agents in multiple tumor types. These include:

- COTEZO, a phase 3 pivotal trial evaluating the combination of cobimetinib and atezolizumab, an anti-PD-L1 antibody, or atezolizumab alone versus regorafenib, in unresectable locally advanced or metastatic colorectal cancer, or CRC. COTEZO is expected to enroll 360 patients who have received at least two prior chemotherapies in the metastatic disease setting, and the primary endpoint of the trial is OS. The decision to start COTEZO was informed by results from the ongoing phase 1b trial of the combination in advanced solid tumors;
- The combination of cobimetinib and vemuarfenib in additional melanoma patient populations and settings;
- A phase 2 trial of cobimetinib in combination with paclitaxel in triple negative breast cancer;
- Phase 1 studies of cobimetinib in combination with atezolizumab in melanoma and non-small cell lung cancer, or NSCLC, in combination with vemurafenib and atezolizumab in melanoma, and in combination with venetoclax in relapsed or refractory acute myeloid leukemia; and
- A phase 1b study evaluating the safety, tolerability and pharmacokinetics of cobimetinib in combination with atezolizumab and bevacizumab in patients with metastatic colorectal cancer.

On the basis of encouraging anti-tumor activity and acceptable tolerability observed in the phase 1b trial combining cobimetinib, atezolizumab and vemurafenib in patients with previously untreated BRAF V600 mutation-positive advanced melanoma, a phase 3 pivotal trial, Trilogy is planned by Roche, details of which have been posted to www.ClinicalTrials.gov.

A complete listing of all ongoing trials can be found at www.ClinicalTrials.gov.

Under the terms of our collaboration agreement with Genentech for cobimetinib, we are entitled to a share of U.S. profits and losses received in connection with commercialization of cobimetinib. The profit share has multiple tiers: we are entitled to 50% of profits and losses from the first $200.0 million of U.S. actual sales, decreasing to 30% of profits and losses

Table of Contents

from U.S. actual sales in excess of $400.0 million. We are entitled to low double-digit royalties on ex-U.S. net sales. In November 2013, we exercised an option under the collaboration agreement to co-promote in the United States. Following the approval of COTELLIC in the United States in November 2015, we began fielding 25% of the sales force promoting COTELLIC in combination with vemurafenib as a treatment for patients with BRAF V600E or V600K mutation-positive advanced melanoma.

We believe that cobimetinib has the potential to provide us with an additional meaningful source of revenue. Our objective, therefore, is and has been to work with Genentech on the execution of the U.S. COTELLIC commercial plan in order to maximize the product's revenue potential. However, to date, we believe Genentech's pricing of and cost and revenue allocations for COTELLIC, as determined exclusively by Genentech, have been contrary to the applicable terms of the collaboration agreement. We raised this concern with Genentech, along with other material concerns regarding Genentech's performance under the collaboration agreement, but were unable to come to resolution on any of these issues. Accordingly, on June 3, 2016, following a 30 day dispute resolution period, we filed a demand for arbitration asserting claims against Genentech related to its clinical development, pricing and commercialization of COTELLIC, and cost and revenue allocations in connection with COTELLIC's commercialization in the United States, and shortly thereafter, Genentech filed a counterclaim against us.

Other Collaborations

With respect to our partnered compounds, other than cabozantinib and cobimetinib, we are eligible to receive potential contingent payments totaling approximately $3.1 billion in the aggregate on a non-risk adjusted basis, of which 8% are related to clinical development milestones, 38% are related to regulatory milestones and 54% are related to commercial milestones, all to be achieved by the various licensees, which may not be paid, if at all, until certain conditions are met.

Business Highlights for the Three Months Ended September 30, 2016 and Recent Events

Data Presented at the 2016 European Society of for Medical Oncology (ESMO) Congress

In October 2016, clinical data from cabozantinib and cobimetinib was the subject of 15 separate data presentations at the 2016 ESMO Congress, including a Presidential Symposium session covering data from CABOSUN, a randomized phase 2 trial comparing cabozantinib to sunitinib in the first-line treatment of intermediate- or poor-risk RCC patients being conducted by The Alliance through our CRADA with NCI-CTEP. CABOSUN met its primary endpoint demonstrating a statistically significant and clinically meaningful improvement of PFS compared with sunitinib. Based on these results, we plan to submit an sNDA for cabozantinib as a treatment for first-line advanced RCC. Additionally, data from a phase 1 trial of cabozantinib in combination with nivolumab in patients with previously treated genitourinary tumors and preliminary results from a phase 1b clinical trial evaluating the safety and clinical activity of the triple combination of cobimetinib, vemurafenib, and atezolizumab in patients with previously untreated BRAF V600 mutation-positive advanced melanoma were also presented in poster discussion presentations.

Initiation of Phase 3 Clinical Development for CS-3150 by Daiichi Sankyo

On September 26, 2016, we announced that our collaboration partner, Daiichi Sankyo, had initiated a phase 3 pivotal trial to evaluate CS-3150, an oral, non-steroidal, selective mineralocorticoid receptor antagonist, as a treatment for essential hypertension in Japanese patients. As a result of Daiichi Sankyo enrolling the first patient in the phase 3 pivotal trial, we became eligible for a $15.0 million milestone payment, which we received in October 2016.

Election of Julie Anne Smith to the Board of Directors

On September 22, 2016, accomplished biopharmaceutical executive Julie Anne Smith was elected to our Board of Directors. Ms. Smith has nearly two decades of operational leadership experience in high growth public, private, startup, and established biopharmaceutical businesses. She served as president and chief executive officer of Raptor Pharmaceuticals, a commercial-stage, global innovator in the development and commercialization of orphan disease therapies, from January 2015 through the company's acquisition by Horizon Pharma plc, or Horizon. Ms. Smith is continuing to provide transition services to Horizon through December 31, 2016. Ms. Smith previously held key commercial and strategic leadership positions at companies including Enobia Pharma, Jazz Pharmaceuticals, and Genzyme.

EC Approval of CABOMETYX for the Treatment of Advanced RCC Following VEGF-Targeted Therapy

On September 9, 2016, the EC approved CABOMETYX tablets for the treatment of advanced RCC in adults following prior VEGF targeted therapy. This approval allows for the marketing of CABOMETYX in all 28 member states of the European Union, Norway and Iceland.

Table of Contents

Outcome of First Planned Interim Analysis of CELESTIAL

On September 6, 2016, we announced the outcome from the first planned interim analysis of CELESTIAL, a randomized global phase 3 trial of cabozantinib compared with placebo in patients with advanced HCC who have been previously treated with sorafenib. Following this interim analysis, which was scheduled to take place when 50% of the events for the primary endpoint of OS had occurred, the trial's IDMC determined that the study should continue without modifications per the study protocol. The trial protocol calls for a second interim analysis to take place once 75% of events have been observed.

Conversion and Redemption of 4.25% Convertible Senior Subordinated Notes

On August 9, 2016 and August 19, 2016, respectively, we entered into separate, privately negotiated exchange transactions with certain holders of the 4.25% Convertible Senior Subordinated Notes due 2019, or the 2019 Notes. Under the terms of the associated exchange agreements, the holders agreed to convert an aggregate principal amount of $239.4 million of 2019 Notes held by them in exchange for an aggregate of 45,064,456 shares of our common stock and an aggregate cash payment of approximately $2.4 million. Following completion of the exchange transactions, on August 24, 2016, we provided public notice of the redemption of the final $48.1 million of the 2019 Notes, representing all remaining notes outstanding. Following a required redemption period, holders of the remaining 2019 Notes had the option to convert their notes into shares of our common stock, plus cash in lieu of any fractional share, at a conversion rate of 188.2353 shares of common stock per $1,000 principal amount of their notes at any time before close of business on October 31, 2016. During the required redemption period, $47.5 million of the 2019 Notes were converted into shares of our common stock and the remaining $0.6 million of the 2019 Notes outstanding on November 2, 2016 were redeemed in cash for 100% of the principal amount thereof, plus accrued and unpaid interest to, but excluding such date.

Certain Factors Important to Understanding Our Financial Condition and Results of Operations

Successful development and commercialization of drugs is inherently difficult and uncertain. Products often fail during the research and development process and, if and when they are approved by regulatory authorities, they must then compete in highly competitive therapeutic areas, such as cancer treatment. Our financial performance is driven by many factors, including those described below, and is subject to the risks set forth in "Item 1A - Risk Factors" below.

Limited Sources of Revenues and the Need to Raise Additional Capital

We have incurred net losses since inception through September 30, 2016, with the exception of the 2011 fiscal year. For the nine months ended September 30, 2016, we incurred a net loss of $105.3 million and as of September 30, 2016, we had an accumulated deficit of $2.0 billion. These losses have had an adverse effect on our stockholders' equity and working capital. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses or when we will become profitable. Excluding fiscal 2011, our research and development expenditures and selling, general and administrative expenses have exceeded our revenues for each fiscal year, and we expect to spend significant additional amounts to fund the continued development and commercialization of cabozantinib. In addition, we are evaluating the expansion of our pipeline through drug discovery and corporate development activities. As a result, we expect to continue to incur substantial operating expenses and, consequently, we will need to generate significant additional revenues to achieve future profitability. Since the launch of our first commercial product in January 2013, through September 30, 2016, we have generated an aggregate of $157.7 million in net product revenues. Other than sales of CABOMETYX and COMETRIQ, we have derived substantially all of our revenues since inception from collaborative research and development agreements, which depend on royalties, license fees, the achievement of milestones, and research funding we earn from any products developed from the collaborative research.

The amount of our net losses will depend, in part, on: the level of sales of CABOMETYX and COMETRIQ in the United States; achievement of clinical, regulatory and commercial milestones and the amount of royalties, if any, from sales of CABOMETYX and COMETRIQ under our collaboration with Ipsen; our share of the net profits and losses for the commercialization of COTELLIC in the U.S. under our collaboration with Genentech (a member of the Roche group); the amount of royalties from COTELLIC sales outside the U.S. under our collaboration with Genentech; other

license and contract revenues; and, the level of our expenses, including commercialization activities for cabozantinib and any pipeline expansion efforts.

As of September 30, 2016, we had $379.6 million in cash and investments, which included $293.8 million available for operations, $81.6 million of compensating balance investments that we are required to maintain on deposit with Silicon Valley Bank, and $4.2 million of long-term restricted investments. We anticipate that our current cash and cash equivalents, and

Table of Contents

short-term investments available for operations, and product revenues, will enable us to maintain our operations for a period of at least 12 months following the filing date of this report. Our capital requirements will depend on many factors, and we may need to use available capital resources and raise additional capital significantly earlier than we currently anticipate. For a description of the factors upon which our capital requirements depend, please see "– Liquidity and Capital Resources – Capital Requirements."

Clinical Development and Commercialization of Cabozantinib

Our primary development and commercialization program is focused on cabozantinib, currently approved under the brand name CABOMETYX for the treatment of advanced RCC and COMETRIQ for the treatment of MTC, in the United States and the European Union. The future development path of cabozantinib beyond advanced RCC and MTC will depend upon the results of each stage of clinical development. We have and expect to continue to incur significant expenses for the development of cabozantinib as it advances in clinical development.

The commercial success of cabozantinib depends upon the degree of market acceptance of both CABOMETYX and COMETRIQ among physicians, patients, health care payers such as Medicare and Medicaid, and the medical community. It also depends upon how cabozantinib fares in competition with other products. In connection with the FDA's approval of cabozantinib for the treatment of patients with advanced RCC who have received prior anti-angiogenic therapy, we increased our sales, marketing and distribution capabilities. Establishing and maintaining sales, marketing and distribution capabilities are expensive and time-consuming and may be disproportional compared to the revenues we may be able to generate.

Convertible Senior Subordinated Notes

In August 2012, we issued and sold $287.5 million aggregate principal amount of the 2019 Notes, for net proceeds of $277.7 million, all of which remained outstanding at December 31, 2015. On August 9, 2016 and August 19, 2016, respectively, we entered into separate, privately negotiated exchange transactions with certain holders of the 2019 Notes. Under the terms of the associated exchange agreements, the holders agreed to convert an aggregate principal amount of $239.4 million of 2019 Notes held by them in exchange for an aggregate of 45,064,456 shares of our common stock. In addition, the holders received inducements of $6.0 million, including an aggregate cash payment of approximately $2.4 million, which is included in the loss on extinguishment of debt. Following the completion of the exchange transactions, on August 24, 2016, we provided public notice of the redemption of the final $48.1 million of the 2019 Notes, representing all remaining notes outstanding. Following a required redemption period, holders of the remaining 2019 Notes had the option to convert their notes into shares of our common stock, plus cash in lieu of any fractional share, at a conversion rate of 188.2353 shares of common stock per $1,000 principal amount of the 2019 Notes at any time before close of business on October 31, 2016. During the required redemption period, $47.5 million of the 2019 Notes were converted into shares of our common stock and the remaining $0.6 million of the 2019 Notes outstanding on November 2, 2016 were redeemed in cash for 100% of the principal amount thereof, plus accrued and unpaid interest to, but excluding such date.

Deerfield Notes

In June 2010, we entered into a note purchase agreement with Deerfield Private Design Fund, L.P. and Deerfield Private Design International, L.P., or the Original Deerfield Purchasers, pursuant to which, on July 1, 2010, we sold to the Original Deerfield Purchasers an aggregate of $124.0 million principal amount of our Secured Convertible Notes due July 1, 2015, which we refer to as the Original Deerfield Notes, for an aggregate purchase price of $80.0 million, less closing fees and expenses of approximately $2.0 million. On January 22, 2014, the note purchase agreement was amended to provide us with an option to extend the maturity date of our indebtedness under the note purchase agreement to July 1, 2018. On July 1, 2015, we made a $4.0 million principal payment and then extended the maturity date of the Original Deerfield Notes from July 1, 2015 to July 1, 2018. In connection with the extension, affiliates of the Original Deerfield Purchasers, which we refer to as the New Deerfield Purchasers, acquired the $100.0 million principal amount of the Original Deerfield Notes and we issued restated notes, which we refer to as the Restated Deerfield Notes with each of the New Deerfield Purchasers, representing the $100.0 million principal amount. We refer to the Original Deerfield Purchasers and the New Deerfield Purchasers collectively as Deerfield, and to the Original Deerfield Notes and Restated Deerfield Notes, collectively as the Deerfield Notes.

As of September 30, 2016 and December 31, 2015, the outstanding principal balance on the Deerfield Notes was $109.8 million and $103.8 million, respectively, which, subject to certain limitations, is payable in cash or in stock at our discretion. Beginning on July 2, 2015, the outstanding principal amount of the Deerfield Notes bears interest at the rate of 7.5% per annum to be paid in cash, quarterly in arrears, and 7.5% per annum to be paid in kind, quarterly in arrears, for a total interest rate of 15% per annum. Through July 1, 2015, the outstanding principal amount of the Deerfield Notes bore interest in the annual amount of $6.0 million, payable quarterly in arrears.

Table of Contents

On August 6, 2012, the parties amended the note purchase agreement to permit the issuance of the 2019 Notes and modify certain optional prepayment rights. The amendment became effective upon the issuance of the 2019 Notes and the payment to the Original Deerfield Purchasers of a $1.5 million consent fee. On August 1, 2013, the parties further amended the note purchase agreement to clarify certain of our other rights under the note purchase agreement. On January 22, 2014, the note purchase agreement was amended to provide us with an option to extend the maturity date of our indebtedness under the note purchase agreement to July 1, 2018, which extension was completed on July 1, 2015. On July 10, 2014, the parties further amended the note purchase agreement to clarify certain provisions of the note purchase agreement.

The following is a summary of the interest expense for the Deerfield Notes (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Stated coupon interest	$2,031	$1,891	$5,939	$4,866
Amortization of debt discount, debt issuance costs and accrual of interest paid in kind	2,152	1,959	6,266	7,279
Total interest expense	$4,183	$3,850	$12,205	$12,145

The balance of unamortized fees and costs was $0.5 million and $0.7 million as of September 30, 2016 and December 31, 2015, respectively, which is recorded as a reduction of the carrying amount of the 2019 Notes on the accompanying Condensed Consolidated Balance Sheets. Effective March 4, 2015, upon notification of our election to require the New Deerfield Purchasers to acquire the Deerfield Notes and extend the maturity date to July 1, 2018, we began to amortize the remaining unamortized discount, fees and costs through July 1, 2018 using the effective interest method and an effective interest rate of 15.3%.

In each of January 2014 and 2013, we made mandatory prepayments of $10.0 million on the Deerfield Notes. We were required to make an additional mandatory prepayment on the Deerfield Notes in January 2015 and 2016 equal to 15% of certain revenues from collaborative arrangements, which we refer to as Development/Commercialization Revenue, received during the prior fiscal year, subject to a maximum prepayment amount of $27.5 million. We made no such mandatory prepayments due to the fact that we received no such revenues during the fiscal year ended December 31, 2014 and Deerfield's election not to receive the mandatory prepayment in January 2016 related to development/commercialization revenue received during the year ended December 31, 2015. As a result of the extension of the maturity date of the Deerfield Notes to July 1, 2018, our obligation to make annual mandatory prepayments equal to 15% of Development/Commercialization Revenue received by us during the prior fiscal year will continue to apply in January 2017 and January 2018. However, we will only be obligated to make any such annual mandatory prepayment if the note holders provide notice to us of their election to receive the prepayment. Pursuant to this requirement, we may be required make a mandatory prepayment of $27.5 million in January 2017 as a result of the $200.0 million upfront nonrefundable payment received in March 2016 in consideration for the exclusive license and other rights contained in the collaboration and license agreement with Ipsen and the $5.0 million milestone payment from Merck we received in the first quarter of 2016 related to its worldwide license of our phosphoinositide-3 kinase-delta program. That portion of the Deerfield Notes is included in current liabilities. The definition of "Development/Commercialization Revenue" expressly excludes any sale or distribution of drug or pharmaceutical products in the ordinary course of our business, and any proceeds from any Intellectual Property Sale, but would include our share of the net profits from the commercialization of cobimetinib in the U.S. and the receipt of royalties from cobimetinib sales outside the U.S., if any.

Under the note purchase agreement, we may at our sole discretion prepay all of the principal amount of the Deerfield Notes at a prepayment price equal to 105% of the outstanding principal amount of the Deerfield Notes, plus all accrued and unpaid interest through the date of such prepayment, plus, if prior to July 1, 2017, all interest that would have accrued on the principal amount of the Deerfield Notes between the date of such prepayment and July 1, 2017, if the outstanding principal amount of the Deerfield Notes as of such prepayment date had remained outstanding through July 1, 2017, plus all other accrued and unpaid obligations, collectively referred to as the Prepayment Price.

In lieu of making any portion of the Prepayment Price or mandatory prepayment in cash, subject to certain limitations (including a cap on the number of shares issuable under the note purchase agreement), we have the right to convert all or a portion of the principal amount of the Deerfield Notes into, or satisfy all or any portion of the Prepayment Price amounts or mandatory prepayment amounts with shares of our common stock. Additionally, in lieu of making any payment of accrued and unpaid interest in respect of the Deerfield Notes in cash, subject to certain limitations, we may elect to satisfy any such payment with shares of our common stock. The number of shares of our common stock issuable upon conversion or in settlement of principal and interest obligations will be based upon the discounted trading price of our common stock over a specified trading period. Upon certain changes of control of Exelixis, a sale or transfer of assets in one transaction or a series of

Table of Contents

related transactions for a purchase price of more than (i) $400 million or (ii) 50% of our market capitalization, Deerfield may require us to prepay the Deerfield Notes at the Prepayment Price. Upon an event of default, as defined in the Deerfield Notes, Deerfield may declare all or a portion of the Prepayment Price to be immediately due and payable.

We are required to notify the applicable Deerfield entities of certain sales, assignments, grants of exclusive licenses or other transfers of our intellectual property pursuant to which we transfer all or substantially all of our legal or economic interests, defined as an Intellectual Property Sale, and the Deerfield entities may elect to require us to prepay the principal amount of the Deerfield Notes in an amount equal to (i) 100% of the cash proceeds of any Intellectual Property Sale relating to cabozantinib and (ii) 50% of the cash proceeds of any other Intellectual Property Sale.

In connection with the January 2014 amendment to the note purchase agreement, on January 22, 2014, we issued to the New Deerfield Purchasers two-year warrants, which we refer to as the 2014 Warrants, to purchase an aggregate of 1,000,000 shares of our common stock at an exercise price of $9.70 per share. Subsequent to our election to extend the maturity date of the Deerfield Notes, the exercise price of the 2014 Warrants was reset to $3.445 per share and the term was extended by two years to January 22, 2018. In August 2015 the New Deerfield Purchasers assigned the 2014 Warrants to OTA LLC. The 2014 Warrants contain certain limitations that prevent the holder from acquiring shares upon exercise that would result in the number of shares beneficially owned by the holder to exceed 9.98% of the total number of shares of our common stock then issued and outstanding. In addition, upon certain changes in control of Exelixis, to the extent the 2014 Warrants are not assumed by the acquiring entity, or upon certain defaults under the 2014 Warrants, the holder has the right to net exercise the 2014 Warrants for shares of common stock, or be paid an amount in cash in certain circumstances where the current holders of our common stock would also receive cash, equal to the Black-Scholes Merton value of the 2014 Warrants.

In connection with the issuance of the 2014 Warrants, we entered into a registration rights agreement with Deerfield, pursuant to which we filed a registration statement with the SEC covering the resale of the shares of common stock issuable upon exercise of the 2014 Warrants.

In connection with the note purchase agreement, we also entered into a security agreement in favor of Deerfield which provides that our obligations under the Deerfield Notes will be secured by substantially all of our assets except intellectual property. On August 1, 2013, the security agreement was amended to limit the extent to which voting equity interests in any of our foreign subsidiaries shall be secured assets.

The note purchase agreement as amended and the security agreement include customary representations and warranties and covenants made by us, including restrictions on the incurrence of additional indebtedness.

Loan Agreement with Silicon Valley Bank

On May 22, 2002, we entered into a loan and security agreement with Silicon Valley Bank for an equipment line of credit. On June 2, 2010, we amended the loan and security agreement to provide for a new seven-year term loan in the amount of $80.0 million. As of both September 30, 2016 and December 31, 2015, the outstanding principal balance due under the term loan was $80.0 million. All other amounts due under the agreement were repaid prior to December 31, 2015. The principal amount outstanding under the term loan accrues interest at 1.0% per annum, which interest is due and payable monthly. We are required to repay the term loan in one balloon principal payment, representing 100% of the principal balance and accrued and unpaid interest, on May 31, 2017, and therefore have classified the term loan as a current liability as of September 30, 2016. We have the option to prepay all, but not less than all, of the amounts advanced under the term loan, provided that we pay all unpaid accrued interest thereon that is due through the date of such prepayment and the interest on the entire principal balance of the term loan that would otherwise have been paid after such prepayment date until the maturity date of the term loan. In accordance with the terms of the loan and security agreement, we are required to maintain an amount equal to at least 100%, but not to exceed 107%, of the outstanding principal balance of the term loan and all equipment lines of credit under the loan and security agreement, if any, on deposit in one or more investment accounts with Silicon Valley Bank or one of its affiliates as support for our obligations under the loan and security agreement (although we are entitled to retain income earned or the amounts maintained in such accounts). Any amounts outstanding under the term loan during the continuance of an event of default under the loan and security agreement will, at the election of Silicon Valley Bank, bear interest at a

per annum rate equal to 6.0%. If one or more events of default under the loan and security agreement occurs and continues beyond any applicable cure period, Silicon Valley Bank may declare all or part of the obligations under the loan and security agreement to be immediately due and payable and stop advancing money or extending credit to us under the loan and security agreement.

Critical Accounting Estimates

The preparation of our consolidated financial statements is in conformity with accounting principles generally accepted in the United States that requires management to make judgments, estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosures. On an ongoing basis, management evaluates its

Table of Contents

estimates including, but not limited to, those related to revenue recognition, including for deductions from revenues (such as rebates, chargebacks, sales returns and sales allowances) and the period of performance, identification of deliverables and evaluation of milestones with respect to our collaborations, recoverability of inventory, certain accrued liabilities including clinical trial and collaboration liability accruals, the valuation of the debt and equity components of our convertible debt and share-based compensation. We base our estimates on historical experience and on various other market-specific and other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ materially from those estimates. An accounting policy is considered to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, and if different estimates that reasonably could have been used, or changes in the accounting estimates that are reasonably likely to occur periodically, could materially impact the financial statements. We believe our critical accounting policies relating to inventory, revenue recognition, clinical trial accruals, restructuring liability, share based compensation and warrant valuation reflect the more significant estimates and assumptions used in the preparation of our consolidated financial statements.

Revenue Recognition

Net Product Revenues including Discounts and Allowances

In the United States, we sell our products, CABOMETYX and COMETRIQ, to specialty pharmacies and distributors that benefit from customer incentives and have a right of return under certain circumstance. Historically we have relied on payer data received from the specialty pharmacy that sells COMETRIQ in the United States and historical utilization rates in determining our discounts and allowances. In determining discounts and allowances for the sale of CABOMETYX, in addition to using payer data received from the specialty pharmacies and distributors that sell CABOMETYX and historical data for COMETRIQ, we also utilized claims data from third party sources for competitor products for the treatment of advanced RCC. Based in part on the availability of this third party data, we made the determination that we had sufficient experience and data to reasonably estimate expected future returns and the discounts and allowances due to payers at the time of shipment to the specialty pharmacy or distributor, and therefore record revenue for the product using the “sell-in” revenue recognition model.

Royalty, License and Contract Revenues

We enter into corporate collaboration and license agreements under which we may obtain upfront license fees, research funding, and contingent, milestone and royalty payments. Our deliverables under these arrangements may include intellectual property rights, distribution rights, delivery of manufactured product, and participation on joint steering committees and/or research and development services. In order to account for the multiple-element arrangements, we identify the deliverables included within the arrangement and evaluate whether the delivered elements under these arrangements have value to our collaboration partner on a stand-alone basis and represent separate units of accounting. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver future goods or services, a right or license to use an asset, or another performance obligation. If we determine that multiple deliverables exist, the consideration is allocated to one or more units of accounting based upon the best estimate of the selling price of each deliverable. The selling price used for each deliverable will be based on vendor-specific objective evidence, if available, third-party evidence if vendor-specific objective evidence is not available, or estimated selling price if neither vendor-specific or third-party evidence is available. A delivered item or items that do not qualify as a separate unit of accounting within the arrangement shall be combined with the other applicable undelivered items within the arrangement. The allocation of arrangement consideration and the recognition of revenue then shall be determined for those combined deliverables as a single unit of accounting. For a combined unit of accounting, non-refundable upfront fees are recognized in a manner consistent with the final deliverable, which has generally been ratably over the period of continued involvement. Amounts received in advance of performance are recorded as deferred revenue. Upfront fees are classified as license revenues in our consolidated statements of operations.

We consider sales-based contingent payments to be royalty revenue which is generally recognized at the date the contingency is achieved. Royalties are recorded based on sales amounts reported to us for the preceding quarter.

For certain contingent payments under collaboration and license arrangements, we recognize revenue using the milestone method. Under the milestone method a payment that is contingent upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is an event: (i) that can be achieved based in whole or in part on either our performance or on the occurrence of a specific outcome resulting from our performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to us. The determination that a milestone is substantive requires estimation and judgment and is made at the inception of the arrangement. Milestones are considered substantive when the

Table of Contents

consideration earned from the achievement of the milestone is: (i) commensurate with either our performance to achieve the milestone or the enhancement of value of the item delivered as a result of a specific outcome resulting from our performance to achieve the milestone, (ii) relates solely to past performance and (iii) reasonable relative to all deliverables and payment terms in the arrangement. In making the determination as to whether a milestone is substantive or not, we consider all facts and circumstances relevant to the arrangement, including factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether any portion of the milestone consideration is related to future performance or deliverables.

Valuation of Debt and Equity Instruments issued in Connection with August 2012 Offering

The 2019 Notes are accounted for in accordance with ASC Subtopic 470-20, Debt with Conversion and Other Options. Under ASC Subtopic 470-20, issuers of certain convertible debt instruments that have a net settlement feature and may be settled in cash upon conversion, including partial cash settlement, are required to separately account for the liability (debt) and equity (conversion option) components of the instrument. The carrying amount of the liability component of any outstanding debt instrument is computed by estimating the fair value of a similar liability without the conversion option. The amount of the equity component is then calculated by deducting the fair value of the liability component from the principal amount of the convertible debt instrument at issuance and the total settlement consideration transferred to the holders upon conversion. The effective interest rate used in determining the original component of the 2019 Notes was 10.09% when issued in August 2012 and 9.50% during the three months ended September 30, 2016. See “Note 6 - Debt” of the Note to Consolidated Financial Statements for further information regarding the 2019 Notes.

There have been no other significant changes in our critical accounting policies and estimates during the nine months ended September 30, 2016, as compared to the critical accounting policies and estimates disclosed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report on Form 10-K for the year ended December 31, 2015.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Updates, or ASU, No. 2014-09, Revenue from Contracts with Customers, or ASU 2014-09. ASU 2014-09 will replace most existing revenue recognition guidance when it becomes effective and permits the use of either the retrospective or cumulative effect transition method. In August 2015, the FASB issued an update to defer the effective date of this update by one year. ASU 2014-09, as amended, becomes effective for us in the first quarter of fiscal year 2018, but allows us to adopt the standard one year earlier if we so choose. We currently plan to adopt this accounting standard in the first quarter of fiscal year 2018. We have not yet selected a transition method and are evaluating the effect that ASU 2014-09 will have on our Consolidated Financial Statements and related disclosures.

In April 2015, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update No. 2015-05, Customer’s Accounting for Fees Paid in a Cloud Computing Arrangement, or ASU 2015-05. ASU 2015-05 provides guidance to customers about whether a cloud computing arrangement includes a software license. If a cloud computing arrangement includes a software license, then the customer should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the customer should account for the arrangement as a service contract. ASU 2015-05 was effective for all interim and annual reporting periods beginning after December 15, 2015 and therefore we adopted ASU 2015-05 in the three months ended March 31, 2016 on a prospective basis. The adoption of ASU 2015-05 did not have a material impact on our Condensed Consolidated Statements of Operations for the three months ended March 31, 2016 and is not expected to have a material effect on our Consolidated Financial Statements in future periods.

In July 2015, the FASB issued ASU No. 2015-11, Inventory: Simplifying the Measurement of Inventory, or ASU No. 2015-11”). ASU No. 2015-11 requires inventory measurement at the lower of cost and net realizable value. ASU No. 2015-11 are effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. Early adoption is permitted by all entities as of the beginning of an interim or annual reporting period. We are in the process of assessing the impact, if any, of ASU No. 2015-11 on our condensed consolidated financial

statements.

In March 2016, the FASB issued Accounting Standards Update No. 2016-09, Improvements to Employee Share-Based Payment Accounting, or ASU 2016-09. ASU 2016-09 is aimed at the simplification of several aspects of the accounting for employee share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for all interim and annual reporting periods beginning after December 15, 2016. Early adoption is permitted. We are currently evaluating the impact that the adoption of ASU 2016-09 will have on our consolidated financial statements and related disclosures.

Table of Contents

In August 2016, the FASB issued Accounting Standards Update No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments, or ASU 2016-15. ASU 2016-15 addresses eight specific cash flow issues including, debt prepayment or debt extinguishment costs, settlement of zero-coupon debt instruments or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing and contingent consideration payments made after a business combination. We do not expect the adoption of ASU 2016-15 to have a material impact on our Consolidated Statements of Cash Flows.

Fiscal Year Convention

We adopted a 52- or 53-week fiscal year that generally ends on the Friday closest to December 31st. Fiscal year 2016 will end on December 30, 2016, and fiscal year 2015, ended on January 1, 2016. For convenience, references in this report as of and for the fiscal periods ended September 30, 2016, and October 2, 2015, and as of and for the fiscal years ended December 30, 2016 and January 1, 2016, are indicated as being as of and for the periods ended September 30, 2016, September 30, 2015, and the years ended December 31, 2016, and December 31, 2015, respectively.

Results of Operations

Revenues

Revenues by category were as follows (dollars in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Gross product revenues	$46,720	$7,230	$92,383	$25,794
Discounts and allowances	(3,978)	(376)	(8,924)	(1,560)
Net product revenues	42,742	6,854	83,459	24,234
Royalty and license revenues [1]	4,452	—	10,414	—
Contract revenues [2]	15,000	3,000	20,000	3,000
Total revenues	$62,194	$9,854	$113,873	$27,234
Dollar change	$52,340		$86,639	
Percentage change	531 %		318 %	

(1) Includes royalties and amortization of upfront payments.

(2) Includes contingent and milestone payments.

Net product revenues by product were as follows (dollars in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
CABOMETYX	$31,238	$—	$48,812	$—
COMETRIQ	11,504	6,854	34,647	24,234
Net product revenues	$42,742	$6,854	$83,459	$24,234
Dollar change	$35,888		$59,225	
Percentage change	524 %		244 %	

The increase in net product revenues for the three and nine months ended September 30, 2016, as compared to the comparable periods in 2015, reflects the impact of the commercial launch of CABOMETYX in late April 2016. CABOMETYX was approved by the FDA on April 25, 2016 as a treatment for patients with advanced RCC who have received prior anti-angiogenic therapy. Net product revenues during the nine months ended September 30, 2016 were impacted by the build of channel inventory related to the initial launch period for CABOMETYX. Net product revenues for both CABOMETYX and COMETRIQ are recorded using the “sell-in” method of revenue recognition.

Royalty and license revenues for the three and nine months ended September 30, 2016 included recognition of $3.8 million and $8.6 million, respectively, of the $200.0 million upfront nonrefundable payment received in March 2016

in consideration for the exclusive license and other rights contained in the collaboration and license agreement with Ipsen and the $60.0 million milestone we achieved upon the approval of cabozantinib by the EMA in second-line RCC in September 2016. During the three and nine months ended September 30, 2016, we also recognized $0.7 million and $1.8 million, respectively, of

Table of Contents

royalties on ex-U.S. net sales of COTELLIC. There were no such royalty and license revenue during the comparable periods in 2015.

Contract revenues for the three and nine months ended September 30, 2016 reflect recognition of $15.0 million from a milestone payment earned from Daiichi Sankyo related to its worldwide license of our compounds that modulate mineralocorticoid receptor ("MR"), including CS-3150 (an isomer of XL550) in September 2016 and $5.0 million from a milestone payment earned from Merck related to its worldwide license of our phosphoinositide-3 kinase-delta program in July 2016. Contract revenues for the three and nine months ended September 30, 2015 reflect an additional $3.0 million contingent payment earned in March 2016 from Merck related to that same license.

Total revenues by significant customer were as follows (dollars in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Diplomat Specialty Pharmacy	$19,392	$6,457	$46,770	$21,567
Daiichi Sankyo	15,000	—	15,000	—
Merck	—	3,000	5,000	3,000
Swedish Orphan Biovitrum	1,350	397	2,453	2,667
Others, individually less than 10% of total revenues for all periods presented	26,452	—	44,650	—
Total revenues	$62,194	$9,854	$113,873	$27,234
Dollar change	$52,340		$86,639	
Percentage change	531 %		318 %	

Cost of Goods Sold

Cost of goods sold is related to our product revenues and consists primarily of a 3% royalty on net sales of any product incorporating cabozantinib payable to GlaxoSmithKline, indirect labor costs, the cost of manufacturing, write-downs related to expiring and excess inventory, and other third party logistics costs of our product. A portion of the manufacturing costs for inventory was incurred prior to regulatory approval of CABOMETYX and COMETRIQ and, therefore, were expensed as research and development costs when those costs were incurred, rather than capitalized as inventory.

The cost of goods sold and our gross margins were as follows (dollars in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Cost of goods sold	$2,455	$1,420	$4,700	$2,872
Gross margin	94 %	79 %	94 %	88 %

The increase in gross margins for the three and nine months ended September 30, 2016 as compared to the comparable period in 2015, was primarily related to the launch of CABOMETYX which has lower manufacturing costs than COMETRIQ. Cost of goods sold also include write-downs related to excess and expiring inventory. Such write-downs were $0.4 million for both the three and nine months ended September 30, 2016 as compared to $1.1 million and $0.9 million for the comparable periods in 2015. The cost of goods sold and gross margin we have experienced in this early stage of the CABOMETYX product launch may not be representative of what we may experience going forward.

Research and Development Expenses

Total research and development expenses were as follows (dollars in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Research and development expenses	$20,256	$26,091	$72,166	$72,879
Dollar change	$(5,835)		$(713)	

Percentage change	(22)%	(1)%

Research and development expenses consist primarily of clinical trial expenses, personnel expenses, stock-based compensation, consulting and outside services, the allocation of general corporate costs, and temporary personnel expenses.

Table of Contents

The decrease in research and development expenses for the three months ended September 30, 2016 as compared to the comparable period in 2015, was primarily related to decreases in stock-based compensation, clinical trial costs, which includes services performed by third-party contract research organizations and other vendors who support our clinical trials , which was partially offset by increases in personnel expenses. The decrease in stock-based compensation of $5.5 million for the three months ended September 30, 2016 as compared to the comparable period in 2015 was primarily related to the vesting of performance-based stock options tied to top-line METEOR data received in July 2015 and was expensed during the three months ended months ended September 30, 2015. The decrease in clinical trial costs of $2.9 million for the three months ended September 30, 2016 as compared to the comparable period in 2015 was predominantly due to decreases in costs related to METEOR and was partially offset by increases in costs related to CELESTIAL. Personnel expenses increased by $2.6 million for the three months ended September 30, 2016 as compared to the comparable period in 2015 primarily due to the hiring of medical science liaisons as a result of the launch of CABOMETYX and an increase in the accrual for corporate bonuses.

The decrease in research and development expenses for the nine months ended September 30, 2016 as compared to the comparable period in 2015, was primarily related to clinical trial costs, which includes services performed by third-party contract research organizations and other vendors who support our clinical trials, and a decrease in the allocation of general corporate costs; those decreases were partially offset by increases in personnel expenses and consulting and outside services. The decrease in clinical trial costs was $9.2 million for the nine months ended September 30, 2016 as compared to the comparable period in 2015. The decrease in clinical trial costs was predominantly due to decreases in costs related to METEOR, our phase 3 pivotal trial in advanced RCC and was partially offset by increases in costs related to CELESTIAL, our phase 3 pivotal trial in advanced HCC. The allocation of general corporate costs decreased by $3.7 million for the nine months ended September 30, 2016 as compared to the comparable period in 2015, primarily due to headcount growth in the selling, general and administrative functions. Personnel expenses increased by $7.6 million for the nine months ended September 30, 2016 as compared to the comparable period in 2015 primarily due to the hiring of medical science liaisons as a result of the launch of CABOMETYX and an increase in the accrual for corporate bonuses. Consulting and outside services increased by $2.3 million for the nine months ended September 30, 2016 as compared to the comparable period in 2015 primarily due to increases in activities related to medical affairs and drug safety.

We are focusing our development and commercialization efforts primarily on cabozantinib to maximize the therapeutic and commercial potential of this compound, and as a result, we expect our near-term research and development expenses to relate to the clinical development of cabozantinib. We expect to continue to incur significant development costs for cabozantinib in future periods as we evaluate its potential in a broad development program comprising over 45 ongoing or planned clinical trials across multiple indications. The most notable study of this program is our company-sponsored phase 3 trial of cabozantinib in advanced HCC called CELESTIAL. In addition, postmarketing commitments in connection with the approval of COMETRIQ in progressive, metastatic MTC dictate that we conduct an additional study in that indication.

We do not have reliable estimates regarding the timing of our clinical trials. We estimate that typical phase 1 clinical trials last approximately one year, phase 2 clinical trials last approximately one to two years and phase 3 clinical trials last approximately two to four years. However, the length of time may vary substantially according to factors relating to the particular clinical trial, such as the type and intended use of the drug candidate, the clinical trial design and the ability to enroll suitable patients.

We do not have reliable estimates of total costs for a particular drug candidate, or for cabozantinib for a particular indication, to reach the market. Our potential therapeutic products are subject to a lengthy and uncertain regulatory process that may involve unanticipated additional clinical trials and may not result in receipt of the necessary regulatory approvals. Failure to receive the necessary regulatory approvals would prevent us from commercializing the product candidates affected. In addition, clinical trials of our potential product candidates may fail to demonstrate safety and efficacy, which could prevent or significantly delay regulatory approval.

Selling, General and Administrative Expenses

Total selling, general and administrative expenses were as follows (dollars in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Selling, general and administrative expenses	$32,463	$17,842	$103,143	$40,162
Dollar change	$14,621		$62,981	
Percentage change	82 %		157 %	

Selling, general and administrative expenses consist primarily of personnel expenses, marketing, consulting and outside services, employee stock-based compensation, facility costs, travel and entertainment and legal and accounting costs.

Table of Contents

The increase in selling, general and administrative expenses for the three months ended September 30, 2016 was primarily related to increases in personnel expenses, marketing and consulting and outside services; those increases were partially offset by a decrease in stock-based compensation. Personnel expenses increased by $11.1 million for the three months ended September 30, 2016 as compared to the comparable period in 2015 primarily due an increase in headcount connected with the build-out of our U.S. commercial organization as a result of the launch of CABOMETYX as well as an increase in incentive compensation and the accrual for corporate bonuses. Consulting and outside services increased by $2.7 million and Marketing expenses increased by $1.3 million for the three months ended September 30, 2016 as compared to the comparable period in 2015, primarily due to costs incurred supporting the commercialization and launch of CABOMETYX. The decrease in stock-based compensation was $2.9 million in the three months ended September 30, 2016 as compared to the comparable period in 2015 primarily as a result of the vesting of performance-based stock options tied to top-line data received in July 2015 from METEOR which met its primary endpoint and were expensed during the three months ended September 30, 2015.

The increase in selling, general and administrative expenses for the nine months ended September 30, 2016 as compared to the comparable period in 2015 was primarily related to personnel expenses, consulting and outside services and marketing. Personnel expenses increased by $30.6 million for the nine months ended September 30, 2016 as compared to the comparable period in 2015 primarily due to an increase in headcount connected with the build-out of our U.S. commercial organization as a result of the launch of CABOMETYX as well as an increase in incentive compensation and the accrual for corporate bonuses. Consulting and outside services increased by $12.3 million and Marketing expenses increased by $9.7 million for the nine months ended September 30, 2016 as compared to the comparable period in 2015, primarily due to costs incurred supporting the commercialization and launch of CABOMETYX.

Total Other Income (Expense), Net

Certain historical amounts in other income (expense), net have been revised to reflect the correction of the accounting for non-cash interest expense associated with the 2019 Notes. See “Note 1 - Organization and Summary of Significant Accounting Policies - Correction of an Immaterial Error” in the Notes to the Condensed Consolidated Financial Statements for additional information on the correction.

Total other income (expense), net, was as follows (dollars in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Interest income and other, net	$3,059	$276	$4,010	$146
Interest expense	(7,834)	(10,037)	(28,575)	(30,501)
Loss on extinguishment of debt	(13,773)	—	(13,773)	—
Total other income (expense), net	$(18,548)	$(9,761)	$(38,338)	$(30,355)
Dollar change	$(8,787)		$(7,983)	
Percentage change	90%		26%	

Total other income (expense), net consists primarily of the loss on extinguishment of debt, interest expense incurred on our debt, gains on the sale of equity investments, gains and losses on derivatives, foreign exchange fluctuations and interest income earned on our cash and investments.

The increase in net expense in the three and nine months ended September 30, 2016 was primarily related to the $13.8 million loss associated with the conversion of $285.3 million in aggregate principal amount of the 2019 Notes for 53,704,911 shares of our Common Stock. See “Note 6 - Debt” in our “Notes to Condensed Consolidated Financial Statements” for more information on the conversions. Interest expenses decreased by $2.2 million and $1.9 million for the three and nine months ended September 30, 2016, respectively, as compared to the comparable periods in 2015 primarily due those conversions.

During the three and nine months ended September 30, 2016 we also recognized a $2.5 million gain on the sale of our 9% interest in Akarna Therapeutics, Ltd, which we acquired in 2015 in exchange for intellectual property rights related to XL335.

34

Table of Contents

Liquidity and Capital Resources

Sources and Uses of Cash

The following table summarizes our cash flow activities (in thousands):

	Nine Months Ended September 30,	
	2016	2015
Net loss	$(105,345)	$(120,176)
Net cash provided by (used in) operating activities	122,582	(106,152)
Net cash (used in) provided by investing activities	(155,638)	26,068
Net cash provided by financing activities	2,641	145,331
Net (decrease) increase in cash and cash equivalents	(30,415)	65,247
Cash and cash equivalents at beginning of period	141,634	80,395
Cash and cash equivalents at end of period	$111,219	$145,642

Since the launch of our first commercial product in January 2013, through September 30, 2016, we have generated an aggregate of $157.7 million in net product revenues. Other than sales of CABOMETYX and COMETRIQ, we have derived substantially all of our revenues since inception from collaborative research and development agreements, which depend on royalties, license fees, the achievement of milestones, and research funding we earn from any products developed from the collaborative research. For a discussion of potential future capital requirements, please see "– Liquidity and Capital Resources – Capital Requirements."

Operating Activities

Our operating activities provided cash of $122.6 million for the nine months ended September 30, 2016, compared to cash used of $106.2 million for the same period in 2015. Operating cash flows can differ from our consolidated net loss as a result of differences in the timing of cash receipts and non-cash charges.

Cash provided by operating activities for the nine months ended September 30, 2016 was primarily a result of the $200.0 million upfront payment Ipsen paid us in consideration for the exclusive license and other rights contained in the collaboration and license agreement we entered into on February 29, 2016 and cash receipts from net product revenues. Those proceeds were partially offset by operating expenses of $180.9 million for the period, less non-cash expenses for stock-based compensation totaling $18.3 million and the amortization of debt discount, debt issuance costs and accrual of interest paid in kind totaling $14.2 million. Our operating expenses were largely attributable to the development and commercialization of cabozantinib. In addition, cash provided by operating activities also increased as a result of a $18.8 million increase in accounts payable, accrued compensation, and other accrued liabilities and a $7.8 million increase in our accrued collaboration liability, and was partially offset by a $3.3 million increase in prepaid expenses and other current assets and a $3.2 million reduction in accrued clinical trial liabilities. Trade receivables increased by $85.9 million primarily due to the $60.0 million milestone achieved under our collaboration with Ipsen that we expect to receive in November 2016. That milestone resulted in a corresponding increase to deferred revenue and as a result did not impact cash provided by operating activities for the nine months ended September 30, 2016.

Cash used in operating activities for the nine months ended September 30, 2015 related primarily to our $117.1 million operating expenses for the period, less non-cash expenses for accretion of debt discount totaling $14.3 million on the Deerfield Notes, the 2019 Notes and stock-based compensation totaling $15.4 million and revenues totaling $27.2 million. Our operating expenses were largely attributable to the development of cabozantinib. In addition to current period operating expenses, we made cash payments that resulted in an $11.8 million reduction in accrued clinical trial liabilities. We also paid $6.2 million for restructuring activities.

Investing Activities

Our investing activities used cash of $155.6 million for the nine months ended September 30, 2016, compared to $26.1 million of cash provided for the same period in 2015.

Cash used by investing activities for the nine months ended September 30, 2016 was primarily due to investment purchases of $262.7 million, less cash from the maturity of unrestricted and restricted investments of $103.3 million.

35

Table of Contents

Cash provided by investing activities for the nine months ended September 30, 2015 was primarily due to the maturity of unrestricted and restricted investments of $147.1 million, less investment purchases of $122.3 million.

Financing Activities

Cash provided by financing activities was $2.6 million for the nine months ended September 30, 2016, compared to $145.3 million of cash used for the same period in 2015.

Cash provided by financing activities for the nine months ended September 30, 2016 was primarily a result of the issuance of common stock under our equity incentive plans which was partially offset by cash payments from the conversions of the 2019 Notes.

Cash provided by our financing activities for the nine months ended September 30, 2015 was primarily due to the issuance of 28,750,000 shares of common stock in July 2015 for net proceeds of $145.7 million. The cash provided by the issuance of common stock was partially offset by principal payments on debt of $4.4 million.

Proceeds from common stock and debt issuances are used for general working capital purposes, including for clinical trials, build-out of commercial infrastructure, research and development, capital expenditures and working capital. Over the next several years, we are required to make certain payments on notes and bank obligations. See “--Certain Factors Important to Understanding Our Financial Condition and Results of Operations,” for a description of those payment obligations.

Capital Requirements

We have incurred net losses since inception through September 30, 2016, with the exception of the 2011 fiscal year. For the nine months ended September 30, 2016, we incurred a net loss of $105.3 million and as of September 30, 2016, we had an accumulated deficit of $2.0 billion. These losses have had an adverse effect on our stockholders’ equity and working capital. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses or when we will become profitable. Excluding fiscal 2011, our research and development expenditures and selling, general and administrative expenses have exceeded our revenues for each fiscal year, and we expect to spend significant additional amounts to fund the continued development and commercialization of cabozantinib. In addition, we are evaluating the expansion of our pipeline through drug discovery and corporate development activities. As a result, we expect to continue to incur substantial operating expenses and, consequently, we will need to generate significant additional revenues to achieve future profitability. Since the launch of our first commercial product in January 2013, through September 30, 2016, we have generated an aggregate of $157.7 million in net product revenues. Other than sales of CABOMETYX and COMETRIQ, we have derived substantially all of our revenues since inception from collaborative research and development agreements, which depend on royalties, license fees, the achievement of milestones, and research funding we earn from any products developed from the collaborative research.

The amount of our net losses will depend, in part, on: the level of sales of CABOMETYX in the U.S. for the treatment of advanced RCC; our sales of COMETRIQ; achievement of clinical, regulatory and commercial milestones and the amount of royalties, if any, from sales of cabozantinib under our collaboration with Ipsen; our share of the net profits and losses for the commercialization of COTELLIC in the U.S. under our collaboration with Genentech (a member of the Roche group); the amount of royalties from COTELLIC sales outside the U.S. under our collaboration with Genentech; other license and contract revenues; and, the level of our expenses, primarily with respect to expanded commercialization activities for cabozantinib.

As of September 30, 2016, we had $379.6 million in cash and investments, which included $293.8 million available for operations, $81.6 million of compensating balance investments that we are required to maintain on deposit with Silicon Valley Bank, and $4.2 million of long-term restricted investments. We anticipate that our current cash and cash equivalents, and short-term investments available for operations, and product revenues, will enable us to maintain our operations for a period of at least 12 months following the filing date of this report. Our capital requirements will depend on many factors, and we may need to use available capital resources and raise additional capital significantly earlier than we currently anticipate. Our capital requirements will depend on many factors including but not limited to:

- the commercial success of both CABOMETYX and COMETRIQ and the revenues we generate from those approved products;

- costs associated with maintaining our expanded sales, marketing, medical affairs and distribution capabilities for CABOMETYX in the approved advanced RCC indications and COMETRIQ in the approved MTC indications;
- the achievement of stated regulatory and commercial milestones under our collaboration with Ipsen;

Table of Contents

- the commercial success of COTELLIC and the calculation of our share of related profits and losses for the commercialization of COTELLIC in the U.S. and royalties from COTELLIC sales outside the U.S. under our collaboration with Genentech;
- the outcome of our arbitration against Genentech in which we have asserted claims related to Genentech's clinical development, pricing and commercialization of COTELLIC, and cost and revenue allocations arising from COTELLIC's commercialization in the United States and Genentech's counterclaim for breach of contract, seeking monetary damages and interest related to the cost allocations under the collaboration agreement;
- the potential regulatory approval of cabozantinib as a treatment for previously untreated advanced RCC in the United States, and in other indications both in the United States and abroad;
- future clinical trial results, notably the results from CELESTIAL, our phase 3 pivotal trial in patients with advanced HCC;
- our future investments in the expansion of our pipeline through drug discovery and corporate development activities;
- repayment of the Deerfield Notes (see "Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations - Certain Factors Important to Understanding Our Financial Condition and Results of Operations - Deerfield Notes" for a description of these notes) which mature on July 1, 2018, subject to a requirement to make a mandatory prepayment in each of 2017 and 2018 equal to 15% of certain revenues from collaborative arrangements (other than intercompany arrangements) received during the prior fiscal year, subject to a maximum annual prepayment amount of $27.5 million;
- our ability to repay the Deerfield Notes with our common stock, which we are only able to do under specified conditions;
- repayment of our term loan from Silicon Valley Bank, which had an outstanding balance at September 30, 2016, of $80.0 million and is due in May 2017;
- our ability to control costs;
- our ability to remain in compliance with, or amend or cause to be waived, financial covenants contained in agreements with third parties;
- the cost of clinical drug supply for our clinical trials;
- trends and developments in the pricing of oncologic therapeutics in the United States and abroad, especially in the European Union;
- scientific developments in the market for oncologic therapeutics and the timing of regulatory approvals for competing oncologic therapies; and
- the filing, maintenance, prosecution, defense and enforcement of patent claims and other intellectual property rights.

Contractual Obligations

We have contractual obligations in the form of debt, operating leases, purchase obligations and other long-term liabilities. During the three months ended September 30, 2016, $285.3 million in aggregate principal amount of the 2019 Notes were converted into 53,704,911 shares of our Common Stock. On August 24, 2016, we provided public notice of the redemption of all remaining 2019 Notes outstanding on November 2, 2016. See "Note 6 - Debt" in the accompanying Notes to the Condensed Consolidated Financial Statements for more information on the conversions and redemption of the 2019 Notes. There were no other material changes outside of the ordinary course of business in our contractual obligations from those as of December 31, 2015.

Off-Balance Sheet Arrangements

As of September 30, 2016, we did not have any material off-balance-sheet arrangements, as defined by applicable SEC regulations.

Table of Contents

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our market risks at September 30, 2016 have not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the Securities and Exchange Commission on February 29, 2016.

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio and our long-term debt. As of September 30, 2016, and December 31, 2015, a decrease in the interest rates of one percentage point would have had a net adverse change in the fair value of interest rate sensitive assets and liabilities of $1.2 million and $7.0 million, respectively.

In addition, we have exposure to fluctuations in certain foreign currencies in countries in which we conduct clinical trials. As of September 30, 2016, and December 31, 2015, approximately $3.5 million and $3.7 million, respectively, of our accrued clinical trial liability was owed in foreign currencies. An adverse change of one percentage point in the foreign currency exchange rates would not have resulted in a material impact for any periods presented. We recorded a $0.2 million loss and a $0.1 million gain relating to foreign exchange fluctuations for nine months ended September 30, 2016 and 2015, respectively.

Item 4. Controls and Procedures.

Evaluation of disclosure controls and procedures. Based on the evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) of the Securities Exchange Act of 1934, as amended, or the Exchange Act) required by Rules 13a-15(b) or 15d-15(b) of the Exchange Act, our Chief Executive Officer and Chief Financial Officer have concluded that as of the end of the period covered by this report, our disclosure controls and procedures were effective at the reasonable assurance level.

Limitations on the effectiveness of controls. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our principal executive officer and principal financial officer have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were effective to provide reasonable assurance that the objectives of our disclosure control system were met.

Changes in internal control over financial reporting. There were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

On June 3, 2016, we filed a Demand for Arbitration before JAMS in San Francisco, California asserting claims against Genentech (a member of the Roche Group) related to its clinical development, pricing and commercialization of COTELLIC, and cost and revenue allocations arising from COTELLIC's commercialization in the United States. In December 2006, we entered into a worldwide collaboration for the development and commercialization of cobimetinib with Genentech. The terms of the collaboration agreement provide Genentech with authority over the global development and commercialization plans for cobimetinib and the execution of those plans. The collaboration agreement further provides that we are entitled to an initial equal share of U.S. profits and losses for cobimetinib, with our share decreasing as sales increase, as well as low double-digit royalties on ex-U.S. net sales of cobimetinib. To date, cobimetinib has been approved for use exclusively in combination with vemurafenib (ZELBORAF) and launched by Genentech in the United States and multiple other territories, including the European Union, Canada, Australia and Brazil as a treatment for patients with advanced melanoma harboring a BRAF V600E or V600K mutation. It is marketed as COTELLIC.

Our arbitration demand asserts that Genentech has breached the parties' contract for, amongst other breaches, failing to meet its diligence and good faith obligations. The demand seeks various forms of declaratory, monetary, and equitable relief, including without limitation that the cost and revenue allocations for COTELLIC be shared equitably consistent with the collaboration agreement's terms, along with attorneys' fees and costs of the arbitration. Genentech has asserted a counterclaim for breach of contract, which seeks monetary damages and interest related to the cost allocations under the collaboration agreement. While the ultimate outcome of the arbitration is difficult to predict, a resolution of the matter adverse to us could result in, among other things, higher than expected commercialization costs, which may have a material adverse effect on our results of operations, cash flows or financial condition.

We may from time to time become a party to other legal proceedings arising in the ordinary course of business.

Item 1A. Risk Factors

In addition to the factors discussed elsewhere in this report and our other reports filed with the SEC, the following are important factors that could cause actual results or events to differ materially from those contained in any forward-looking statements made by us or on our behalf. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not currently known to us or that we deem immaterial also may impair our business operations. If any of the following risks or such other risks actually occurs, our business could be harmed.

We have marked with an asterisk (*) those risk factors below that reflect substantive changes in risks facing us from the risk factors included in our Annual Report on Form 10-K for the fiscal year ended January 1, 2016 filed with the Securities and Exchange Commission on February 29, 2016.

Risks Related to Cabozantinib and Cobimetinib

In the short-term, our prospects are critically dependent upon the commercial success of CABOMETYX for advanced RCC in the United States and the European Union.*

The success of our business is dependent upon the successful development and commercialization of cabozantinib. Of greatest short-term importance is the commercialization of CABOMETYX for the treatment of advanced RCC in the United States and European Union. The commercial potential of CABOMETYX for the treatment of advanced RCC remains subject to a variety of factors, most importantly, CABOMETYX's perceived benefit/risk profile as compared to the benefit/risk profiles of other treatments available for the treatment of advanced RCC. If we are unable to successfully commercialize CABOMETYX, we may need to reduce our operating expenses or raise additional funds, which would have a material adverse effect on our business and financial condition, results of operations and growth prospects. Furthermore, as a consequence of our exclusive collaboration agreement with Ipsen, we rely heavily upon Ipsen's regulatory, commercial, medical affairs, and other expertise and resources for commercialization of CABOMETYX in territories outside of the United States, Canada, and Japan. If Ipsen is unable to, or does not invest the resources necessary to, successfully commercialize CABOMETYX for the treatment of advanced RCC in the European Union and other international territories where it may be approved, this could diminish the amount of revenue we are due to receive under our collaboration agreement with Ipsen, thus resulting in harm to our business

and operations.

Table of Contents

Our longer-term prospects remain dependent on cabozantinib's further clinical development and commercial success in additional indications beyond advanced RCC.*

We are dedicating substantially all of our proprietary resources to developing cabozantinib into a broad and significant oncology franchise. Even following the approval of CABOMETYX for the treatment of advanced RCC in the United States and European Union, our longer-term success remains contingent upon, among other things, successful clinical development, regulatory approval and market acceptance of cabozantinib in additional indications, such as first-line RCC, advanced HCC, NSCLC, and other forms of cancer. In 2014, the failure of COMET-1 and COMET-2, our two phase 3 pivotal trials of cabozantinib in mCRPC, to meet their respective primary endpoints negatively impacted our ability to achieve our development and commercialization goals for cabozantinib in prostate cancer. The failure in mCRPC demonstrates that cabozantinib will not likely be successful in all future clinical trials. Should we prove unsuccessful in the further development of cabozantinib beyond MTC or advanced RCC, our longer-term prospects, revenues and financial condition would be materially adversely affected. With top-line results from CELESTIAL, our phase 3 pivotal trial comparing cabozantinib to placebo in patients with advanced HCC, expected in 2017, the successful development of cabozantinib in advanced HCC is important to our long-term success.

We are heavily dependent on our partner, Genentech (a member of the Roche group), for the successful development, regulatory approval and commercialization of cobimetinib.*

The terms of our collaboration agreement with Genentech provide them with exclusive authority over the global development and commercialization plans for cobimetinib and the execution of those plans. We have no effective influence over those plans and are heavily dependent on Genentech's decision making. The collaboration agreement provides that we are entitled to an initial equal share of U.S. profits and losses in connection with the commercialization of cobimetinib, with our share decreasing as sales increase. We are also entitled to low double-digit royalties on ex-U.S. net sales of cobimetinib. In both cases, we are heavily dependent on Genentech's internal accounting procedures for determining how much, if any, profit we may derive from the collaboration. To date, we believe Genentech's pricing of, and cost and revenue allocations for, COTELLIC, as determined exclusively by Genentech, have been contrary to the applicable terms of the collaboration agreement. We raised this concern with Genentech, along with other material concerns regarding Genentech's performance under the collaboration agreement, but were unable to come to resolution on any of these issues. Accordingly, on June 3, 2016, following a 30 day dispute resolution period, we filed a demand for arbitration asserting claims against Genentech related to its clinical development, pricing and commercialization of COTELLIC, and cost and revenue allocations in connection with COTELLIC's commercialization in the United States. Soon thereafter, Genentech asserted a counterclaim for breach of contract seeking monetary damages and interest related to the cost allocations under the collaboration agreement. While the ultimate outcome of the arbitration is difficult to predict, a resolution of the matter adverse to us could result in, among other things, significant payments and higher than expected commercialization costs, which may have a material adverse effect on our results of operations, cash flows or financial condition.

We are also heavily dependent upon Genentech's leadership and expertise to develop cobimetinib further. Any significant changes to Genentech's business strategy and priorities, over which we have no control, could adversely affect Genentech's willingness or ability to complete their obligations under our collaboration agreement and result in harm to our business and operations. Genentech has complete financial responsibility for cobimetinib's development program and regulatory strategy and execution, and we are not able to control the amount or timing of resources that Genentech will devote to the product. Of particular significance are Genentech's development efforts with respect to the combination of cobimetinib with immuno-oncology agents, a promising and competitive area of clinical research. While Genentech recently initiated a phase 3 pivotal trial combining cobimetinib with its anti-PD-L1 antibody atezolizumab, we are dependent on Genentech for all future development of cobimetinib in combination with atezolizumab or any other immuno-oncology agents. Regardless of Genentech's efforts toward the further development of cobimetinib, such additional clinical investigation may not provide positive results supporting product label expansions or approval in additional indications.

The commercial success of cabozantinib, as CABOMETYX tablets for advanced RCC and as COMETRIQ capsules for MTC, or if approved for additional indications, will depend upon the degree of market acceptance among

physicians, patients, health care payers, and the medical community.*

Our ability to commercialize cabozantinib, as CABOMETYX tablets for the approved advanced RCC indications, COMETRIQ capsules for the approved MTC indications, or if approved for additional indications, will be highly dependent upon the extent to which cabozantinib gains market acceptance among physicians, patients, health care payers such as Medicare and Medicaid, and the medical community. If cabozantinib does not achieve an adequate level of acceptance, we may not generate significant future product revenues, and we may not become profitable. The degree of market acceptance of CABOMETYX, COMETRIQ and other cabozantinib products, if approved, will depend upon a number of factors, including:

- the effectiveness, or perceived effectiveness, of cabozantinib in comparison to competing products;

Table of Contents

- the existence of any significant side effects of cabozantinib, as well as their severity in comparison to those of any competing products;
- cabozantinib's potential advantages or disadvantages in relation to alternative treatments;
- the timing of market entry relative to competitive treatments;
- indications for which cabozantinib is approved;
- the ability to offer cabozantinib for sale at competitive prices;
- relative convenience and ease of administration;
- the strength of sales, marketing, medical affairs and distribution support; and
- sufficient third-party coverage and by government and commercial and other payers.

If we are unable to maintain or scale adequate sales, marketing and distribution capabilities or enter into or maintain agreements with third parties to do so, we may be unable to commercialize cabozantinib successfully.*

We have designed our commercial organization and strategic commercial approach to maintain flexibility in response to market opportunities. In connection with the FDA's approval of CABOMETYX for the treatment of patients with advanced RCC, we increased our sales, marketing, market access and distribution capabilities. Establishing and maintaining sales, marketing and distribution capabilities are expensive and time-consuming. Such expenses may be disproportionate compared to the revenues we may be able to generate and may have an adverse impact on our results of operations. We expect to be able to scale up our commercialization capabilities quickly if additional indications for cabozantinib are approved in the future, or to scale down, if necessary. Overall, we believe the design of our commercial organization, and our strategic commercial approach, are efficient, taking advantage of outsourcing options where prudent to maximize the effectiveness of our commercial expenditures. However, we believe the commercial opportunity for cabozantinib will grow over time, but we may not properly judge the requisite size, and experience of the commercialization teams or the scale of distribution necessary to market and sell cabozantinib successfully. Maintaining sales, marketing, medical affairs, and distribution capabilities is expensive and time-consuming. Such expenses may be eventually prove to be disproportionate compared to the revenues we may be able to generate on sales of cabozantinib, which could have an adverse impact on our results of operations. If we are unable to maintain adequate sales, marketing, medical affairs, and distribution capabilities, independently or with others, we may not be able to generate product revenues and our business may be adversely affected.

We currently rely on a single third party logistics provider to handle shipping and warehousing for our commercial supply of both CABOMETYX and COMETRIQ in the U.S. While we have expanded our U.S. distribution and pharmacy channels in connection with the approval of CABOMETYX by the FDA for the treatment of patients with advanced RCC in the United States, we still rely on a single specialty pharmacy to dispense COMETRIQ to patients in fulfillment of prescriptions in the United States. Furthermore, we rely on Ipsen for the commercialization and distribution of CABOMETYX and COMETRIQ in territories outside of the United States, Canada and Japan, as well as for access and distribution activities for the approved products under our named patient use, or NPU, program. Our current and anticipated future dependence upon the activities, and legal and regulatory compliance, of these or other third parties may adversely affect our future profit margins and our ability to supply cabozantinib to the marketplace on a timely and competitive basis. For example, if one of the warehouses of our third party logistics provider suffers a fire or damage from another type of disaster, a significant portion of the commercial supply of CABOMETYX and COMETRIQ could be destroyed, resulting in a disruption in our commercialization efforts. These or other third parties may not be able to provide services in the time we require to meet our commercial timelines and objectives or to meet regulatory requirements. We may not be able to maintain or renew our arrangements with third parties, or enter into new arrangements, on acceptable terms, or at all. Third parties could terminate or decline to renew our arrangements based on their own business priorities, at a time that is costly or inconvenient for us. If we are unable to contract for logistics services or distribution of cabozantinib on acceptable terms, our commercialization efforts may be delayed or otherwise adversely affected.

We are subject to certain healthcare laws, regulation and enforcement; our failure to comply with those laws could have a material adverse effect on our results of operations and financial condition.

We are subject to certain healthcare laws and regulations and enforcement by the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include, without limitation:

the federal Anti-Kickback Law, which constrains our business activities, including our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for,

- 41

Table of Contents

or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;
- the Foreign Corrupt Practices Act, a U.S. law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals);
- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- state and federal government price reporting laws that require us to calculate and report complex pricing metrics to government programs, where such reported priced may be used in the calculation of reimbursement and/or discounts on our marketed drugs (participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our products, increased infrastructure costs, and potentially limit our ability to offer certain marketplace discounts); and
- state and federal marketing expenditure tracking and reporting laws, which generally require certain types of expenditures in the United States to be tracked and reported (compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships, which could potentially have a negative effect on our business and/or increase enforcement scrutiny of our activities).

In addition, certain marketing practices, including off-label promotion, may also violate certain federal and state health regulatory fraud and abuse laws as well as false claims laws. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we, or our officers or employees, may be subject to penalties, including administrative civil and criminal penalties, damages, fines, withdrawal of regulatory approval, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to sell our products or operate our business and also adversely affect our financial results.

Numerous federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use and disclosure of personal information. Other countries also have, or are developing, laws governing the collection, use and transmission of personal information. In addition, most healthcare providers who are expected to prescribe our products and from whom we obtain patient health information are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA, we could be subject to criminal penalties if we knowingly obtain individually identifiable health information from a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect our business, including recently enacted laws in a majority of states requiring security breach notification. These laws could create liability for us or increase our cost of doing business. International laws, such as the EU Data Privacy Directive (95/46/EC) and Swiss Federal Act on Data Protection, regulate the processing of personal data within Europe and between European countries and the United States. Failure to provide adequate privacy protections and maintain compliance with safe harbor mechanisms could jeopardize business transactions across borders and result in

significant penalties.

Table of Contents

If we are unable to obtain both adequate coverage and adequate reimbursement from third-party payers for CABOMETYX or COMETRIQ, our revenues and prospects for profitability will suffer.*

Our ability to commercialize CABOMETYX or COMETRIQ successfully is highly dependent on the extent to which coverage and reimbursement for it is, and will be, available from third-party payers, including governmental payers, such as Medicare and Medicaid, and private health insurers. Many patients will not be capable of paying for CABOMETYX or COMETRIQ themselves and will rely on third-party payers to pay for, or subsidize, their medical needs. If third-party payers do not provide coverage or reimbursement for CABOMETYX or COMETRIQ, our revenues and prospects for profitability will suffer. In addition, even if third-party payers provide some coverage or reimbursement for CABOMETYX or COMETRIQ, the availability of such coverage or reimbursement for prescription drugs under private health insurance and managed care plans often varies based on the type of contract or plan purchased. There has been recent negative publicity regarding the use of specialty pharmacies and drug pricing, which may result in physicians being less willing to participate in our patient access programs and thereby limit our ability to increase patient access and adoption of cabozantinib.

In addition, in some foreign countries, particularly the countries in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, price negotiations with governmental authorities can take six to twelve months or longer after the receipt of regulatory marketing approval for a product, which has the potential to substantially delay broad availability of the product in some of those countries. To obtain reimbursement and/or pricing approval in some countries, we and our collaboration partner, Ipsen, may be required to conduct a clinical trial that compares the cost effectiveness of CABOMETYX to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in the commercialization of CABOMETYX.

Third-party payers are challenging the prices charged for medical products and services, and many third-party payers limit reimbursement for newly-approved health care products. In particular, third-party payers may limit the indications for which they will reimburse patients who use CABOMETYX or COMETRIQ. Cost-control initiatives could decrease the price we and our collaboration partner, Ipsen, might establish for CABOMETYX, which would result in lower product revenues to us.

Current healthcare laws and regulations and future legislative or regulatory reforms to the healthcare system may affect our ability to sell CABOMETYX and COMETRIQ profitably.*

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell CABOMETYX and COMETRIQ profitably. Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

We expect that the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, or PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved product. An expansion in the government’s role in the U.S. healthcare industry may cause general downward pressure on the prices of prescription drug products, lower reimbursements for providers using our products, reduce product utilization and adversely affect our business and results of operations. It is unclear whether and to what extent, if at all, other potential developments resulting from the PPACA may provide us with additional revenue to offset the annual excise tax (on certain drug product sales) enacted under the PPACA, subject to limited exceptions. It is possible that the tax burden, if ours is not excepted, would adversely affect our financial performance. The PPACA, among other things, also established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D and expanded manufacturers’ Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations. Moreover, certain politicians, including presidential candidates, have announced plans to regulate the prices of pharmaceutical products. We cannot know what form any such legislation may take or the market’s perception of how such legislation would affect us. Any

reduction in reimbursement from government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our current products and/or those for which we may receive regulatory approval in the future.

As a result of the overall trend towards cost-effectiveness criteria and managed healthcare in the United States, third-party payers are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs. They may use tiered reimbursement and may adversely affect demand for CABOMETYX or COMETRIQ by placing a particular product in an expensive tier. They may also refuse to provide any coverage of uses of approved products

Table of Contents

for medical indications other than those for which the FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payers will reimburse for newly approved drugs, which in turn will put pressure on the pricing of drugs. Further, we do not have experience in ensuring approval by applicable third-party payers outside of the United States for coverage and reimbursement of COMETRIQ. We also anticipate pricing pressures in connection with the sale of CABOMETYX and COMETRIQ due to the increasing influence of health maintenance organizations and additional legislative proposals.

Our competitors may develop products and technologies that impair the value of cabozantinib and cobimetinib.*

The pharmaceutical, biopharmaceutical and biotechnology industries are highly fragmented and are characterized by rapid technological change. In particular, the area of kinase-targeted therapies is a rapidly evolving and competitive field. We face, and will continue to face, intense competition from biotechnology, biopharmaceutical and pharmaceutical companies, as well as academic research institutions, clinical reference laboratories and government agencies that are pursuing research activities similar to ours. Some of our competitors have entered into collaborations with leading companies within our target markets, including some of our existing collaborators. Some of our competitors are further along in the development of their products than we are. In addition, delays in the further development of cabozantinib or cobimetinib for the treatment of additional tumor types, could allow our competitors to bring products to market before us. Our future success will depend upon our ability to maintain a competitive position with respect to technological advances and the shifting landscape of therapeutic strategy following the advent of immunotherapy. Our products may become less marketable if we are unable to successfully adapt our development strategy to address the likelihood that this new approach to treating cancer with immuno-oncoloy agents will become prevalent in indications for which our products are approved, most notably advanced RCC, and in additional indications where we may seek regulatory approval. Furthermore, the complexities of such a strategy may require collaboration with some of our competitors.

The markets for which we intend to pursue regulatory approval of cabozantinib and for which Roche and Genentech intend to pursue regulatory approval for cobimetinib are highly competitive. Further, our competitors may be more effective at using their technologies to develop commercial products. Many of the organizations competing with us have greater capital resources, larger research and development staff and facilities, more experience in obtaining regulatory approvals and more extensive product manufacturing and commercial capabilities than we do. As a result, our competitors may be able to more easily develop technologies and products that would render our technologies and products, and those of our collaborators, obsolete and noncompetitive. There may also be drug candidates of which we are not aware at an earlier stage of development that may compete with cabozantinib and cobimetinib.

Competition for cabozantinib

We believe the principal competition for CABOMETYX in advanced RCC includes: Bristol-Myers Squibb’s nivolumab; Pfizer’s axitinib, sunitinib and temsirolimus; Novartis’ everolimus and pazopanib; Bayer’s and Onyx Pharmaceuticals’ sorafenib; Genentech’s bevacizumab; and Eisai’s lenvatinib.

The immediate competition we face from Bristol-Myers Squibb’s nivolumab is particularly significant. Nivolumab was approved for the treatment of advanced RCC on November 23, 2015, following a rapid review by the FDA. That approval was based in large part on the results of Bristol-Myers Squibb’s phase 3 trial comparing nivolumab to everolimus in patients who had received previous antiangiogenic therapy for advanced RCC (Checkmate 025), in which nivolumab met its primary endpoint of showing a statistically-significant improvement in OS over everolimus, a current standard of care for the treatment of second line RCC patients. Nivolumab failed to demonstrate a statistically-significant PFS benefit over everolimus. Nivolumab also demonstrated an acceptable safety profile. Based on publicly available information, it appears nivolumab is being rapidly adopted by physicians for the treatment of advanced RCC.

We believe that the principal competing anti-cancer therapy to COMETRIQ in progressive, metastatic MTC is Genzyme’s RET, VEGFR and EGFR inhibitor vandetanib, which has been approved by the FDA and the EMA for the treatment of symptomatic or progressive MTC in patients with unresectable, locally advanced, or metastatic disease. On October 21, 2015, AstraZeneca announced the global completion of the sale of vandetanib to Genzyme, a Sanofi company. We anticipate the potential for increased competition for COMETRIQ in progressive, metastatic MTC as a result of the consolidation of vandetanib into Genzyme’s endocrinology portfolio and the company’s rare disease

expertise. In addition, we believe that COMETRIQ also faces competition as a treatment for progressive, metastatic MTC from off-label use of Bayer's and Onyx Pharmaceuticals' (a wholly-owned subsidiary of Amgen) multikinase inhibitor sorafenib, Pfizer's multikinase inhibitor sunitinib, Ariad Pharmaceutical's multikinase inhibitor ponatinib, Novartis' multikinase inhibitor pazopanib, and Eisai's multikinase inhibitor lenvatinib.

Should cabozantinib be approved for the treatment of HCC, the other indication for which we have an ongoing phase 3 pivotal trial, we believe its principal competition may include Bayer's and Onyx Pharmaceuticals' sorafenib, Bayer's

Table of Contents

regorafenib, ArQule's tivantinib, Eisai's lenvatinib, Bristol-Myers Squibb's nivolumab and Merck's pembrolizumab. In particular, Bayer recently announced positive results from a Phase 3 trial that compared regorafenib to placebo in the same HCC patient population that is being enrolled in our Phase 3 trial.

Examples of potential competition for cabozantinib in other cancer indications include: other VEGF pathway inhibitors, including Genentech's bevacizumab; other RET inhibitors including Eisai's lenvatinib and Ariad's ponatinib; and other MET inhibitors, including Amgen's AMG 208, Pfizer's crizotinib, ArQule's tivantinib, and Mirati's MGCD265; and immunotherapies such as Bristol-Myers Squibb's ipilimumab and nivolimab, Merck's pembrolizumab and Roche's atezolizumab.

Competition for cobimetinib

We believe that cobimetinib's principal competition amongst targeted agents includes Novartis' trametinib and dabrafenib, and Array's encorafenib and binimetinib; and within the class of immunotherapies, Bristol-Myers Squibb's ipilimumab and nivolumab and Merck's pembrolizumab. The second category, immunotherapies, are of particular competitive importance vis-a-vis cobimetinib in advanced melanoma as they are already FDA approved in melanoma patient populations that overlap with those that may be eligible for cobimetinib, they have been rapidly incorporated into the National Comprehensive Cancer Network treatment guidelines, and they are viewed with a high degree of enthusiasm by physicians and key opinion leaders. Ongoing and future trials incorporating immune-oncology agents, including combination trials, may further impact usage of cobimetinib in melanoma and potentially in additional tumor types in which cobimetinib may ultimately gain approval.

We lack the manufacturing capabilities necessary to enable us to produce cabozantinib for clinical development or for commercial sale and rely on third parties to do so, which subjects us to various risks.*

We do not have the manufacturing capabilities necessary to enable us to produce materials for our clinical trials or for commercial sale of cabozantinib in either its capsule formulation or tablet formulation, and rely on third party manufacturers to do so. These third parties must comply with applicable regulatory requirements, including the FDA's current Good Manufacturing Practices and the European Commission's Guidelines on Good Distribution Practice. Our current and anticipated future dependence upon these third parties may adversely affect our future profit margins and our ability to develop and commercialize cabozantinib on a timely and competitive basis. These third parties may not be able to produce material on a timely basis or manufacture material at the quality or in the quantity required to meet our development and commercial timelines and applicable regulatory requirements. We may not be able to maintain or renew our existing third party manufacturing and supply arrangements, or enter into new arrangements, on acceptable terms, or at all. Our third party manufacturers and suppliers could terminate or decline to renew our manufacturing and supply arrangements based on their own business priorities, at a time that is costly or inconvenient for us. If we are unable to contract for the production of materials in sufficient quantity and of sufficient quality on acceptable terms, our clinical trials and commercialization efforts may be delayed or otherwise adversely affected. This risk is especially acute during the current period as we continue to ramp up production of CABOMETYX for the treatment of patients advanced RCC in the United States.

Furthermore, if we are required to enter into new manufacturing or supply arrangements, we may not be able to obtain approval from the FDA of any alternate manufacturer or supplier in a timely manner, or at all, which could delay or prevent the clinical development and commercialization of cabozantinib. Failure of our third party manufacturers or suppliers or us to obtain approval from the FDA or to comply with applicable regulations could result in sanctions being imposed on us, including fines, civil penalties, delays in or failure to grant marketing approval of cabozantinib, injunctions, suspension or withdrawal of approvals, license revocation, seizures or recalls of products and compounds, operating restrictions and criminal prosecutions, any of which could have a significant adverse effect on our business. Our third party manufacturers are subject to routine regulatory inspections. Failure of our third party manufacturers to meet these appropriate standards and/or perform manufacturing as required could result in a batch not passing quality inspection or meeting regulatory standards. This could result in product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could have also a significant adverse effect on our business.

Clinical testing of cabozantinib beyond advanced RCC and MTC is a lengthy, costly, complex and uncertain process and may fail to demonstrate safety and efficacy.*

Cabozantinib is being evaluated in a comprehensive development program for the treatment of advanced HCC and a variety of other indications beyond advanced RCC and MTC. Clinical trials are inherently risky and may reveal that cabozantinib is ineffective or has unacceptable toxicity or other side effects that may significantly decrease the likelihood of regulatory approval in such indications. For example, COMET-1 and COMET-2, our two phase 3 pivotal trials of cabozantinib in mCRPC, failed to meet their respective primary endpoints of demonstrating a statistically significant increase in OS for patients treated with cabozantinib as compared to prednisone and to demonstrate improvement in pain response for patients

Table of Contents

treated by cabozantinib as compared to mitoxantrone/prednisone. Based on the outcome of the COMET trials, we deprioritized the clinical development of cabozantinib in mCRPC.

The results of preliminary studies do not necessarily predict clinical or commercial success, and later-stage clinical trials may fail to confirm the results observed in earlier-stage trials or preliminary studies. Although we have established timelines for manufacturing and clinical development of cabozantinib based on existing knowledge of our compounds in development and industry metrics, we may not be able to meet those timelines.

We may experience numerous unforeseen events, during or as a result of clinical testing, that could delay or prevent commercialization of cabozantinib for the treatment of advanced HCC, and other indications, including:

- cabozantinib may not prove to be efficacious or may cause, or potentially cause, harmful side effects;
- negative or inconclusive clinical trial results may require us to conduct further testing or to abandon projects that we had expected to be promising;
- our competitors may discover or commercialize other compounds or therapies that show significantly improved safety or efficacy compared to cabozantinib;
- patient registration or enrollment in our clinical testing may be lower than we anticipate, resulting in the delay or cancellation of clinical testing; and
- regulators or institutional review boards may withhold authorization of cabozantinib, or delay, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or their determination that participating patients are being exposed to unacceptable health risks.

If we were to have significant delays in or termination of our clinical testing of cabozantinib as a result of any of the events described above or otherwise, our expenses could increase and our ability to generate revenues could be impaired, either of which could adversely impact our financial results.

We have limited experience in conducting clinical trials and may not be able to rapidly or effectively continue the further development of cabozantinib or meet current or future requirements of the FDA or regulatory authorities in other jurisdictions, including those identified based on our discussions with the FDA or such other regulatory authorities. Our planned clinical trials may not begin on time, or at all, may not be completed on schedule, or at all, may not be sufficient for registration of cabozantinib or may not result in an approvable product.

Completion of clinical trials may take several years or more, but the length of time generally varies substantially according to the type, complexity, novelty and intended use of cabozantinib. The duration and the cost of clinical trials may vary significantly over the life of a project as a result of factors relating to the clinical trial, including, among others:

- the number of patients who ultimately participate in the clinical trial;
- the duration of patient follow-up that is appropriate in view of the results or required by regulatory authorities;
- the number of clinical sites included in the trials; and
- the length of time required to enroll suitable patient subjects.

Any delay could limit our ability to generate revenues, cause us to incur additional expense and cause the market price of our common stock to decline significantly. Our partners under our collaboration agreements may experience similar risks with respect to the compounds we have out-licensed to them. If any of the events described above were to occur with such programs or compounds, the likelihood of receipt of milestones and royalties under such collaboration agreements could decrease.

If third parties upon which we rely do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize cabozantinib for the treatment of additional indications beyond advanced RCC and MTC.*

We do not have the ability to independently conduct clinical trials for cabozantinib, including our post-marketing commitments in connection with the approvals of CABOMETYX in advanced RCC and COMETRIQ in progressive, metastatic MTC, and we rely on third parties we do not control such as the federal government (including NCI-CTEP, with whom we have our CRADA), third-party contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our clinical protocols

or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for or commercialize cabozantinib for additional indications beyond the approved advanced RCC indications and MTC indications in the United States and European Union.

Table of Contents

Cabozantinib is subject to a lengthy and uncertain regulatory process that may not result in the necessary regulatory approvals, which could adversely affect our ability to commercialize cabozantinib.

The activities associated with cabozantinib's research, development and commercialization, are subject to extensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain additional regulatory approval for cabozantinib would prevent us from promoting its use in those indications. We have only limited experience in preparing and filing the applications necessary to gain regulatory approvals. The process of obtaining regulatory approvals in the United States and other foreign jurisdictions is expensive, and often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidates involved. For example, before an NDA or NDA supplement can be submitted to the FDA, or MAA to the EMA or any application or submission to regulatory authorities in other jurisdictions, the product candidate must undergo extensive clinical trials, which can take many years and require substantial expenditures.

Any clinical trial may fail to produce results satisfactory to the FDA or regulatory authorities in other jurisdictions. For example, the FDA could determine that the design of a clinical trial is inadequate to produce reliable results. The regulatory process also requires preclinical testing, and data obtained from preclinical and clinical activities are susceptible to varying interpretations. The FDA has substantial discretion in the approval process and may refuse to approve any NDA or decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. For example, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of cabozantinib for any individual, additional indications.

In addition, delays or rejections may be encountered based upon changes in regulatory policy for product approval during the period of product development and regulatory agency review. Changes in regulatory approval policy, regulations or statutes governing the process for regulatory review during the development or review periods for cabozantinib may cause delays in the approval or rejection of an application.

Even if the FDA or a comparable authority in another jurisdiction approves cabozantinib, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, distribution, advertising, promotion, marketing and/or production of cabozantinib and may impose ongoing requirements for post-approval studies, including additional research and development and clinical trials. For example, in connection with the FDA's approval of COMETRIQ for the treatment of progressive, metastatic MTC, we are subject to the various post-marketing requirements, including a requirement to conduct a clinical study comparing a lower dose of cabozantinib to the approved dose of 140 mg daily cabozantinib in progressive, metastatic MTC and to conduct other clinical pharmacology and preclinical studies. Failure to complete any post-marketing requirements in accordance with the timelines and conditions set forth by the FDA could significantly increase costs or delay, limit or eliminate the commercialization of cabozantinib. Further, these agencies may also impose various civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval.

Risks Related to Our Need for Additional Financing and Our Financial Results

If additional capital is not available to us, we may be forced to delay, reduce or eliminate our product development programs or commercialization efforts and we may breach our financial covenants.*

We may need to access additional capital to:

- fund our operations and clinical trials;
- continue our research and development efforts;
- expand our sales, marketing and distribution capabilities;
- commercialize cabozantinib or any other future product candidates, if any such candidates receive regulatory approval for commercial sale; and
- fund the portion of U.S. sales and marketing costs for cobimetinib that we are obligated to fund under our collaboration with Genentech (a member of the Roche Group), or any similar costs we are obligated to fund under collaborations we may enter into in the future.

As of September 30, 2016, we had $379.6 million in cash and investments, which included $293.8 million available for operations, $81.6 million of compensating balance investments that we are required to maintain on deposit with Silicon Valley Bank, and $4.2 million of long-term restricted investments. We anticipate that our current cash and

cash equivalents, and short-term investments available for operations, and product revenues, will enable us to maintain our operations for a period of at least 12 months following the filing date of this report. Our capital requirements will depend on many factors, and we may need to use available capital resources and raise additional capital significantly earlier than we currently anticipate. Our capital requirements will depend on many factors including but not limited to:

Table of Contents

- the commercial success of both CABOMETYX and COMETRIQ and the revenues we generate from those approved products;
- costs associated with maintaining our expanded sales, marketing, medical affairs and distribution capabilities for CABOMETYX in advanced RCC and COMETRIQ in the approved MTC indications;
- the achievement of stated regulatory and commercial milestones under our collaboration with Ipsen;
- the commercial success of COTELLIC and the calculation of our share of related profits and losses for the commercialization of COTELLIC in the U.S. and royalties from COTELLIC sales outside the U.S. under our collaboration with Genentech;
- the outcome of our arbitration against Genentech in which we have asserted claims related to Genentech's clinical development, pricing and commercialization of COTELLIC, and cost and revenue allocations arising from COTELLIC's commercialization in the United States and Genentech's counterclaim for breach of contract, seeking monetary damages and interest related to the cost allocations under the collaboration agreement;
- the potential regulatory approval of cabozantinib as a treatment for previously untreated advanced RCC and in other indications, both in the United States and abroad;
- future clinical trial results, notably the results from CELESTIAL, our phase 3 pivotal trial in patients with advanced HCC;
- our future investments in the expansion of our pipeline through drug discovery and corporate development activities;
- repayment of the Deerfield Notes (see "Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations - Certain Factors Important to Understanding Our Financial Condition and Results of Operations - Deerfield Notes" for a description of these notes) which mature on July 1, 2018, subject to a requirement to make a mandatory prepayment in each of 2017 and 2018 equal to 15% of certain revenues from collaborative arrangements (other than intercompany arrangements) received during the prior fiscal year, subject to a maximum annual prepayment amount of $27.5 million;
- our ability to repay the Deerfield Notes with our common stock, which we are only able to do under specified conditions;
- repayment of our term loan from Silicon Valley Bank, which had an outstanding balance at September 30, 2016, of $80.0 million and is due in May 2017;
- our ability to control costs;
- our ability to remain in compliance with, or amend or cause to be waived, financial covenants contained in agreements with third parties;
- the cost of clinical drug supply for our clinical trials;
- trends and developments in the pricing of oncologic therapeutics in the United States and abroad, especially in the European Union;
- scientific developments in the market for oncologic therapeutics and the timing of regulatory approvals for competing oncologic therapies; and
- the filing, maintenance, prosecution, defense and enforcement of patent claims and other intellectual property rights.

We have a history of net losses. We expect to continue to incur net losses, and we may not achieve or maintain profitability.*

We have incurred net losses since inception through September 30, 2016, with the exception of the 2011 fiscal year. For the nine months ended September 30, 2016, we incurred a net loss of $105.3 million and as of September 30, 2016, we had an accumulated deficit of $2.0 billion. These losses have had an adverse effect on our stockholders' equity and working capital. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses or when we will become profitable. Excluding fiscal 2011, our research and development expenditures and selling, general and administrative expenses have exceeded our revenues for each fiscal year, and we expect to spend significant additional amounts to fund the continued development and commercialization of cabozantinib. In addition, we are evaluating the expansion of our pipeline through drug discovery and corporate development activities. As a result, we expect to continue to incur substantial operating expenses and, consequently, we will need to generate significant additional revenues to achieve future profitability.

Since the launch of our first commercial product in January 2013, through September 30, 2016, we have generated an aggregate of $157.7 million in net product revenues. Other than sales of CABOMETYX and COMETRIQ, we have derived

Table of Contents

substantially all of our revenues since inception from collaborative research and development agreements, which depend on royalties, license fees, the achievement of milestones, and research funding we earn from any products developed from the collaborative research.

The amount of our net losses will depend, in part, on: the level of sales of CABOMETYX and COMETRIQ in the United States; achievement of clinical, regulatory and commercial milestones and the amount of royalties, if any, from sales of CABOMETYX and COMETRIQ under our collaboration with Ipsen; our share of the net profits and losses for the commercialization of COTELLIC in the U.S. under our collaboration with Genentech (a member of the Roche group); the amount of royalties from COTELLIC sales outside the U.S. under our collaboration with Genentech; other license and contract revenues; and, the level of our expenses, including commercialization activities for cabozantinib and any pipeline expansion efforts.

Our significant level of indebtedness could limit cash flow available for our operations and expose us to risks that could adversely affect our business, financial condition and results of operations.*

We have significant indebtedness and substantial debt service requirements as a result of the Deerfield Notes and our loan and security agreement with Silicon Valley Bank. As of September 30, 2016, our total consolidated indebtedness through maturity was $204.1 million (excluding trade payables). We may also incur additional indebtedness to meet future financing needs. If we incur additional indebtedness, it would increase our interest expense, leverage and operating and financial costs.

Our indebtedness could have significant negative consequences for our business, results of operations and financial condition, including:

- making it more difficult for us to meet our payment and other obligations under the Deerfield Notes and our loan and security agreement with Silicon Valley Bank or our other indebtedness;
- resulting in an event of default if we fail to comply with the covenants contained in our debt agreements, which event of default could result in all of our debt becoming immediately due and payable;
- increasing our vulnerability to adverse economic and industry conditions;
- subjecting us to the risk of increased sensitivity to interest rate increases on our indebtedness with variable interest rates, including borrowings under our loan and security agreement with Silicon Valley Bank;
- limiting our ability to obtain additional financing;
- requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness, thereby reducing the amount of our cash flow available for other purposes, including clinical trials, research and development, capital expenditures, working capital and other general corporate purposes;
- limiting our flexibility in planning for, or reacting to, changes in our business;
- dilution experienced by our existing stockholders as a result of the conversion of the Deerfield Notes into shares of common stock; and
- placing us at a possible competitive disadvantage with less leveraged competitors and competitors that may have better access to capital resources.

We cannot assure you that we will continue to maintain sufficient cash reserves or that our business will generate cash flow from operations at levels sufficient to permit us to pay principal, premium, if any, and interest on our indebtedness, or that our cash needs will not increase. If we are unable to generate sufficient cash flow or otherwise obtain funds necessary to make required payments, or if we fail to comply with the various requirements of the Deerfield Notes, our loan and security agreement with Silicon Valley Bank, or any indebtedness which we have incurred or may incur in the future, we would be in default, which would permit the holders of the Deerfield Notes or other indebtedness to accelerate the maturity of such notes or other indebtedness and could cause defaults under the Deerfield Notes, our loan and security agreement with Silicon Valley Bank or our other indebtedness. Any default under the Deerfield Notes, our loan and security agreement with Silicon Valley Bank, or any indebtedness that we have incurred or may incur in the future could have a material adverse effect on our business, results of operations and financial condition.

We are exposed to risks related to foreign currency exchange rates.

Most of our foreign expenses incurred are associated with establishing and conducting clinical trials for cabozantinib. The amount of these expenses will be impacted by fluctuations in the currencies of those countries in which we

conduct clinical trials. Our agreements with the foreign sites that conduct such clinical trials generally provide that payments for the services provided will be calculated in the currency of that country, and converted into U.S. dollars using various exchange rates based upon when services are rendered or the timing of invoices. When the U.S. dollar weakens against foreign currencies, the U.S. dollar value of the foreign-currency denominated expense increases, and when the U.S. dollar strengthens

Table of Contents

against these currencies, the U.S. dollar value of the foreign-currency denominated expense decreases. Consequently, changes in exchange rates may affect our financial position and results of operations.

Global credit and financial market conditions could negatively impact the value of our current portfolio of cash equivalents, short-term investments or long-term investments and our ability to meet our financing objectives.

Our cash and cash equivalents are maintained in highly liquid investments with remaining maturities of 90 days or less at the time of purchase. Our short-term and long-term investments consist primarily of readily marketable debt securities with remaining maturities of more than 90 days at the time of purchase. While as of the date of this report we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents, short-term investments or long-term investments since September 30, 2016, no assurance can be given that a deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or investments or our ability to meet our financing objectives.

Risks Related to Our Relationships with Third Parties

We are dependent upon our collaborations with major companies, which subjects us to a number of risks.*

We have established collaborations with leading pharmaceutical and biotechnology companies, including, Ipsen, Genentech (a member of the Roche group), Bristol-Myers Squibb, Sanofi, Merck (known as MSD outside of the United States and Canada) and Daiichi Sankyo, for the development and ultimate commercialization of certain compounds generated from our research and development efforts. Our dependence on our relationships with existing collaborators for the development and commercialization of compounds under the collaborations subjects us to, and our dependence on future collaborators for development and commercialization of additional compounds will subject us to, a number of risks, including:

- we are not able to control the amount and timing of resources that our collaborators or potential future collaborators will devote to the development or commercialization of drug candidates or to their marketing and distribution;
- we are not able to control the U.S. commercial resourcing decisions made and resulting costs incurred by Genentech for cobimetinib, which reasonable costs we are obligated to share, in part, under our collaboration agreement with Genentech;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a drug candidate, repeat or conduct new clinical trials or require a new formulation of a drug candidate for clinical testing;
- disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization of our drug candidates, or that diminish or delay receipt of the economic benefits we are entitled to receive under the collaboration, or that result in costly litigation or arbitration that diverts management's attention and resources, such as the demand for arbitration we filed on June 3, 2016 asserting claims against Genentech for breaches of the collaboration agreement connected with its clinical development, pricing and commercialization of COTELLIC, and cost and revenue allocations arising from COTELLIC's commercialization in the United States;
- collaborators may experience financial difficulties;
- collaborators may not be successful in their efforts to obtain regulatory approvals in a timely manner, or at all;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- collaborators may not comply with applicable healthcare regulatory laws;
- business combinations or significant changes in a collaborator's business strategy may adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- a collaborator could independently move forward with a competing drug candidate developed either independently or in collaboration with others, including our competitors;
- we may be precluded from entering into additional collaboration arrangements with other parties in an area or field of exclusivity;
- future collaborators may require us to relinquish some important rights, such as marketing and distribution rights; and
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collaborations may be terminated or allowed to expire, which would delay, and may increase the cost of development of our drug candidates.

Table of Contents

If any of these risks materialize, we may not receive collaboration revenue or otherwise realize anticipated benefits from such collaborations, our product development efforts could be delayed and our business, operating results and financial condition could be adversely affected.

We may be unable to establish collaborations for selected preclinical and clinical compounds.

We may pursue new collaborations with leading pharmaceutical and biotechnology companies for the development and ultimate commercialization of selected preclinical and clinical programs and compounds, particularly those drug candidates for which we believe that the capabilities and resources of a partner can accelerate development and help to fully realize their therapeutic and commercial potential. However, we may not be able to close any such additional collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional collaborations because of the numerous risks and uncertainties associated with establishing additional collaborations. If we are unable to close additional collaborations on mutually-advantageous terms with partners qualified to achieve the collaboration's objectives, we may not be able to realize value from a particular drug candidate.

Risks Related to Our Intellectual Property

Data breaches and cyber-attacks could compromise our intellectual property or other sensitive information and cause significant damage to our business and reputation.

In the ordinary course of our business, we collect, maintain and transmit sensitive data on our networks and systems, including our intellectual property and proprietary or confidential business information (such as research data and personal information) and confidential information with respect to our customers, clinical trial patients and our business partners. We have also outsourced significant elements of our information technology infrastructure and, as a result, third parties may or could have access to our confidential information. The secure maintenance of this information is critical to our business and reputation. We believe that companies have been increasingly subject to a wide variety of security incidents, cyber-attacks and other attempts to gain unauthorized access. These threats can come from a variety of sources, ranging in sophistication from an individual hacker to a state-sponsored attack and motive (including corporate espionage). Cyber threats may be generic, or they may be custom-crafted against our information systems. Over the past year, cyber-attacks have become more prevalent and much harder to detect and defend against. Our network and storage applications and those of our vendors may be subject to unauthorized access by hackers or breached due to operator error, malfeasance or other system disruptions. It is often difficult to anticipate or immediately detect such incidents and the damage caused by such incidents. These data breaches and any unauthorized access or disclosure of our information or intellectual property could compromise our intellectual property and expose sensitive business information. A data security breach could also lead to public exposure of personal information of our clinical trial patients, customers and others. Cyber-attacks could cause us to incur significant remediation costs, result in product development delays, disrupt key business operations and divert attention of management and key information technology resources. Our network security and data recovery measures and those of our vendors may not be adequate to protect against such security breaches and disruptions. These incidents could also subject us to liability, expose us to significant expense and cause significant harm to our reputation and business.

If we are unable to adequately protect our intellectual property, third parties may be able to use our technology, which could adversely affect our ability to compete in the market.

Our success will depend in part upon our ability to obtain patents and maintain adequate protection of the intellectual property related to our technologies and products. The patent positions of biopharmaceutical companies, including our patent position, are generally uncertain and involve complex legal and factual questions. We will be able to protect our intellectual property rights from unauthorized use by third parties only to the extent that our technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. We will continue to apply for patents covering our technologies and products as, where and when we deem appropriate. However, these applications may be challenged or may fail to result in issued patents. Our issued patents have been and may in the future be challenged by third parties as invalid or unenforceable under U.S. or foreign laws, or they may be infringed by third parties. As a result, we are from time to time involved in the defense and enforcement of our patents or other intellectual property rights in a court of law, U.S. Patent and Trademark Office inter partes review or reexamination proceeding, foreign opposition proceeding or related legal and administrative proceeding in the United States and

elsewhere. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings and litigation may be substantial and the outcome can be uncertain. An adverse outcome may allow third parties to use our intellectual property without a license and negatively impact our business.

In addition, because patent applications can take many years to issue, third parties may have pending applications, unknown to us, which may later result in issued patents that cover the production, manufacture, commercialization or use of our product candidates. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Furthermore, others may independently develop similar or alternative technologies or design around our patents. In addition, our patents may be challenged or invalidated or

Table of Contents

may fail to provide us with any competitive advantages, if, for example, others were the first to invent or to file patent applications for closely related inventions.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, the patent owner has failed to "work" the invention in that country or the third party has patented improvements). In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. Compulsory licensing of life-saving drugs is also becoming increasingly popular in developing countries either through direct legislation or international initiatives. Such compulsory licenses could be extended to include our products or product candidates, which could limit our potential revenue opportunities. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patent and other intellectual property protection, which makes it difficult to stop infringement. We rely on trade secret protection for some of our confidential and proprietary information. We have taken security measures to protect our proprietary information and trade secrets, but these measures may not provide adequate protection. While we seek to protect our proprietary information by entering into confidentiality agreements with employees, collaborators and consultants, we cannot assure you that our proprietary information will not be disclosed, or that we can meaningfully protect our trade secrets. In addition, our competitors may independently develop substantially equivalent proprietary information or may otherwise gain access to our trade secrets.

Litigation or third-party claims of intellectual property infringement could require us to spend substantial time and money and adversely affect our ability to develop and commercialize products.

Our commercial success depends in part upon our ability to avoid infringing patents and proprietary rights of third parties and not to breach any licenses that we have entered into with regard to our technologies and the technologies of third parties. Other parties have filed, and in the future are likely to file, patent applications covering genes and gene fragments, techniques and methodologies relating to model systems and products and technologies that we have developed or intend to develop. If patents covering technologies required by our operations are issued to others, we may have to obtain licenses from third parties, which may not be available on commercially reasonable terms, or at all, and may require us to pay substantial royalties, grant a cross-license to some of our patents to another patent holder or redesign the formulation of a product candidate so that we do not infringe third-party patents, which may be impossible to obtain or could require substantial time and expense.

Third parties may accuse us of employing their proprietary technology without authorization. In addition, third parties may obtain patents that relate to our technologies and claim that use of such technologies infringes on their patents. Regardless of their merit, such claims could require us to incur substantial costs, including the diversion of management and technical personnel, in defending ourselves against any such claims or enforcing our patents. In the event that a successful claim of infringement is brought against us, we may be required to pay damages and obtain one or more licenses from third parties. We may not be able to obtain these licenses at a reasonable cost, or at all. Defense of any lawsuit or failure to obtain any of these licenses could adversely affect our ability to develop and commercialize products.

We may be subject to damages resulting from claims that we, our employees or independent contractors have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees and independent contractors were previously employed at universities or other biotechnology, biopharmaceutical or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, independent contractors or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or used or sought to use patent inventions belonging to their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and divert management's attention. If we fail in defending such claims, in addition to paying money claims, we may lose valuable intellectual property rights or personnel. A loss of key research personnel and/or their work product could hamper or prevent our

ability to commercialize certain product candidates, which could severely harm our business.

Risks Related to Employees and Location

The loss of key personnel or the inability to retain and, where necessary, attract additional personnel could impair our ability to operate and expand our operations.

We are highly dependent upon the principal members of our management, as well as clinical and commercial staff, the loss of whose services might adversely impact the achievement of our objectives. Also, we may not have sufficient personnel

Table of Contents

to execute our business plan. Retaining and, where necessary, recruiting qualified clinical and commercial personnel will be critical to support activities related to advancing the development program for cabozantinib and our other compounds, and successfully executing upon our commercialization plan for cabozantinib. Competition is intense for experienced clinical and commercial personnel, and we may be unable to retain or recruit clinical and commercial personnel with the expertise or experience necessary to allow us to successfully develop and commercialize our products. Further, all of our employees are employed "at will" and, therefore, may leave our employment at any time.

Our collaborations with outside scientists may be subject to restriction and change.

We work with scientific and clinical advisors and collaborators at academic and other institutions that assist us in our research and development efforts. These advisors and collaborators are not our employees and may have other commitments that limit their availability to us. Although these advisors and collaborators generally agree not to do competing work, if a conflict of interest between their work for us and their work for another entity arises, we may lose their services. In such a circumstance, we may lose work performed by them, and our development efforts with respect to the matters on which they were working may be significantly delayed or otherwise adversely affected. In addition, although our advisors and collaborators sign agreements not to disclose our confidential information, it is possible that valuable proprietary knowledge may become publicly known through them.

Our headquarters are located near known earthquake fault zones, and the occurrence of an earthquake or other disaster could damage our facilities and equipment, which could harm our operations.

Our headquarters are located in South San Francisco, California, and therefore our facilities are vulnerable to damage from earthquakes. We do not carry earthquake insurance. We are also vulnerable to damage from other types of disasters, including fire, floods, power loss, communications failures, terrorism and similar events since any insurance we may maintain may not be adequate to cover our losses. If any disaster were to occur, our ability to operate our business at our facilities could be seriously, or potentially completely, impaired. In addition, the unique nature of our research activities could cause significant delays in our programs and make it difficult for us to recover from a disaster. Accordingly, an earthquake or other disaster could materially and adversely harm our ability to conduct business.

Facility security breaches may disrupt our operations, subject us to liability and harm our operating results.

Any break-in or trespass at our facilities that results in the misappropriation, theft, sabotage or any other type of security breach with respect to our proprietary and confidential information, including research or clinical data, or that results in damage to our research and development equipment and assets, could subject us to liability and have a material adverse impact on our business, operating results and financial condition.

Risks Related to Environmental and Product Liability

We use hazardous chemicals and radioactive and biological materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our research and development processes involve the controlled use of hazardous materials, including chemicals and radioactive and biological materials. Our operations produce hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. We may face liability for any injury or contamination that results from our use or the use by third parties of these materials, and such liability may exceed our insurance coverage and our total assets. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development and production efforts.

In addition, our collaborators may use hazardous materials in connection with our collaborative efforts. In the event of a lawsuit or investigation, we could be held responsible for any injury caused to persons or property by exposure to, or release of, these hazardous materials used by these parties. Further, we may be required to indemnify our collaborators against all damages and other liabilities arising out of our development activities or products produced in connection with these collaborations.

We face potential product liability exposure far in excess of our limited insurance coverage.

We may be held liable if any product we or our collaborators develop or commercialize causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing or sale. Regardless of merit or eventual

outcome, product liability claims could result in decreased demand for our products and product candidates, injury to our reputation, withdrawal of patients from our clinical trials, product recall, substantial monetary awards to third parties and the inability to commercialize any products that we may develop. These claims might be made directly by consumers, health care providers, pharmaceutical companies or others selling or testing our products. We have obtained limited product liability insurance

Table of Contents

coverage for our clinical trials and commercial activities for cabozantinib in the amount of $20.0 million per occurrence and $20.0 million in the aggregate. However, our insurance may not reimburse us or may not be sufficient to reimburse us for expenses or losses we may suffer. Moreover, if insurance coverage becomes more expensive, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. On occasion, juries have awarded large judgments in class action lawsuits for claims based on drugs that had unanticipated side effects. In addition, the pharmaceutical, biopharmaceutical and biotechnology industries, in general, have been subject to significant medical malpractice litigation. A successful product liability claim or series of claims brought against us could harm our reputation and business and would decrease our cash reserves.

Risks Related to Our Common Stock

We expect that our quarterly results of operations will fluctuate, and this fluctuation could cause our stock price to decline, causing investor losses.*

Our quarterly operating results have fluctuated in the past and are likely to fluctuate in the future. A number of factors, many of which we cannot control, could subject our operating results to volatility, including:

- the commercial success of both CABOMETYX and COMETRIQ and the revenues we generate from those approved products;
- customer ordering patterns for CABOMETYX and COMETRIQ, which may vary significantly from period to period;
- the overall level of demand for CABOMETYX and COMETRIQ, including the impact of any competitive products and the duration of therapy for patients receiving CABOMETYX or COMETRIQ;
- costs associated with maintaining our expanded sales, marketing, medical affairs and distribution capabilities for CABOMETYX and COMETRIQ;
- our ability to obtain regulatory approval for cabozantinib as a treatment of first-line advanced RCC;
- the achievement of stated regulatory and commercial milestones, under our collaboration with Ipsen;
- the outcome of our arbitration against Genentech in which we have asserted claims related to Genentech's clinical development, pricing and commercialization of COTELLIC, and cost and revenue allocations arising from COTELLIC's commercialization in the United States and Genentech's counterclaim for breach of contract, seeking monetary damages and interest related to the cost allocations under the collaboration agreement;
- the progress and scope of other development and commercialization activities for cabozantinib and our other compounds;
- future clinical trial results, notably the results from CELESTIAL, our phase 3 pivotal trial in patients with advanced HCC;
- our future investments in the expansion of our pipeline through drug discovery and corporate development activities;
- the inability to obtain adequate product supply for any approved drug product or inability to do so at acceptable prices;
- recognition of upfront licensing or other fees or revenues;
- payments of non-refundable upfront or licensing fees, or payment for cost-sharing expenses, to third parties;
- the success rate of our efforts leading to milestone payments and royalties;
- the introduction of new technologies or products by our competitors;
- the timing and willingness of collaborators to further develop or, if approved, commercialize our product candidates out-licensed to them;
- the termination or non-renewal of existing collaborations or third party vendor relationships;
- regulatory actions with respect to our product candidates and any approved products or our competitors' products;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- the timing and amount of expenses incurred for clinical development and manufacturing of cabozantinib;
- adjustments to expenses accrued in prior periods based on management's estimates after the actual level of activity relating to such expenses becomes more certain;
- the impairment of acquired goodwill and other assets;
- additions and departures of key personnel;

54

Table of Contents

- general and industry-specific economic conditions that may affect our or our collaborators' research and development expenditures; and
- other factors described in this "Risk Factors" section.

Due to the possibility of fluctuations in our revenues and expenses, we believe that quarter-to-quarter comparisons of our operating results are not a good indication of our future performance. As a result, in some future quarters, our operating results may not meet the expectations of securities analysts and investors, which could result in a decline in the price of our common stock.

Our stock price may be extremely volatile.*

The trading price of our common stock has been highly volatile, and we believe the trading price of our common stock will remain highly volatile and may fluctuate substantially due to factors such as the following, many of which we cannot control:

- adverse results or delays in our or our collaborators' clinical trials;
- announcement of FDA approval or non-approval, or delays in the FDA review process, of cabozantinib or our collaborators' product candidates or those of our competitors or actions taken by regulatory agencies with respect to our, our collaborators' or our competitors' clinical trials;
- the commercial success of both CABOMETYX and COMETRIQ and the revenues we generate from those approved products;
- the timing of achievement of our clinical, regulatory, partnering and other milestones, such as the commencement of clinical development, the completion of a clinical trial, the filing for regulatory approval or the establishment of collaborative arrangements for cabozantinib or any of our other programs or compounds;
- actions taken by regulatory agencies with respect to cabozantinib or our clinical trials for cabozantinib;
- the announcement of new products by our competitors;
- quarterly variations in our or our competitors' results of operations;
- developments in our relationships with our collaborators, including the termination or modification of our agreements;
- conflicts or litigation with our collaborators, including the outcome of our arbitration with Genentech regarding COTELLIC;
- litigation, including intellectual property infringement and product liability lawsuits, involving us;
- failure to achieve operating results projected by securities analysts;
- changes in earnings estimates or recommendations by securities analysts;
- financing transactions;
- developments in the biotechnology, biopharmaceutical or pharmaceutical industry;
- sales of large blocks of our common stock or sales of our common stock by our executive officers, directors and significant stockholders;
- departures of key personnel or board members;
- FDA or international regulatory actions;
- third-party coverage and reimbursement policies;
- disposition of any of our technologies or compounds; and
- general market, economic and political conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

These factors, as well as general economic, political and market conditions, may materially adversely affect the market price of our common stock. Excessive volatility may continue for an extended period of time following the date of this report.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. A securities class action suit against us could result in substantial costs and divert management's attention and resources, which could have a material and adverse effect on our business.

Table of Contents

Future sales of our common stock or conversion of the Deerfield Notes, or the perception that such sales or conversions may occur, may depress our stock price.

A substantial number of shares of our common stock is reserved for issuance upon the exercise of stock options, upon vesting of restricted stock unit awards, upon sales under our employee stock purchase program, upon exercise of certain outstanding warrants and upon conversion of the Deerfield Notes. The issuance and sale of substantial amounts of our common stock, including upon conversion of the Deerfield Notes, or the perception that such issuances and sales may occur, could adversely affect the market price of our common stock and impair our ability to raise capital through the sale of additional equity or equity-related securities in the future at a time and price that we deem appropriate.

Certain provisions applicable to the Deerfield Notes could delay or prevent an otherwise beneficial takeover or takeover attempt.

Certain provisions applicable to the Deerfield Notes and the note purchase agreement governing the Deerfield Notes, could make it more difficult or more expensive for a third party to acquire us. For example, if an acquisition event constitutes a Major Transaction under the note purchase agreement governing the Deerfield Notes, holders of the Deerfield Notes will have the right to require us to purchase their notes in cash. In this case, and in other cases, our obligations under the Deerfield Notes and the note purchase agreement governing the Deerfield Notes, could increase the cost of acquiring us or otherwise discourage a third party from acquiring us or removing incumbent management.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent or deter attempts by our stockholders to replace or remove our current management, which could cause the market price of our common stock to decline.

Provisions in our corporate charter and bylaws may discourage, delay or prevent an acquisition of us, a change in control, or attempts by our stockholders to replace or remove members of our current Board of Directors. Because our Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include:

- a classified Board of Directors;
- a prohibition on actions by our stockholders by written consent;
- the inability of our stockholders to call special meetings of stockholders;
- the ability of our Board of Directors to issue preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our Board of Directors;
- limitations on the removal of directors; and
- advance notice requirements for director nominations and stockholder proposals.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our ability to use net operating losses to offset future taxable income may be subject to limitations.*

Under the Internal Revenue Code, or the Code, and similar state provisions, certain substantial changes in our ownership could result in an annual limitation on the amount of net operating loss carry-forwards that can be utilized in future years to offset future taxable income. The annual limitation may result in the expiration of net operating losses and credit carry-forwards before utilization. We concluded, as of December 31, 2015, that an ownership change, as defined under Section 382, had not occurred. However, if there is an ownership change under Section 382 of the Code in the future, we may not be able to utilize a material portion of our NOLs. Furthermore, our ability to utilize our NOLs is conditioned upon our attaining profitability and generating United States federal taxable income. As described above, we have incurred significant net losses since our inception; thus, we do not know whether or when we will generate the United States federal taxable income necessary to utilize our NOLs. A full valuation allowance has been provided for the entire amount of our NOLs.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Not applicable.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits.

(a) Exhibits

See the Exhibit Index immediately following the signature page to this Quarterly Report on Form 10-Q, which is incorporated by reference here.

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.

EXELIXIS, INC.

November 3, 2016	/s/ CHRISTOPHER J. SENNER
Date	Christopher J. Senner
	Executive Vice President and Chief Financial Officer
	(Duly Authorized Officer and Principal Financial and Accounting Officer)

Table of Contents

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit/ Appendix Reference	Filing Date	
3.1	Amended and Restated Certificate of Incorporation of Exelixis, Inc.	10-K	000-30235	3.1	3/10/2010	
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Exelixis, Inc.	10-K	000-30235	3.2	3/10/2010	
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Exelixis, Inc.	8-K	000-30235	3.1	5/25/2012	
3.4	Certificate of Ownership and Merger Merging X-Ceptor Therapeutics, Inc. with and into Exelixis, Inc.	8-K	000-30235	3.1	10/15/2014	
3.5	Certificate of Change of Registered Agent and/or Registered Office of Exelixis, Inc.	8-K	000-30235	3.2	10/15/2014	
3.6	Amended and Restated Bylaws of Exelixis, Inc.	8-K	000-30235	3.1	12/5/2011	
4.1	Specimen Common Stock Certificate.	S-1, as amended	333-96335	4.1	4/7/2000	
4.2	Amended and Restated Secured Convertible Note dated July 1, 2015 in favor of Deerfield Partners, L.P.	10-Q	000-30235	4.2	8/11/2015	
4.3	Amended and Restated Secured Convertible Note dated July 1, 2015 in favor of Deerfield International Master Fund, L.P.	10-Q	000-30235	4.3	8/11/2015	
4.4	Registration Rights Agreement dated January 22, 2014 by and among Exelixis, Inc., Deerfield Partners, L.P. and Deerfield International Master Fund, L.P.	8-K	000-30235	4.2	1/22/2014	
4.5	Form of Warrant to Purchase Common Stock of Exelixis, Inc. issued to OTA LLC	10-Q	000-30235	4.5	11/10/2015	
4.6	Indenture dated August 14, 2012 by and between Exelixis, Inc. and Wells Fargo Bank, National Association	8-K	000-30235	4.1	8/14/2012	
4.7	First Supplemental Indenture dated August 14, 2012 to Indenture dated August 14, 2012 by and between Exelixis, Inc. and Wells Fargo Bank, National Association	8-K	000-30235	4.2	8/14/2012	
4.8	Form of 4.25% Convertible Senior Subordinated Note due 2019	8-K	000-30235	4.2 (Exhibit A)	8/14/2012	
10.1	Form of Exchange Agreement Related to 4.25% Convertible Senior Subordinated Notes	8-K	000-30235	99.1	8/9/2016	
10.2	Form of Exchange Agreement Related to 4.25% Convertible Senior Subordinated Notes	8-K	000-30235	99.1	8/22/2016	

12.1	Statement Re Computation of Earnings to Fixed Charges	X
31.1	Certification required by Rule 13a-14(a) or Rule 15d-14(a).	X

Table of Contents

Exhibit Number	Exhibit Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit/ Appendix Reference	Filing Date	
31.2	Certification required by Rule 13a-14(a) or Rule 15d-14(a).					X
32.1‡	Certification by the Chief Executive Officer and the Chief Financial Officer of Exelixis, Inc., as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).					X
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					X

‡ This certification accompanies this Quarterly Report on Form 10-Q, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of Exelixis, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of this Quarterly Report on Form 10-Q), irrespective of any general incorporation language contained in such filing.