EXELIXIS, INC.
Form 10-Q
November 10, 2015
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 October 2, 2015
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 29, 2015, there were 227,216,551 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, 2015 (unaudited)	December 31, 2014*
ASSETS		
Current assets:		
Cash and cash equivalents	$145,642	$80,395
Short-term investments	52,169	63,890
Short-term restricted cash and investments	—	12,212
Trade and other receivables	3,470	4,882
Inventory	2,121	2,381
Prepaid expenses and other current assets	3,949	3,481
Total current assets	207,351	167,241
Long-term investments	81,600	81,579
Long-term restricted cash and investments	2,650	4,684
Property and equipment, net	1,448	2,432
Goodwill	63,684	63,684
Other assets	6,508	8,340
Total assets	$363,241	$327,960
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$2,256	$6,413
Accrued clinical trial liabilities	29,788	41,545
Accrued compensation and benefits	3,725	3,350
Other accrued liabilities	15,969	12,282
Current portion of convertible notes	450	98,880
Current portion of loans payable	—	381
Current portion of restructuring	3,734	6,426
Deferred revenue	—	2,583
Total current liabilities	55,922	171,860
Long-term portion of convertible notes	297,436	182,395
Long-term portion of loans payable	80,000	80,000
Long-term portion of restructuring	2,230	4,365
Other long-term liabilities	1,881	4,169
Total liabilities	437,469	442,789
Commitments		
Stockholders' deficit:		
Preferred stock	—	—
Common stock, $0.001 par value; 400,000,000 shares authorized; issued and outstanding: 226,154,354 and 195,895,769 shares at September 30, 2015 and December 31, 2014, respectively	225	196
Additional paid-in capital	1,818,988	1,652,400
Accumulated other comprehensive loss	(41)	(121)
Accumulated deficit	(1,893,400)	(1,767,304)

Total stockholders' deficit	(74,228)	(114,829)
Total liabilities and stockholders' deficit	$363,241	$327,960

* The condensed consolidated balance sheet as of December 31, 2014 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,	
	2015	2014	2015	2014
Revenues:				
Net product revenues	$6,854	$6,291	$24,234	$17,758
Contract revenues	3,000	—	3,000	—
Total revenues	9,854	6,291	27,234	17,758
Operating expenses:				
Cost of goods sold	1,420	573	2,872	1,359
Research and development	26,091	43,628	72,879	149,451
Selling, general and administrative	17,842	9,906	40,162	41,063
Restructuring charge	282	3,758	1,142	4,135
Total operating expenses	45,635	57,865	117,055	196,008
Loss from operations	(35,781)	(51,574)	(89,821)	(178,250)
Other income (expense), net:				
Interest income and other, net	276	1,296	146	3,786
Interest expense	(12,059)	(12,282)	(36,421)	(36,125)
Total other income (expense), net	(11,783)	(10,986)	(36,275)	(32,339)
Net loss	$(47,564)	$(62,560)	$(126,096)	$(210,589)
Net loss per share, basic and diluted	$(0.22)	$(0.32)	$(0.62)	$(1.09)
Shares used in computing basic and diluted net loss per share	217,587	195,126	203,153	193,855

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,	
	2015	2014	2015	2014
Net loss	$(47,564)	$(62,560)	$(126,096)	$(210,589)
Other comprehensive income (loss) (1)	133	(153)	80	(122)
Comprehensive loss	$(47,431)	$(62,713)	$(126,016)	$(210,711)

(1) Other comprehensive income (loss) consisted solely of unrealized losses or gains, net on available for sale securities arising during the periods presented. There were no reclassification adjustments to net loss resulting from realized losses or gains on the sale of securities and there was no income tax expense related to other comprehensive income (loss) 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,	
	2015	2014
Cash flows from operating activities:		
Net loss	$(126,096)	$(210,589)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,063	3,014
Stock-based compensation expense	15,420	8,454
Restructuring charge for property and equipment	—	667
Accretion of debt discount	20,194	21,826
Accrual of interest paid in kind	1,890	—
Gain on sale of business and other equity investment	(95)	(838)
Change in the fair value of warrants	549	(1,916)
Other	1,338	3,602
Changes in assets and liabilities:		
Trade and other receivables	1,034	(781)
Inventory	259	(986)
Prepaid expenses and other assets	(108)	(2,834)
Accounts payable, accrued compensation, and other accrued liabilities	(162)	(11,600)
Clinical trial liabilities	(11,757)	10,144
Restructuring liability	(5,731)	(2,705)
Other long-term liabilities	(1,367)	(756)
Deferred revenue	(2,583)	(131)
Net cash used in operating activities	(106,152)	(185,429)
Cash flows from investing activities:		
Purchases of property and equipment	(114)	(452)
Proceeds from sale of property and equipment	1,300	286
Proceeds from sale of business and other equity investment	95	838
Proceeds from maturities of restricted cash and investments	16,754	20,397
Purchase of restricted cash and investments	(2,616)	(8,184)
Proceeds from maturities of investments	130,341	212,506
Purchases of investments	(119,692)	(109,237)
Net cash provided by investing activities	26,068	116,154
Cash flows from financing activities:		
Proceeds from issuance of common stock, net	145,651	75,646
Proceeds from exercise of stock options and warrants	3,787	120
Proceeds from employee stock purchase plan	274	929
Principal payments on debt	(4,381)	(11,333)
Net cash provided by financing activities	145,331	65,362
Net increase (decrease) in cash and cash equivalents	65,247	(3,913)
Cash and cash equivalents at beginning of period	80,395	103,978
Cash and cash equivalents at end of period	$145,642	$100,065

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

5

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 developing small molecule therapies for the treatment of cancer. Our two most advanced assets are cabozantinib, our wholly-owned inhibitor of multiple receptor tyrosine kinases, and cobimetinib (GDC-0973/XL518), a selective inhibitor of MEK, a dual-specificity kinase, which we out-licensed to Genentech, Inc. (a member of the Roche Group), ("Genentech").

Our development and commercialization efforts are focused primarily on cabozantinib. Cabozantinib was approved by the United States Food and Drug Administration ("FDA") on November 29, 2012, for the treatment of progressive, metastatic medullary thyroid cancer ("MTC") in the United States under the brand name COMETRIQ®. COMETRIQ became commercially available in the United States in January 2013. In March 2014, the European Commission granted cabozantinib conditional marketing authorization for the treatment of adult patients with progressive, unresectable locally advanced or metastatic MTC, also under the brand name COMETRIQ.

We are evaluating cabozantinib in a broad development program comprising over 40 clinical trials across multiple indications, including ongoing phase 3 pivotal trials focusing on advanced renal cell carcinoma ("RCC") and advanced hepatocellular carcinoma ("HCC").

In July 2015, we announced that the phase 3 pivotal trial for RCC met its primary endpoint of demonstrating a statistically significant increase in progression free survival ("PFS") for cabozantinib, as determined by an independent radiology review committee. In August 2015 the FDA granted Breakthrough Therapy Designation for cabozantinib as a potential treatment for patients with advanced RCC. In October 2015, we initiated rolling submission of our U.S. New Drug Application ("NDA") with the FDA.

On November 10, 2015, our second most advanced oncology asset, cobimetinib, was approved in the U.S. by the FDA under the brand name COTELLIC™ in combination with vemurafenib as a treatment for patients with BRAF V600 mutation-positive advanced melanoma. In Switzerland, cobimetinib in combination with vemurafenib was approved in August 2015 as a treatment for patients with BRAF V600 mutation-positive advanced melanoma. Roche also filed a Marketing Authorization Application for cobimetinib in combination with vemurafenib for the same indication with the European Medicines Agency and anticipates a regulatory decision before the end of 2015 following a positive opinion issued by the European Committee for Medicinal Products for Human Use, announced in late September 2015. Cobimetinib is subject to a collaboration agreement we entered into with Genentech in December 2006. Pursuant to the collaboration agreement's financial terms, we believe that cobimetinib has the potential to provide us with a second significant source of revenue.

Basis of Consolidation

The 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 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 period presented have been included.

Exelixis adopted a 52- or 53-week fiscal year that generally ends on the Friday closest to December 31st. Fiscal year 2015, a 52-week year, will end on January 1, 2016, and fiscal year 2014, a 53-week year, ended on January 2, 2015. For convenience, references in this report as of and for the fiscal periods ended October 2, 2015 and September 26, 2014, and as of and for the fiscal years ended January 1, 2016 and January 2, 2015, are indicated as being as of and for the periods ended September 30, 2015, September 30, 2014, December 31, 2015, and December 31, 2014, respectively.

Operating results for the nine months ended September 30, 2015 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2015 or for any future period. These financial statements and notes should

Table of Contents

be read in conjunction with the consolidated financial statements and notes thereto for the year ended December 31, 2014, included in our Annual Report on Form 10-K filed with the SEC on March 2, 2015.

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 which 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 inventory, revenue recognition, valuation of long-lived assets, certain accrued liabilities including clinical trial accruals and restructuring liability, valuation of warrants, share-based compensation and the valuation of the debt and equity components of our convertible debt at issuance. 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.

Need to Access Additional Capital

We have incurred net losses since inception through September 30, 2015, with the exception of the 2011 fiscal year. We anticipate net losses and negative operating cash flow for the foreseeable future. For the nine months ended September 30, 2015, we incurred a net loss of $126.1 million and as of September 30, 2015, we had an accumulated deficit of $1.9 billion. These losses have had, and will continue to have, an adverse effect on our stockholders' deficit 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 whether or when we will become profitable, if at all. Our research and development expenditures and selling, general and administrative expenses have exceeded our revenues for each fiscal year other than the 2011 fiscal year, and we expect to spend significant additional amounts to fund the continued development and commercialization of cabozantinib. 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. We commercially launched COMETRIQ for the treatment of progressive, metastatic MTC in the United States in late January 2013, and from the commercial launch through September 30, 2015 we have generated $64.4 million in net revenues from the sale of COMETRIQ. Other than revenues from COMETRIQ, we have derived substantially all of our revenues since inception from collaborative research and development agreements, which depend on research funding, the achievement of milestones, and royalties we earn from any future products developed from the collaborative research.

The amount of our net losses will depend, in part, on: the rate of growth, if any, in our sales of COMETRIQ; our share of the net profits and losses for the commercialization for cobimetinib in the U.S., if any; the receipt of royalties from cobimetinib sales outside the U.S., if any; partnering activities for cabozantinib; other license and contract revenues; and, the level of expenses primarily with respect to development and commercialization activities for cabozantinib. As of September 30, 2015, we had $282.1 million in cash and investments, which included $197.8 million available for operations, $81.6 million of compensating balance investments that we are required to maintain on deposit with Silicon Valley Bank, and $2.7 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 end of the third quarter of 2015. While a forecast of future events is inherently uncertain, our ability to sustain our business operations for this time period without additional financing is highly dependent upon the commercial success of COMETRIQ and the revenues we generate, as well as the commercial success of COTELLIC and our share of related net profits and losses and royalties under our collaboration with Genentech. It is also dependent upon whether and when we partner cabozantinib with a global pharmaceutical organization for further development and sales outside the U.S., and the upfront payments and milestones associated with any such transaction. Consistent with the actions we have taken in the past, we will prioritize necessary and appropriate steps to ensure the continued operation of our business and preservation of the value of our assets. However, our future capital requirements will be substantial, and we may need to raise additional

capital in the future. 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 the sale of COMETRIQ and have historically recognized revenue from license fees and

Table of Contents

milestones earned on research and collaboration arrangements. During the three months ended September 30, 2015, we recognized $3.0 million in contract revenues from a milestone payment received from Merck related to its worldwide license of our PI3K-delta program. 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, 2014 for a description of our policies for revenue recognition on research and collaboration agreements. We did not enter into any new collaboration agreements during the nine months ended September 30, 2015. 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, 2014 for a description of our existing collaboration agreements.

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 the specialty pharmacy. For product sales in Europe, this generally occurs when our European distribution partner has accepted the product, at which time they are no longer able to return the product.

We sell our product, COMETRIQ, in the United States to a specialty pharmacy that benefits from customer incentives and has a right of return. 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 the specialty pharmacy, therefore we recognized revenue when the specialty pharmacy provided the product to a patient based on the fulfillment of a prescription, frequently referred to as the “sell-through” revenue recognition model. Recently we have established sufficient historical experience and data to reasonably estimate expected future returns of the product 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 our U.S. 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 and related costs that had previously been deferred at December 31, 2014, resulting in additional gross product revenues of $2.6 million and a nominal amount of cost of goods sold for the nine months ended September 30, 2015; there were no such adjustments recorded for the three months ended September 30, 2015 or during the comparable periods in 2014.

We also utilize the “sell-in” revenue recognition model for sales to our European distribution partner for all periods presented. Once the European distributer has accepted the product, the product is no longer subject to return; therefore, we record revenue at the time our European distribution partner has accepted the product.

Product Sales Discounts and Allowances

We calculate gross product revenues based on the price that we charge our United States specialty pharmacy and our European distribution partner. We estimate our domestic net product revenues by deducting from our gross product revenues (a) trade allowances, such as discounts for prompt payment, (b) estimated government rebates and chargebacks, and (c) estimated costs of patient assistance programs. Discounts and allowances for foreign sales for the nine months ended September 30, 2015 and three and nine months ended September 30, 2014 included portions of a one-time $2.4 million project management fee payable to our European distribution partner upon its achievement of a cumulative revenue goal. During the three months ended September 30, 2014, we determined that the achievement of the revenue goal was probable and therefore we recorded $1.8 million of the project management fee. $1.0 million of the $1.8 million we recorded during the three months ended September 30, 2014 represented amounts that would have been previously recorded had the cumulative revenue goal been determined to be probable in those periods. During the nine months ended September 30, 2015 we recorded an additional $0.1 million of the project management fee; no such fees were recognized within product sales during the three months ended September 30, 2015. We also deduct from gross product revenues an estimated credit for product originally delivered with expiry of 18 months or less that is potentially payable to our European distribution partner; such deductions were nominal during the three and nine months ended September 30, 2015 and 2014.

We initially record estimates for these deductions at the time we recognize the gross revenue. We update our estimates on a recurring basis as new information becomes available. 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, 2014 for a further description of our discounts and allowances.

Table of Contents

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, and to a lesser extent, 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 product sales were incurred prior to regulatory approval of COMETRIQ for the treatment of progressive, metastatic MTC and, therefore, were expensed as research and development costs when those costs were incurred, rather than capitalized as inventory. 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, 2014 for additional information related to the 3% royalty payable to GlaxoSmithKline.

Recently Issued Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-09, Revenue from Contracts with Customers (“ASU 2014-09”). ASU 2014-09 supersedes the revenue recognition requirements of FASB Accounting Standards Codification (“ASC”) Topic 605, Revenue Recognition and most industry-specific guidance throughout the Accounting Standards Codification, resulting in the creation of FASB ASC Topic 606, Revenue from Contracts with Customers. ASU 2014-09 requires entities to recognize revenue in a way that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. On July 9, 2015, the FASB deferred the effective date by one year for public entities for annual and interim reporting periods beginning after December 15, 2017. Early adoption is permitted for periods after December 15, 2016. We are currently evaluating the impact of adopting ASU 2014-09, inclusive of available transitional methods on our consolidated financial statements and related disclosures.

In August 2014, the FASB issued ASU No. 2014-15, Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern (“ASU 2014-15”). ASU 2014-15 explicitly requires management to evaluate, at each annual or interim reporting period, whether there are conditions or events that exist that raise substantial doubt about an entity’s ability to continue as a going concern within one year after the date the financial statements are issued and to provide related disclosures. ASU 2014-15 is effective for annual periods ending after December 15, 2016 and earlier application is permitted. The adoption of this guidance will not have any impact on the Company’s financial position and results of operations and, at this time, we do not expect any impact on its disclosures.

In April 2015, the FASB issued Accounting Standards Update No. 2015-03, Simplifying the Presentation of Debt Issuance Costs which Changes the Presentation of Debt Issuance Costs in Financial Statements (“ASU 2015-03”), which requires an entity to present such costs in the balance sheet as a direct deduction from the related debt liability rather than as an asset. Amortization of the costs will continue to be reported as interest expense. ASU 2015-03 will be effective for annual reporting periods beginning after December 15, 2015 and interim periods within fiscal years beginning after December 15, 2016, with early adoption permitted. The new guidance will be applied retrospectively to each prior period presented. If we had adopted ASU 2015-03, as of September 30, 2015, it would have resulted in a reduction of Other assets and total debt by $3.5 million and $4.7 million as September 30, 2015 and December 31, 2014, respectively.

NOTE 2: RESTRUCTURINGS

The restructuring charges that we expect to incur in connection with our restructurings are subject to a number of assumptions, including facility exit activity, sublease activity, the results of asset sales and the timing of employee terminations, and actual results may materially differ.

2014 Restructuring

On September 2, 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 the 2014 Restructuring to reduce our workforce. Personnel reductions were initiated across our entire organization that resulted in an aggregate reduction in headcount of 143 full-time employees as of September 30, 2015. The principal objective of the 2014 Restructuring was to enable us to focus our financial resources on the phase 3 pivotal trials of cabozantinib in advanced RCC and advanced HCC.

For the nine months ended September 30, 2015 and 2014, we recorded restructuring charges of $0.5 million and $3.3 million, respectively, for the 2014 Restructurings. The restructuring charge for the nine months ended September 30, 2015 included $1.5 million in additional charges due to the partial termination of one of our building leases and additional facility-related charges related to the decommissioning and exit of certain buildings. The restructuring charge for the nine months ended September 30, 2015 was partially offset by $0.9 million in recoveries recorded in connection with the sale of excess

Table of Contents

equipment and other assets. The restructuring charge for the nine months ended September 30, 2014 includes $2.6 million of employee severance and other benefits that are recognized ratably during the period from the implementation date of the 2014 Restructuring through the employees' termination dates. In addition, during the nine months ended September 30, 2014 we recorded $0.7 million of property and equipment write-downs. Employee severance and other benefits are recognized ratably during the period from the implementation date of the 2014 Restructuring through the employees' termination dates.

The restructuring liability related to the 2014 Restructuring is included in the current and long-term portion of restructuring on the accompanying Consolidated Balance Sheets. The components of and changes to these liabilities during the nine months ended September 30, 2015 are summarized in the following table (in thousands):

	Employee Severance and Other Benefits	Facility Charges	Asset Sales	Legal and Other Fees	Total
Restructuring liability as of December 31, 2014	$1,290	$—	$—	$47	$1,337
Restructuring charge (recovery)	(150)	1,542	(905)	—	487
Cash (payments) receipts, net	(1,021)	(1,020)	1,284	—	(757)
Other non-cash items	—	278	(379)	3	(98)
Restructuring liability as of September 30, 2015	$119	$800	$—	$50	$969

We expect to pay the accrued facility charges of $0.8 million through April 2017.

2010 Restructurings

Between March 2010 and May 2013, we implemented five restructurings (referred 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. The aggregate reduction in headcount from the 2010 Restructurings was 429 employees. Charges and recoveries related to the 2010 Restructurings were recorded in periods other than those in which the 2010 Restructurings were implemented as a result of sublease activities for certain of our buildings in South San Francisco, California, changes in assumptions regarding anticipated sublease activities, the effect of the passage of time on our discounted cash flow computations, previously planned employee terminations, and sales of excess equipment and other assets.

For the nine months ended September 30, 2015 and 2014, we recorded restructuring charges of $0.7 million and $0.8 million, respectively, for the 2010 Restructurings. The charges for both periods presented were related to 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, 2015, the restructuring charge also included the impact of a new sublease executed in June 2015 and additional changes in assumptions regarding anticipated sublease activities.

The total outstanding restructuring liability related to the 2010 Restructurings is included in the current and long-term portion of restructuring on the accompanying Consolidated Balance Sheets. The changes to this liability during the nine months ended September 30, 2015 is summarized in the following table (in thousands):

	Facility Charges
Restructuring liability as of December 31, 2014	$9,454
Restructuring charge	655
Cash payments	(5,439)
Adjustments or non-cash credits	325
Restructuring liability as of September 30, 2015	$4,995

We expect to pay accrued facility charges of $5.0 million, net of cash received from our subtenants, through the end of our lease terms of the buildings, the last of which ends in 2017. We expect to incur additional restructuring charges of approximately $0.4 million relating to the effect of accretion expense through to the end of the building lease terms.

10

Table of Contents

NOTE 3: 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, 2015 and December 31, 2014 (in thousands):

	September 30, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents	$145,642	$—	$—	$145,642
Short-term investments	52,142	38	(11)	52,169
Long-term investments	81,559	43	(2)	81,600
Long-term restricted cash and investments	2,650	—	—	2,650
Total cash and investments	$281,993	$81	$(13)	$282,061

	December 31, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents	$80,395	$—	$—	$80,395
Short-term investments	63,988	37	(135)	63,890
Short-term restricted cash and investments	12,105	107	—	12,212
Long-term investments	81,600	1	(22)	81,579
Long-term restricted cash and investments	4,684	—	—	4,684
Total cash and investments	$242,772	$145	$(157)	$242,760

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 as of September 30, 2015 and December 31, 2014 were $81.6 million and $82.0 million, respectively, and are reflected in our Consolidated Balance Sheets in short- and long-term investments. See “Note 8 - Debt” to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2014, for more information regarding the collateral balance requirements under our Silicon Valley Bank loan and security agreement.

The following tables summarize our cash equivalents and investments by security type as of September 30, 2015 and December 31, 2014. The amounts presented exclude cash, but include investments classified as cash equivalents (in thousands):

	September 30, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$34,895	$—	$—	$34,895
Commercial paper	140,144	—	—	140,144
Corporate bonds	89,778	79	(13)	89,844
U.S. government sponsored entities	14,978	1	—	14,979
Total investments	$279,795	$80	$(13)	$279,862

Table of Contents

	December 31, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$23,376	$—	$—	$23,376
Commercial paper	56,714	—	—	56,714
Corporate bonds	143,444	35	(157)	143,322
U.S. government sponsored entities	12,105	107	—	12,212
Municipal bonds	2,659	3	—	2,662
Total investments	$238,298	$145	$(157)	$238,286

There were no sales of investments during the nine months ended September 30, 2015 and 2014.

All of our investments are subject to a quarterly impairment review. During the nine months ended September 30, 2015 and 2014, we did not record any other-than-temporary impairment charges on our available-for-sale securities. As of September 30, 2015, there were 14 investments in an unrealized loss position with gross unrealized losses of $13 thousand and an aggregate fair value $27.9 million. Investments in an unrealized loss position are all corporate bonds. All of our investments in an unrealized loss position have been so for less than one year and 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, 2015 (in thousands):

	Mature within One Year	After One Year through Two Years	Fair Value
Money market funds	$34,895	$—	$34,895
Commercial paper	140,144	—	140,144
Corporate bonds	60,658	29,186	89,844
U.S. government sponsored entities	14,979	—	14,979
Total investments	$250,676	$29,186	$279,862

Cash is excluded from the table above. The classification of certain compensating balances and restricted investments are dependent upon the term of the underlying restriction on the asset and not the maturity date of the investment. Therefore, certain long-term investments and long-term restricted cash and investments have contractual maturities within one year.

NOTE 4. INVENTORY

Inventory consists of the following (in thousands):

	September 30, 2015	December 31, 2014
Raw materials	$1,063	$1,118
Work in process	2,203	2,845
Finished goods	745	559
Total	4,011	4,522
Less: non-current portion included in Other assets	(1,890)	(2,141)
Inventory	$2,121	$2,381

Table of Contents

We generally relieve inventory on a first-expiry, first-out basis. Write-downs related to expiring and excess inventory are charged to cost of goods sold. Such write-downs were $1.1 million for the nine months ended September 30, 2015 and were nominal for the nine months ended September 30, 2014. The non-current portion of inventory is recorded within Other assets on the accompanying Condensed Consolidated Balance Sheets and is comprised of a portion of the active pharmaceutical ingredient that is included in raw materials and work in process inventories. There were no other write-downs for obsolete inventory.

NOTE 5. DEBT

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

	September 30, 2015	December 31, 2014
Convertible Senior Subordinated Notes due 2019	$196,371	$182,395
Secured Convertible Notes due 2018	101,515	98,880
Silicon Valley Bank term loan	80,000	80,000
Silicon Valley Bank line of credit	—	381
Total debt	377,886	361,656
Less: current portion	(450)	(99,261)
Long-term debt	$377,436	$262,395

See “Note 8 - Debt” to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2014, for additional information on the terms of our debt, including a description of the conversion features of the of 4.25% Convertible Senior Subordinated Notes due 2019 (the “2019 Notes”) and our Secured Convertible Notes due June 2018 (the “Deerfield Notes”).

Convertible Senior Subordinated Notes due 2019

In August 2012, we issued and sold $287.5 million aggregate principal amount of the 2019 Notes. As of September 30, 2015, the entire principal balance remains outstanding. The following is a summary of the liability component of the 2019 Notes (in thousands):

	September 30, 2015	December 31, 2014
Net carrying amount of the liability component	$196,371	$182,395
Unamortized discount of the liability component	91,129	105,105
Face amount of the 2019 Notes	$287,500	$287,500

The debt discount and debt issuance costs will be amortized as interest expense through August 2019. The following is a summary of interest expense for the 2019 Notes (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Stated coupon interest	$3,054	$3,055	$9,164	$9,198
Amortization of debt discount and debt issuance costs	4,951	4,502	14,505	13,194
Total interest expense	$8,005	$7,557	$23,669	$22,392

The balance of unamortized fees and costs was $2.7 million and $3.3 million as of September 30, 2015 and December 31, 2014, respectively, which is included in Other assets on the accompanying Condensed Consolidated Balance Sheets.

Secured Convertible Notes due June 2018

In June 2010, we entered into a note purchase agreement with Deerfield Private Design Fund, L.P. and Deerfield Private Design International, L.P., (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

13

Table of Contents

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, Deerfield Partners, L.P. and Deerfield International Master Fund, L.P. (the "New Deerfield Purchasers") acquired the $100.0 million principal amount of the Original Deerfield Notes and we entered into 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, 2015 and December 31, 2014, the outstanding principal balance on the Deerfield Notes was $101.9 million and $104.0 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Stated coupon interest paid in cash	$1,891	$1,512	$4,866	$4,487
Amortization of debt discount, debt issuance costs and accrual of interest paid in kind	1,959	3,005	7,279	8,631
Total interest expense	$3,850	$4,517	$12,145	$13,118

The balance of unamortized fees and costs was $0.8 million and $1.4 million as of September 30, 2015 and December 31, 2014, respectively, which is included in Other assets on the accompanying Condensed Consolidated Balance Sheets. Prior to March 4, 2015, the unamortized discount, fees and costs were amortized into interest expense as a yield adjustment through July 1, 2015. 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 15.27%.

We were required to make an additional mandatory prepayment on the Deerfield Notes in January 2015 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. 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 each of 2016, 2017 and 2018. However, we will only be obligated to make any such annual mandatory prepayment if the New Deerfield Purchasers provide notice to us of their election to receive the prepayment. Pursuant to this requirement, we may be required make a mandatory prepayment of $450,000 in January 2016 as a result of to the $3.0 million milestone payment received from Merck during the three months ended September 30, 2015. That portion of the Deerfield Notes is included in current liabilities. Mandatory prepayments relating to Development/Commercialization Revenue will continue to be subject to a maximum annual prepayment amount of $27.5 million. 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.

In connection with the amendment to the note purchase agreement, in January 2014 we issued to the New Deerfield Purchasers two-year warrants (the "2014 Deerfield 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 March 4, 2015 notification of our election to extend the maturity date of the Deerfield Notes, the exercise price of the 2014 Deerfield Warrants was reset to $3.445 per share and the term was extended by two years to January 22, 2018. See "Note 6 - Common Stock and Warrants" for

further information on the 2014 Deerfield Warrants.

NOTE 6. COMMON STOCK AND WARRANTS

Sale of Shares of Common Stock

On July 29, 2015 we completed a registered underwritten public offering of 28,750,000 shares of our common stock, including 3,750,000 shares issued under the underwriters' 30-day option to buy shares, at a price of $5.40 per share pursuant to

Table of Contents

a shelf registration statement previously filed with the SEC, which was filed and automatically became effective on July 1, 2015. We received approximately $145.6 million in net proceeds from the offering after deducting the underwriting discount and other estimated expenses. We estimate that the expenses of the offering, excluding underwriting discount, will be approximately $0.4 million, and are payable by us. The shares of common stock were listed on The NASDAQ Global Select Market. All of the shares in the offering were sold by the Company.

The Underwriting Agreement contains customary representations, warranties and agreements by the Company, indemnification obligations of the Company and the Underwriter, including for liabilities under the Securities Act of 1933, as amended, other obligations of the parties and termination provisions. The representations, warranties and covenants contained in the Underwriting Agreement were made only for purposes of such agreement and as of specific dates, were solely for the benefit of the parties to such agreement and may be subject to limitations agreed upon by the contracting parties.

Warrants

In connection with an amendment to the note purchase agreement for the Original Deerfield Notes, in January 2014 we issued to the New Deerfield Purchasers two-year warrants to purchase an aggregate of 1,000,000 shares of our common stock at an exercise price of $9.70 per share. Under the terms of the 2014 Deerfield Warrants, the warrants would be extended by two years and the exercise price would be reset to the lower of (i) the existing exercise price and (ii) 120% of the volume weighted average price of our common stock for the ten trading days following our election to extend the maturity date of the Deerfield Notes. Subsequent to our March 2015 notification of our election to extend the maturity date of the Deerfield Notes, the exercise price of the 2014 Deerfield Warrants was reset to $3.445 per share and the term was extended by two years to January 22, 2018.

Due to the potential increase in term and decrease of the exercise price, the 2014 Deerfield Warrants were included in Other long-term liabilities at their current estimated fair value, which was $1.5 million and $0.9 million as of March 18, 2015 and December 31, 2014, respectively. We recorded an unrealized loss of $0.5 million and an unrealized gain of $1.9 million on the 2014 Deerfield Warrants during the nine months ended September 30, 2015 and 2014, respectively, which is included in Interest income and other, net. Subsequent to our March 4, 2015 notification of our election to extend the maturity date of the Deerfield Notes, the terms of the 2014 Deerfield Warrants became fixed as of March 18, 2015 and the 2014 Deerfield Warrants were transferred to Additional paid-in capital as of that date at their then estimated fair value of $1.5 million. See “Note 7 - Fair Value Measurements” for more information on the valuation of the 2014 Deerfield Warrants.

NOTE 7. FAIR VALUE MEASUREMENTS

The following table sets forth the fair value of our financial assets and liabilities that were measured and recorded on a recurring basis as of September 30, 2015 and December 31, 2014. We did not have any financial liabilities that were measured and recorded on a recurring basis or Level 3 investments as of September 30, 2015. The amounts presented exclude cash, but include investments classified as cash equivalents (in thousands):

	September 30, 2015		
	Level 1	Level 2	Total
Money market funds	$34,895	$—	$34,895
Commercial paper	—	140,144	140,144
Corporate bonds	—	89,844	89,844
U.S. government sponsored entities	—	14,979	14,979
Total financial assets	$34,895	$244,967	$279,862

Table of Contents

	December 31, 2014			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$23,376	$—	$—	$23,376
Commercial paper	—	56,714	—	56,714
Corporate bonds	—	143,322	—	143,322
U.S. government sponsored entities	—	12,212	—	12,212
Municipal bonds	—	2,662	—	2,662
Total financial assets	$23,376	$214,910	$—	$238,286
Financial liabilities:				
Warrants	$—	$—	$921	$921

The following is a reconciliation of changes in the fair value of warrants which are classified as Level 3 in the fair value hierarchy (in thousands):

Balance at December 31, 2014	$921
Unrealized loss at final re-measurement of warrants on March 18, 2015, included in Interest income and other, net	549
Transfer of warrants from Other long-term liabilities to Additional paid-in capital at their estimated fair value upon warrant repricing on March 18, 2015	(1,470)
Balance at September 30, 2015	$—

The estimated fair value of our financial instruments that are carried at amortized cost for which it is practicable to determine a fair value was as follows (in thousands):

	September 30, 2015		December 31, 2014	
	Carrying Amount	Fair Value	Carrying Amount	Fair Value
2019 Notes	$196,371	$355,638	$182,395	$156,889
Silicon Valley Bank term loan	$80,000	$79,884	$80,000	$79,943
Silicon Valley Bank line of credit	$—	$—	$381	$381

As of September 30, 2015, the carrying value and estimated fair value of our Deerfield Notes was $101.5 million and $103.9 million, respectively. As of December 31, 2014, we had determined that it was not practicable to determine the fair value of the Deerfield Notes due to the unique structure of the instrument, including the Extension Option, which was exercised in March 2015, and was financed by entities affiliated with Deerfield.

The carrying amounts of cash, trade and other receivables, accounts payable, accrued clinical trial liabilities, accrued compensation and benefits, 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 for which it is practicable to estimate a value:

- 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.
- The 2019 Notes are valued using a third-party pricing model that is based in part on average trading prices, which is a Level 2 input. The 2019 Notes are not marked-to-market and are shown at their initial fair value less the unamortized discount; the portion of the value allocated to the conversion option is included in Stockholders' deficit on the accompanying Condensed Consolidated Balance Sheets.
- We estimate the fair value of our other debt instruments, where possible, using the net present value of the payments. For the Silicon Valley Bank term loan and line of credit, 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, 2015, which is a Level 3 input.

16

Table of Contents

The 2014 Deerfield Warrants were valued using a Monte Carlo simulation model until December 31, 2014 and the Black-Scholes Merton option pricing model on March 18, 2015. The expected life is based on the contractual terms of the 2014 Deerfield Warrants, and in certain simulations, assumes the two year extension that would result from our exercise of the Extension Option; as of and subsequent to September 30, 2014, we estimated that it was probable that we would exercise this two-year extension. We consider implied volatility as well as our historical volatility in developing our estimate of expected volatility. The fair value of the 2014 Deerfield Warrants was estimated using the following assumptions, which, except for risk-free interest rate, are Level 3 inputs (dollars in thousands):

	March 18, 2015	December 31, 2014
Risk-free interest rate	0.87 %	1.07 %
Dividend yield	— %	— %
Volatility	95 %	96 %
Average expected life	2.8 years	3.1 years

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,	
	2015	2014	2015	2014
Research and development expense	$6,676	$112	$8,049	$3,148
Selling, general and administrative expense	5,350	624	7,371	5,328
Restructuring-related stock-based compensation (recovery) expense	—	(22)	—	(22)
Total employee stock-based compensation expense	$12,026	$714	$15,420	$8,454

We use the Black-Scholes Merton option pricing model to value our stock options. 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. The fair value of employee stock option awards and ESPP purchases was estimated using the following assumptions and resulted in the following weighted average fair values:

	Stock Options			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Weighted average grant-date fair values	$3.92	$1.19	$2.51	$1.47
Assumptions:				
Risk-free interest rate	1.18 %	1.83 %	1.20 %	1.81 %
Dividend yield	— %	— %	— %	— %
Volatility	88 %	86 %	93 %	85 %
Expected life	4.6 years	5.5 years	4.5 years	5.5 years
	Employee Stock Purchase Plan			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Weighted average grant-date fair values	$1.26	$1.21	$0.97	$1.35
Assumptions:				
Risk-free interest rate	0.06 %	0.05 %	0.09 %	0.06 %
Dividend yield	— %	— %	— %	— %
Volatility	107 %	68 %	101 %	66 %

Expected life	6 months	6 months	6 months	6 months

17

Table of Contents

A summary of all stock option activity for the nine months ended September 30, 2015 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, 2014	27,811,992	$5.00		
Granted	8,505,300	$3.70		
Exercised	(875,504)	$4.33		
Forfeited	(924,890)	$3.67		
Expired	(4,403,827)	$6.52		
Options outstanding at September 30, 2015	30,113,071	$4.48	4.83 years	$58,332
Exercisable September 30, 2015	18,385,413	$5.06	3.89 years	$29,649

As of September 30, 2015, a total of 6,980,194 shares were available for grant under our stock option plans.

As of September 30, 2015, $23.5 million of total unrecognized compensation expense related to employee stock options was expected to be recognized over a weighted-average period of 2.73 years.

On July 20, 2015, as a result of positive top-line results from the primary analysis of METEOR, the Compensation Committee of the Board of Directors of Exelixis convened to determine we had met certain performance objectives for performance-based stock options granted to employees in 2013, 2014 and 2015. As a result of this determination, 6,982,613 performance-based stock options vested on July 20, 2015. Previously, we had not considered achievement of those performance objectives to be probable and therefore, we recorded $9.4 million in employee stock-based compensation expense during the three months ended September 30, 2015 related to those options.

We have an additional 5,934,063 outstanding unvested stock options as of September 30, 2015 which were granted to employees in 2014 and 2015 and are subject to performance objectives tied to the achievement of clinical and regulatory goals set by the Compensation Committee of our Board of Directors and will vest in full or part based on achievement of such goals. As of September 30, 2015, we did not consider achievement of those performance objectives to be probable and therefore we have not recorded any stock-based compensation expense for those stock options. The grant date fair value of the outstanding unvested performance-based stock options was $7.4 million.

A summary of all restricted stock unit (“RSU”) activity for the nine months ended September 30, 2015 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, 2014	961,469	$3.82		
Awarded	673,785	$4.84		
Released	(414,694)	$3.62		
Forfeited	(124,865)	$5.32		
Awards outstanding at September 30, 2015	1,095,695	$4.35	2.11 years	$6,476

As of September 30, 2015, $3.5 million of total unrecognized compensation expense related to employee RSUs was expected to be recognized over a weighted-average period of 2.11 years.

Table of Contents

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,	
	2015	2014	2015	2014
Numerator:				
Net loss	$(47,564)	$(62,560)	$(126,096)	$(210,589)
Denominator:				
Shares used in computing basic and diluted net loss per share	217,587	195,126	203,153	193,855
Net loss per share, basic and diluted	$(0.22)	$(0.32)	$(0.62)	$(1.09)

The following table sets forth outstanding 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	
	2015	2014
Convertible Senior Subordinated Notes due 2019	54,118	54,118
Secured Convertible Notes due 2018	33,890	21,616
Outstanding stock options, unvested RSUs and ESPP contributions	31,331	34,243
2014 Deerfield Warrants	1,000	1,000
Total potentially dilutive shares	120,339	110,977

The 2014 Deerfield Warrants are participating securities and the warrant holders do not have a contractual obligation to share in our losses.

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, 2015, 87% of our trade and other receivables are with the specialty pharmacy that sells COMETRIQ in the United States and 13% are with our European distribution partner. Both of these customers pay promptly and within their respective payment terms. 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. During the second quarter of 2013, we initiated a Named Patient Use program through our distribution partner, Swedish Orphan Biovitrum (“Sobi”), to support the distribution and commercialization of COMETRIQ for metastatic MTC primarily in the European Union and potentially other countries. In March 2014, the European Commission approved cabozantinib for the treatment of adult patients with progressive, unresectable locally advanced or metastatic MTC, also under the brand name COMETRIQ. In June 2014, we began selling COMETRIQ to Sobi in preparation for commercial sales in certain countries in the European Union. The following table shows the percentage of revenues earned in the United States and the European Union.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Percentage of revenues earned in the United States	96%	108%	90%	100%
	4%	(8)%	10%	—%

Percentage of revenues earned in the European Union

Net product revenues in the European Union for the three months and nine months ended September 30, 2014 included a $1.8 million reduction to revenue for a project management fee payable to our European distributor upon its

Table of Contents

achievement of a cumulative revenue goal. As a result, for the three months ended September 30, 2014 discounts and allowances exceeded gross revenues for the European Union causing the percentage of revenues earned in the United States to exceed 100% during the period.

We recorded a $0.1 million gain relating to foreign exchange fluctuations for both the nine months ended September 30, 2015 and 2014.

The following table sets forth the percentage of revenues recognized under our collaboration agreements and product sales to the specialty pharmacies that represent 10% or more of total revenues during one or more of the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Collaboration agreements:				
Merck	30%	—%	11%	—%
Product sales:				
Diplomat Specialty Pharmacy	66%	108%	79%	100%
Swedish Orphan Biovitrum	4%	(8)%	10%	—%

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 ou 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 "progress toward," "objectives," "priority," "expedite," "augment," "potential," "rolling out," "expects," "may b "believes," "suggesting," "could," "continues," "potential," "will be," "plan," "priority," "committed," "entitled," "trend," "em 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, 2014, filed with the Securities and Exchange Commission, or SEC, on March 2, 2015. 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

We are a biopharmaceutical company committed to developing small molecule therapies for the treatment of cancer. Our two most advanced assets are cabozantinib, our wholly-owned inhibitor of multiple receptor tyrosine kinases, and cobimetinib (GDC-0973/XL518), a selective inhibitor of MEK, a dual-specificity kinase, which we out-licensed to Genentech, Inc. (a member of the Roche Group), or Genentech.

Cabozantinib

Our development and commercialization efforts are focused primarily on cabozantinib. Cabozantinib was approved by the United States Food and Drug Administration, or FDA, on November 29, 2012, for the treatment of progressive, metastatic medullary thyroid cancer, or MTC, in the United States under the brand name COMETRIQ®. COMETRIQ became commercially available in the United States in January 2013. In March 2014, the European Commission granted cabozantinib conditional marketing authorization for the treatment of adult patients with progressive, unresectable locally advanced or metastatic MTC, also under the brand name COMETRIQ.

We are evaluating cabozantinib in a broad development program comprising over 40 clinical trials across multiple indications, including ongoing phase 3 pivotal trials focusing on advanced renal cell carcinoma, or RCC, and advanced hepatocellular carcinoma, or HCC.

RCC

On April 8, 2015, the FDA granted Fast Track designation to cabozantinib for the treatment of patients with advanced RCC, who have received one prior therapy. On September 26, 2015, the complete, detailed positive top-line results from the primary analysis of METEOR, the phase 3 pivotal trial comparing cabozantinib to everolimus in 658 patients who experienced disease progression following treatment with a VEGF receptor tyrosine kinase inhibitor, or TKI, were published in The New England Journal of Medicine and also presented during the Presidential Session I at the European Cancer Congress 2015. The trial met its primary endpoint, demonstrating a statistically significant increase in progression free survival, or PFS, for cabozantinib, as determined by an independent radiology review committee. The median PFS was 7.4 months for the cabozantinib arm versus 3.8 months for the everolimus arm, corresponding to a 42% reduction in the rate of disease progression or death for cabozantinib compared to everolimus (hazard ratio [HR]=0.58, 95% confidence interval [CI] 0.45-0.75, p<001). The trial also showed a positive trend for a secondary endpoint of overall survival, or OS, although at the time of the interim analysis the p-value to achieve statistical significance was not reached, and therefore the trial will continue to the final analysis of OS, which is anticipated in 2016. A review of serious adverse events, or SAEs, data demonstrated that the frequency of SAEs of any Grade regardless of causality was approximately balanced between study arms, and the rate of treatment discontinuation due to adverse events were 9% and 10% for cabozantinib and everolimus, respectively. In August 2015 the FDA granted Breakthrough Therapy Designation for cabozantinib as a potential treatment for patients with advanced RCC. In

October 2015, we initiated rolling submission of our U.S. New Drug Application, or NDA. Based on the data from the trial and the Breakthrough Therapy Designation, we expect to complete our NDA in the United States by the end of 2015. In the European Union, where the European Medicines Agency's Committee for Medicinal Products for Human Use has granted accelerated assessment, we expect to complete our filing in early 2016.

HCC

Enrollment continues in CELESTIAL, our phase 3 pivotal trial in advanced HCC, from which we expect top-line results in 2017.

Cobimetinib

On November 10, 2015, our second most advanced oncology asset, cobimetinib, was approved in the U.S. by the FDA under the brand name COTELLIC in combination with vemurafenib as a treatment for patients with BRAF V600 mutation-positive advanced melanoma. In Switzerland, cobimetinib in combination with vemurafenib was approved in August 2015 as a treatment for patients with BRAF V600 mutation-positive advanced melanoma. Roche also filed a Marketing Authorization Application for cobimetinib in combination with vemurafenib for the same indication with the European Medicines Agency and anticipates a regulatory decision before the end of 2015 following a positive opinion issued by the European Committee for Medicinal Products for Human Use, announced in late September 2015. Cobimetinib is subject to a collaboration agreement we entered into with Genentech, in December 2006. Pursuant to the collaboration agreement's financial terms, we believe that cobimetinib has the potential to provide us with a second significant source of revenue.

Our Strategy

Our business strategy focuses predominantly on two Exelixis discovered compounds, cabozantinib and cobimetinib. Cabozantinib is wholly owned by Exelixis and Cobimetinib is partnered with Genentech. We are pursuing commercialization and development of these compounds in multiple tumor indications.

Cabozantinib is an inhibitor of tyrosine kinases, including MET, VEGF receptors, AXL and RET. We believe that cabozantinib has the potential to make a meaningful difference in the lives of patients and that the emerging clinical data support such a view. Our objective, therefore, is to build cabozantinib into a significant oncology franchise as a single agent, and potentially in combination with other therapies.

Cabozantinib's first regulatory approvals, both in the U.S. and EU as COMETRIQ capsules for MTC, presented us with a valuable opportunity to gain experience commercializing this new compound. The results of METEOR in advanced RCC now offer an opportunity to commercialize cabozantinib more broadly with a tablet formulation in a significantly larger market. We are seeking to partner cabozantinib with a global pharmaceutical organization whose international resources will permit us to explore and exploit the potential opportunity cabozantinib presents on its own and in combination with other agents, in RCC, HCC, and other potential indications.

On the development front, our Cooperative Research and Development Agreement, or CRADA, with the National Cancer Institute's Cancer Therapy Evaluation Program, or NCI-CTEP, and investigator sponsored trials, or ISTs, have permitted us to engage with leading clinicians to expand our collective understanding of cabozantinib's potential, while also conserving our internal resources for late stage trials. We believe this staged approach to building cabozantinib's value with a far lesser upfront expenditure of funds has been rational and cost-effective.

Cobimetinib, a selective inhibitor of MEK discovered by us, is being developed and commercialized under a collaboration with Genentech. Based on results from the coBRIM phase 3 clinical trial, cobimetinib was recently approved in the U.S. and Switzerland, and it is under regulatory review in the EU. The coBRIM phase 3 trial evaluated cobimetinib plus vemurafenib versus vemurafenib alone in previously untreated patients with unresectable locally advanced or metastatic melanoma carrying a BRAF V600 mutation. It has returned statistically significant and clinically meaningful results for the combination, both with respect to its primary endpoint of progression free survival, and more recently, with respect to its secondary endpoint of overall survival. Long-term safety data are expected later this year. Beyond coBRIM, Genentech continues to pursue a broad development program for cobimetinib in combination with multiple agents in its oncology pipeline, including immuno-oncology agents. These studies seek to expand the potential use of cobimetinib in additional melanoma patient populations and into other significant tumor types including non-small cell lung cancer, or NSCLC, and KRAS mutant metastatic colorectal cancer.

In the U.S., we are fielding 25% of the sales force promoting cobimetinib, having exercised our option to co-promote the drug. We view this as a valuable opportunity to enhance our commercialization experience in oncology.

Beyond our efforts regarding cabozantinib and cobimetinib, we are working with our corporate partners under the terms of our various collaboration agreements to realize the potential value of the compounds and programs we have out-licensed to them. In the aggregate, these partnered compounds could potentially be of significant value to us if their development programs progress successfully.

Table of Contents

Collaborations

We have established a collaboration with Genentech 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. Pursuant to these collaborations, we have fully out-licensed compounds or programs to a partner for further development and commercialization. We have no further development cost obligations under our collaborations and may be entitled to receive milestones and royalties, or in the case of cobimetinib, a share of profits (or losses) from commercialization.

Cobimetinib Collaboration

Our collaboration with Genentech for cobimetinib continues to be of increasing importance to us as cobimetinib in combination with vemurafenib has been approved in Switzerland as a treatment for patients with advanced melanoma, and is the subject of multiple other regulatory submissions. Cobimetinib is our most advanced partnered compound in development and has the greatest near-term commercial potential. In addition to the coBRIM trial, the following clinical trials of cobimetinib in combination with other agents are active, as disclosed on clinicaltrials.gov:

- A Study of MEHD7945A and Cobimetinib (GDC-0973) in Patients with Locally Advanced or Metastatic Cancers with Mutant KRAS (NCT01986166);
- A Phase 1b Study of MPDL3280A (an Engineered Anti-PDL1 Antibody) in Combination with Cobimetinib in Patients with Locally Advanced or Metastatic Solid Tumors (NCT01988896);
- Trial of Vemurafenib/Cobimetinib with or without Bevacizumab in Patients with Stage IV BRAF V600 Mutant Melanoma (NCT01495988);
- A Phase 1b Study of MPDL3280A (an Engineered Anti-PDL1 Antibody) in Combination with Vemurafenib (Zelboraf®) or Vemurafenib Plus Cobimetinib in Patients with Previously Untreated BRAF V600-Mutation Positive Metastatic Melanoma (NCT01656642);
- A Study of Cobimetinib in Combination with Paclitaxel as First-line Treatment for Patients with Metastatic Triple-negative Breast Cancer (NCT02322814);
- A Study of Neo-adjuvant Use of Vemurafenib Plus Cobimetinib for BRAF Mutant Melanoma with Palpable Lymph Node Metastases (NCT02036086);
- A Phase II Study of Cobimetinib in Combination with Vemurafenib in Active Melanoma Brain Metastases (CoBRIM-B) (NCT02230306);
- Neoadjuvant Vemurafenib + Cobimetinib in Melanoma: NEO-VC (NCT02303951);
- Vemurafenib Plus Cobimetinib in Metastatic Melanoma (REPOSIT) (NCT02414750);
- A Phase Ib, Open-Label, Dose-Escalation Study Of The Safety, Tolerability, and Pharmacokinetics of Cobimetinib and GDC-0994 In Patients with Locally Advanced or Metastatic Solid Tumors (NCT02457793);
- A trial of Vemurafenib and Cobimetinib in Patients with Advanced BRAF V600 Mutant Melanoma (NCT2427893);
- A Study of GDC-0973/XL518 in Patients With Solid Tumors (NCT00467779);
- A Study to Evaluate the Pharmacokinetics and Safety of Cobimetinib in Volunteers With and Without Liver Damage (NCT02300025);
- A Trial of Vemurafenib and Cobimetinib in Patients With Advanced BRAFV600 Mutant Melanoma (NCT02427893);
- Evaluation of Vemurafenib and Cobimetinib Combination in BRAF Mutated Melanoma With Brain Metastasis (CONVERCE) (NCT02537600);

Table of Contents

- A Clinical Trial to Evaluate the Efficacy of Vemurafenib in Combination With Cobimetinib (Continuous and Intermittent) in BRAFV600-mutation Positive Patients With Unresectable Locally Advanced or Metastatic Melanoma (NCT02583516); and
- A Study of Vemurafenib and GDC-0973 in Patients With BRAF-Mutation Positive Metastatic Melanoma (NCT01271803).

Under the terms of our collaboration agreement with Genentech for cobimetinib, we are entitled to an initial equal share of U.S. profits and losses for cobimetinib, with our share decreasing as sales increase, and we will share in the U.S. sales and marketing costs. The profit share has multiple tiers: we are entitled to 50% of profits from the first $200 million of U.S. actual sales, decreasing to 30% of profits from U.S. actual sales in excess of $400 million. The tiers for the profit share reset each calendar year. We are entitled to low double-digit royalties on ex-U.S. net sales. As a result of exercising our option to co-promote cobimetinib in the U.S., we are prepared to provide up to 25% of the total sales force for cobimetinib in the U.S. if commercialized, and will call on customers and otherwise engage in promotional activities using that sales force, consistent with the terms of the collaboration agreement and a co-promotion agreement to be entered into by the parties.

Other Collaborations

With respect to our partnered compounds, other than cobimetinib, we are eligible to receive potential contingent payments totaling approximately $2.3 billion in the aggregate on a non-risk adjusted basis, of which 10% are related to clinical development milestones, 42% are related to regulatory milestones and 48% 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, 2015 and Recent Events

Cabozantinib Highlights

Positive Results from METEOR, the Phase 3 Pivotal Trial of Cabozantinib vs. Everolimus in Patients with Advanced RCC Lead to Initiation of Our U.S. New Drug Application

The METEOR trial met its primary endpoint of demonstrating a statistically significant increase in PFS for cabozantinib as compared to everolimus, as determined by an independent radiology committee. Per the trial protocol, the primary analysis was conducted among the first 375 patients randomized to ensure sufficient follow up and a PFS profile that would not be primarily weighted toward early events. The median PFS was 7.4 months for the cabozantinib arm versus 3.8 months for the everolimus arm, corresponding to a 42% reduction in the rate of disease progression or death for cabozantinib as compared to the everolimus arm (hazard ratio [HR]=0.58, 95% confidence interval [CI] 0.45-0.75, p<0.001). Cabozantinib effects were favorable across patient stratification subgroups including the number of prior VEGF receptor TKI therapies and commonly applied RCC risk criteria developed by Motzer et al.

In a post-hoc subset analysis of patients who had received sunitinib, the most commonly used first-line therapy, as their only prior VEGF receptor TKI, the median PFS for cabozantinib-treated patients (n=76) was 9.1 months versus 3.7 months for everolimus-treated patients (n=77). This corresponds to a 59% reduction in the rate of disease progression or death for patients treated with cabozantinib (HR=0.41, 95% CI 0.28-0.61).

Data pertaining to overall survival (OS) in the entire study population of 658 patients, a secondary endpoint of the trial, were immature at the data cutoff. A pre-specified interim analysis triggered by the primary analysis for PFS showed a strong trend in OS favoring cabozantinib (HR=0.67, 95% CI 0.51-0.89, p=0.005). At the time of the interim analysis, the p-value of 0.0019 to achieve statistical significance was not reached, and the trial will continue to the final analysis of OS anticipated in 2016. Objective response rate among the first 375 patients was significantly higher with cabozantinib (21%) as compared with everolimus (5%; p < 0.001).

Treatment discontinuations for adverse events unrelated to progressive disease were 9% and 10% for cabozantinib and everolimus, respectively. 653 patients were evaluable for safety. Median duration of exposure was 7.6 months for cabozantinib and 4.4 months for everolimus. Investigators employed dose reductions to manage adverse events (AEs), and 60% of patients on the cabozantinib arm and 25% of patients on the everolimus arm had dose reductions. The median average daily dose was 44 mg for cabozantinib and 9 mg for everolimus. The incidence of AEs (any grade), regardless of causality, was 100% with cabozantinib and more than 99% with everolimus. Serious AEs occurred in

40% of cabozantinib patients and 43% of everolimus patients. The most common AEs regardless of causality, grade 3 or higher, for cabozantinib were: hypertension (15%), diarrhea (11%), fatigue (9%), and hand-foot syndrome (8%). The most common AEs regardless of causality, grade 3 or higher, for everolimus were: anemia (16%), fatigue (7%), hyperglycemia (5%), and dyspnea (4%). Grade 5 adverse events occurred in 6.6% of patients in the cabozantinib arm and in 7.8% of patients in the everolimus arm, and were primarily

Table of Contents

related to disease progression. Treatment-related grade 5 events occurred in one patient (0.3%; death not otherwise specified) in the cabozantinib arm and 2 patients (0.6%; aspergillus infection and aspiration pneumonia) in the everolimus arm.

Based on the data from the trial, the FDA granted cabozantinib Breakthrough Therapy Designation, a classification that can confer benefits such as the involvement of FDA senior managers in the review process, allowance for a rolling submission process and potential Priority Review of a sponsor's NDA. In October 2015, we initiated our rolling NDA submission for cabozantinib for the treatment of advanced RCC patients who have received one prior therapy. We expect to complete the submission before the end of 2015.

We are also preparing a European regulatory filing, which we expect to complete in early 2016. In October 2015, the European Medicines Agency's Committee for Medicinal Products for Human Use, or CHMP, notified us that it had granted accelerated assessment to cabozantinib for advanced RCC. As a result, we may be eligible for a 150-day review of our Marketing Authorization Application, versus the standard review time of 210 days (excluding clock stops when written or oral information is requested from CHMP).

Initiation of Phase 1 Trial of Cabozantinib in Combination with Nivolumab or Nivolumab Plus Ipilimumab in Patients with Advanced/Metastatic Urothelial Carcinoma and Other Genitourinary Tumors

On July 13, 2015, we announced the initiation of a phase 1 trial of cabozantinib in combination with Bristol-Myers Squibb's nivolumab alone or in combination with nivolumab plus another Bristol-Myers Squibb agent, ipilimumab, in patients with genitourinary tumors including advanced/metastatic urothelial (bladder) cancer and RCC. The study is being sponsored through our CRADA with NCI-CTEP with our support and support from Bristol-Myers Squibb. The study was initiated based upon preliminary data on objective tumor responses presented at the Annual Meeting of the American Society of Clinical Oncology, or ASCO, conference in June 2014. The primary endpoint of the trial is the determination of dose-limiting toxicities and a recommended phase 2 dose for the combination of cabozantinib and nivolumab, and separately, for the combination of cabozantinib, nivolumab and ipilimumab, in patients with genitourinary solid tumors. Secondary endpoints include evaluating the activity of the two combinations by objective response rate, as well as PFS and OS, in cohorts of patients with urothelial carcinoma of the bladder, urethra, ureter or renal pelvis.

Cobimetinib Highlights

Cobimetinib, in Combination With Vemurafenib For the Treatment of Advanced Melanoma, Makes Significant Advances in Europe, Receiving Regulatory Approval in Switzerland and European CHMP Positive Opinion

On August 27, 2015, we announced that Swissmedic, the Swiss licensing and supervisory authority of Switzerland, approved cobimetinib for use in combination with vemurafenib as a treatment for patients with advanced melanoma. The brand name for cobimetinib in Switzerland is COTELLIC.

On September 25, 2015, we announced that the European Medicines Agency's CHMP adopted a positive opinion of the Marketing Authorization Application for cobimetinib in combination with vemurafenib for the treatment of BRAF V600 mutation-positive unresectable or metastatic melanoma. The CHMP's positive opinion will be reviewed by the European Commission, which has the authority to approve medicines for the European Union. The European Commission is expected to release its final decision regarding the approval of the combination of cobimetinib and vemurafenib by the end of 2015.

Cobimetinib, in Combination With Vemurafenib, Receives Regulatory Approval in the United States as a Treatment for Patients with BRAF V600 Mutation-Positive Advanced Melanoma

On November 10, 2015, the U.S. FDA approved cobimetinib under the brand name COTELLIC for use in combination with vemurafenib as a treatment for patients with BRAF V600 mutation-positive advanced melanoma. We are fielding 25% of the U.S. sales force promoting COTELLIC in the United States alongside our partner Genentech.

Corporate Highlights

Appointment of Key Senior Management

On September 24, 2015, we announced three high-level appointments as we prepare for the potential approval of cabozantinib for the treatment of RCC following positive results from the METEOR pivotal phase 3 trial. William Berg, M.D. has joined the company as Senior Vice President of Medical Affairs, Jonathan Berndt as Vice President of

Sales, and Gregg Bernier as Vice President of Marketing.

Table of Contents

Completion of Underwritten Public Offering

On July 29, 2015 we completed a registered underwritten public offering of 28,750,000 shares of our common stock, including 3,750,000 shares issued under the underwriters' 30-day option to buy shares, at a price of $5.40 per share. We received approximately $145.6 million in net proceeds from the offering after deducting the underwriting discount and other estimated expenses. We estimate that the expenses of the offering, excluding underwriting discount, will be approximately $0.4 million, and are payable by us.

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

Successful development of drugs is inherently difficult and uncertain. Our business requires significant investments in research and development over many years, and products often fail during the research and development process. Our long-term prospects depend upon our ability, and the ability of our partners, to successfully commercialize new therapeutics in highly competitive 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 Part II, Item 1A - Risk Factors.

Limited Sources of Revenues and the Need to Raise Additional Capital

We have incurred net losses since inception through September 30, 2015, with the exception of the 2011 fiscal year. We anticipate net losses and negative operating cash flow for the foreseeable future. For the nine months ended September 30, 2015, we incurred a net loss of $126.1 million and as of September 30, 2015, we had an accumulated deficit of $1.9 billion. These losses have had, and will continue to have, an adverse effect on our stockholders' deficit 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 whether or when we will become profitable, if at all. Our research and development expenditures and selling, general and administrative expenses have exceeded our revenues for each fiscal year other than the 2011 fiscal year, and we expect to spend significant additional amounts to fund the continued development and commercialization of cabozantinib. 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.

We commercially launched COMETRIQ for the treatment of progressive, metastatic MTC in the United States in late January 2013, and from the commercial launch through September 30, 2015 we have generated $64.4 million in net revenues from the sale of COMETRIQ. Other than revenues from COMETRIQ, we have derived substantially all of our revenues since inception from collaborative research and development agreements, which depend on research funding, the achievement of milestones, and royalties we earn from any future products developed from the collaborative research.

The amount of our net losses will depend, in part, on: the rate of growth, if any, in our sales of COMETRIQ; our share of the net profits and losses for the commercialization for cobimetinib in the U.S., if any; the receipt of royalties from cobimetinib sales outside the U.S., if any; partnering activities for cabozantinib; other license and contract revenues; and, the level of expenses primarily with respect to development and commercialization activities for cabozantinib.

As of September 30, 2015, we had $282.1 million in cash and investments, which included $197.8 million available for operations, $81.6 million of compensating balance investments that we are required to maintain on deposit with Silicon Valley Bank, and $2.7 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 end of the third quarter of 2015. While a forecast of future events is inherently uncertain, our ability to sustain our business operations for this time period without additional financing is highly dependent upon the commercial success of COMETRIQ and the revenues we generate, as well as the commercial success of COTELLIC and our share of related net profits and losses and royalties under our collaboration with Genentech. It is also dependent upon whether and when we partner cabozantinib with a global pharmaceutical organization for further development and sales outside the U.S., and the upfront payments and milestones associated with any such transaction. Consistent with the actions we have taken in the past, we will prioritize necessary and appropriate steps to ensure the continued operation of our business and preservation of the value of our assets. However, our future capital requirements will be substantial, and we may need to raise additional capital in the future. 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."

Table of Contents

Clinical Development and Commercialization of Cabozantinib

Our primary development and commercialization program is focused on cabozantinib, our wholly-owned inhibitor of multiple receptor tyrosine kinases, currently approved under the brand name COMETRIQ in the United States and the European Union for the treatment of metastatic MTC. However, cabozantinib may fail to show adequate safety or efficacy as an anti-cancer drug in clinical testing in other types of cancer. For example, our two phase 3 clinical trials (COMET-1 and COMET-2) of cabozantinib in metastatic castration-resistant prostate cancer, or mCRPC failed to meet their primary endpoints. Based on the outcomes of the COMET trials, we terminated the clinical development of cabozantinib in mCRPC, and other studies in mCRPC sponsored by us, including a randomized phase 2 study of cabozantinib in combination with abiraterone, have been halted.

Furthermore, predicting the timing of the initiation or completion of clinical trials is difficult, and our trials may be delayed due to many factors, including factors outside of our control. The future development path of cabozantinib depends upon the results of each stage of clinical development. We 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 COMETRIQ among physicians, patients, health care payers, and the MTC-treating medical community. It also depends upon how COMETRIQ fares in competition with another product for the treatment of MTC, vandetanib. Looking ahead, as a result of the positive results obtained in the METEOR trial, we are currently ramping up our sales, marketing, and distribution capabilities in anticipation of the FDA's potential approval for cabozantinib for the treatment of patients with advanced RCC who have received one prior therapy. Establishing and maintaining sales, marketing, and distribution capabilities are expensive and time-consuming. Such expenses may be disproportional compared to the revenues we may be able to generate and may have an adverse impact on our results of operations.

For a description of the competition cabozantinib faces in the market for products treating MTC, and may face in the future should it be approved for other indications, please see "- Risks Related to Cabozantinib and Cobimetinib - Our competitors may develop products and technologies that impair the value of cabozantinib and cobimetinib - Competition for cabozantinib."

Convertible Senior Subordinated Notes

In August 2012, we issued and sold $287.5 million aggregate principal amount of the 4.25% Convertible Senior Subordinated Notes due 2019, or the 2019 Notes, for net proceeds of $277.7 million. The 2019 Notes mature on August 15, 2019, unless earlier converted, redeemed or repurchased, and bear interest at a rate of 4.25% per annum, payable semi-annually in arrears on February 15 and August 15 of each year, beginning February 15, 2013. Subject to certain terms and conditions, at any time on or after August 15, 2016, we may redeem for cash all or a portion of the 2019 Notes. The redemption price will equal 100% of the principal amount of the 2019 Notes to be redeemed plus accrued and unpaid interest, if any, to, but excluding, the redemption date. Upon the occurrence of certain circumstances, holders may convert their 2019 Notes prior to the close of business on the business day immediately preceding May 15, 2019. On or after May 15, 2019, until the close of business on the second trading day immediately preceding August 15, 2019, holders may surrender their 2019 Notes for conversion at any time. Upon conversion, we will pay or deliver, as the case may be, cash, shares of our common stock or a combination of cash and shares of our common stock, at our election. The initial conversion rate of 188.2353 shares of common stock per $1,000 principal amount of the 2019 Notes is equivalent to a conversion price of approximately $5.31 per share of common stock and is subject to adjustment in connection with certain events. If a Fundamental Change, as defined in the indenture governing the 2019 Notes, occurs, holders of the 2019 Notes may require us to purchase for cash all or any portion of their 2019 Notes at a purchase price equal to 100% of the principal amount of the Notes to be purchased plus accrued and unpaid interest, if any, to, but excluding, the Fundamental Change purchase date. In addition, if certain specified bankruptcy and insolvency-related events of default occur, the principal of, and accrued and unpaid interest on, all of the then outstanding notes will automatically become due and payable. If an event of default other than certain specified bankruptcy and insolvency-related events of default occurs and is continuing, the Trustee by notice to us or the holders of at least 25% in principal amount of the outstanding 2019 Notes by notice to us and the Trustee, may declare the principal of, and accrued and unpaid interest on, all of the then outstanding 2019 Notes to be due and payable.

In connection with the offering of the 2019 Notes, $36.5 million of the proceeds were deposited into an escrow account which contained an amount of permitted securities sufficient to fund, when due, the total aggregate amount of the first six scheduled semi-annual interest payments on the 2019 Notes. As of September 30, 2015, we have used all of the amount held in the escrow account to pay the required semi-annual interest payments and future semi-annual interest payments will be made from unrestricted cash and investments.

Table of Contents

Deerfield Facility

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, the New Deerfield Purchasers acquired the $100.0 million principal amount of the Original Deerfield Notes and we entered into 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, 2015 and December 31, 2014, the outstanding principal balance on the Deerfield Notes was $101.9 million and $104.0 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.

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 interest expense for the Deerfield Notes (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Stated coupon interest paid in cash	$1,891	$1,512	$4,866	$4,487
Amortization of debt discount, debt issuance costs and accrual of interest paid in kind	1,959	3,005	7,279	8,631
Total interest expense	$3,850	$4,517	$12,145	$13,118

The balance of unamortized fees and costs was $0.8 million and $1.4 million as of September 30, 2015 and December 31, 2014, respectively, which is included in Other assets on the accompanying Condensed Consolidated Balance Sheets. Prior to March 4, 2015, the unamortized discount, fees and costs were amortized into interest expense as a yield adjustment through July 1, 2015. 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 15.27%.

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 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 received no such revenues during the fiscal year ended December 31, 2014 and therefore made no minimum prepayment in January 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 each of 2016, 2017 and 2018. However, we will only be obligated to make any such annual mandatory prepayment if the New Deerfield Purchasers provide notice to us of their election to receive the prepayment. Pursuant to this requirement, we may be required make a mandatory prepayment of $450,000 in January 2016 as a result of to the $3.0 million milestone payment received from Merck during the three months ended September 30, 2015. That portion of the Deerfield Notes is included in current liabilities. Mandatory prepayments relating to Development/Commercialization Revenue will continue to be subject to a maximum annual prepayment amount of $27.5 million. The definition of “Development/Commercialization Revenue” expressly excludes any

Table of Contents

sale or distribution of drug or pharmaceutical products in the ordinary course of our business, and any proceeds from any Intellectual Property Sales (as further described below), 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 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 Deerfield 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 Deerfield 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 Purchases assigned 2014 Deerfield Warrants to OTA LLC. The 2014 Deerfield Warrants contain certain limitations that prevent the holder of the 2014 Deerfield Warrants from acquiring shares upon exercise of a 2014 Deerfield Warrant 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. The number of shares for which the 2014 Deerfield Warrants are exercisable and the associated exercise prices are subject to certain adjustments as set forth in the 2014 Deerfield Warrants. In addition, upon certain changes in control of Exelixis, to the extent the 2014 Deerfield Warrants are not assumed by the acquiring entity, or upon certain defaults under the 2014 Deerfield Warrants, the holder has the right to net exercise the 2014 Deerfield 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 Deerfield Warrants.

In connection with the issuance of the 2014 Deerfield 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 Deerfield 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 December 21, 2004, December 21, 2006 and December 21, 2007, we amended the loan and security agreement to provide for additional equipment lines of credit and on June 2, 2010, we further amended the loan and security agreement to

Table of Contents

provide for a new seven-year term loan in the amount of $80.0 million. As of September 30, 2015, the combined outstanding principal balance due under the lines of credit and term loan was $80.0 million, compared to $80.4 million as of December 31, 2014. 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. We are required to repay any advances under an equipment line of credit in 48 equal monthly payments of principal and interest. 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. We have the option to prepay without penalty any advance under an equipment line of credit other than advances under a single equipment line of credit, which has a 1.0% prepayment penalty, provided that we pay all unpaid accrued interest thereon that is due through the date of such prepayment. 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 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.

2014 Restructuring

On September 2, 2014, as a consequence of the failure of COMET-1, one of our two phase 3 pivotal trials of cabozantinib in mCRPC, we initiated the 2014 Restructuring to reduce our workforce. Personnel reductions were initiated across our entire organization and have resulted in an aggregate reduction in headcount of 143 full-time employees as of September 30, 2015. The principal objective of the 2014 Restructuring was to enable us to focus our financial resources on the phase 3 pivotal trials of cabozantinib in advanced RCC and advanced HCC.

For the nine months ended September 30, 2015 and 2014, we recorded restructuring charges of $0.5 million and $3.3 million, respectively, for the 2014 Restructurings. The restructuring charge for the nine months ended September 30, 2015 included $1.5 million in additional charges due to the partial termination of one of our building leases and additional facility-related charges related to the decommissioning and exit of certain buildings. The restructuring charge for the nine months ended September 30, 2015 was partially offset by $0.9 million in recoveries recorded in connection with the sale of excess equipment and other assets. The restructuring charge for the nine months ended September 30, 2014 includes $2.6 million of employee severance and other benefits that are recognized ratably during the period from the implementation date of the 2014 Restructuring through the employees' termination dates. In addition, during the nine months ended 2014 we recorded $0.7 million of property and equipment write-downs. Employee severance and other benefits are recognized ratably during the period from the implementation date of the 2014 Restructuring through the employees' termination dates.

Critical Accounting Estimates

The preparation of our consolidated financial statements is in conformity with accounting principles generally accepted in the United States which 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 inventory, revenue recognition, valuation of long-lived assets, certain accrued liabilities including clinical trial accruals and restructuring liability, valuation of warrants, share-based compensation and the valuation of the debt and equity components of our convertible debt at issuance. 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. Our senior management has discussed the development, selection, and disclosure of these estimates with the Audit Committee of our Board of Directors. Actual results could differ materially from these 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.

Table of Contents

Revenue Recognition

Product Sales

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 the specialty pharmacy. For product sales in Europe, this generally occurs when our European distribution partner has accepted the product, at which time they are no longer able to return the product.

We sell our product, COMETRIQ, in the United States to a specialty pharmacy that benefits from customer incentives and has a right of return. 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 the specialty pharmacy, therefore we recognized revenue when the specialty pharmacy provided the product to a patient based on the fulfillment of a prescription, frequently referred to as the “sell-through” revenue recognition model. Recently we have established sufficient historical experience and data to reasonably estimate expected future returns of the product 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 our U.S. 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 and related costs that had previously been deferred at December 31, 2014, resulting in additional gross product revenues of $2.6 million and a nominal amount of cost of goods sold for the nine months ended September 30, 2015; there were no such adjustments recorded for the three months ended September 30, 2015.

We also utilize the “sell-in” revenue recognition model for sales to our European distribution partner. Once the European distributer has accepted the product, the product is no longer subject to return; therefore, we record revenue at the time our European distribution partner has accepted the product.

Product Sales Discounts and Allowances

We calculate gross product revenues based on the price that we charge our United States specialty pharmacy and our European distribution partner. We estimate our domestic net product revenues by deducting from our gross product revenues (a) trade allowances, such as discounts for prompt payment, (b) estimated government rebates and chargebacks, and (c) estimated costs of patient assistance programs. Discounts and allowances for foreign sales for the nine months ended September 30, 2015 and three and nine months ended September 30, 2014 included portions of a one-time $2.4 million project management fee payable to our European distribution partner upon its achievement of a cumulative revenue goal. During the three months ended September 30, 2014, we determined that the achievement of the revenue goal was probable and therefore we recorded $1.8 million of the project management fee. $1.0 million of the $1.8 million we recorded during the three months ended September 30, 2014 represented amounts that would have been previously recorded had the cumulative revenue goal been determined to be probable in those periods. During the nine months ended September 30, 2015 we recorded an additional $0.1 million of the project management fee; no such fees were recognized within product sales during the three months ended September 30, 2015. We also deduct from gross product revenues an estimated credit for product originally delivered with expiry of 18 months or less that is potentially payable to our European distribution partner; such deductions were nominal during the three and nine months ended September 30, 2015 and 2014.

We initially record estimates for these deductions at the time we recognize the gross revenue. We update our estimates on a recurring basis as new information becomes available. 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, 2014 for a further description of our discounts and allowances.

Other than changes to revenue recognition, there have been no significant changes in our critical accounting policies and estimates during the nine months ended September 30, 2015, 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, 2014.

Fiscal Year Convention

Exelixis adopted a 52- or 53-week fiscal year that generally ends on the Friday closest to December 31st. Fiscal year 2015, a 52-week year, will end on January 1, 2016, and fiscal year 2014, a 53-week year, ended on January 2, 2015. For convenience, references in this report as of and for the fiscal periods ended October 2, 2015 and September 26, 2014, and as of and for the fiscal years ended January 1, 2016 and January 2, 2015, are indicated as being as of and for the periods ended September 30, 2015, September 30, 2014, December 31, 2015, and December 31, 2014, respectively.

Results of Operations

Revenues

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Gross product revenues	$7,230	$8,616	$25,794	$20,761
Discounts and allowances	(376)	(2,325)	(1,560)	(3,003)
Net product revenues	6,854	6,291	24,234	17,758
Contract revenues	3,000	—	3,000	—
Total revenues	$9,854	$6,291	$27,234	$17,758
Dollar change	$3,563		$9,476	
Percentage change	57%		53%	

Product revenues relate to the sale of COMETRIQ. The decrease in gross product revenue for the three months ended September 30, 2015 reflects a decline in shipments of COMETRIQ partially offset by an increase in our average selling price. The increase in gross product revenues for the nine months ended September 30, 2015 reflects an overall increase in shipments of COMETRIQ and the impact of a change to the “sell-in” method which resulted in the one-time recognition of $2.6 million of deferred revenue attributable to sales to the specialty pharmacy that sells COMETRIQ in the United States in the first quarter of 2015; there was no such adjustment recorded for the three months ended September 30, 2015 or during the comparable periods in 2014.

For domestic sales, we have transitioned from the “sell-through” method to the “sell-in” method of recognizing product revenue as we have established sufficient history to reasonably estimate expected returns of the product and the discounts and rebates due to payers. For foreign sales, we continue to utilize the “sell-in” method to recognize product revenue for all periods presented.

We calculate gross product revenues based on the price that we charge our United States specialty pharmacy and our European distribution partner. We estimate our domestic net product revenues by deducting from our gross product revenues (a) trade allowances, such as discounts for prompt payment, (b) estimated government rebates and chargebacks, and (c) estimated costs of patient assistance programs. Discounts and allowances for foreign sales for the nine months ended September 30, 2015 and three and nine months ended September 30, 2014 included portions of a one-time $2.4 million project management fee payable to our European distribution partner upon its achievement of a cumulative revenue goal. During the three months ended September 30, 2014, we determined that the achievement of the revenue goal was probable and therefore we recorded $1.8 million of the project management fee. $1.0 million of the $1.8 million we recorded during the three months ended September 30, 2014 represented amounts that would have been previously recorded had the cumulative revenue goal been determined to be probable in those periods. During the nine months ended September 30, 2015 we recorded an additional $0.1 million of the project management fee; no such fees were recognized within product sales during the three months ended September 30, 2015. We also deduct from gross product revenues an estimated credit for product originally delivered with expiry of 18 months or less that is potentially payable to our European distribution partner.

Contract revenues reflect a $3.0 million milestone payment received from Merck related to its worldwide license of our PI3K-delta program.

Table of Contents

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Collaboration agreements:				
Merck	$3,000	$—	$3,000	$—
Product sales:				
Diplomat Specialty Pharmacy	6,457	6,791	21,567	17,742
Swedish Orphan Biovitrum (1)	397	(500)	2,667	16
Total revenues	$9,854	$6,291	$27,234	$17,758
Dollar change	$3,563		$9,476	
Percentage change	57%		53%	

(1) Revenues from Swedish Orphan Biovitrum for the three and nine months ended September 30, 2014 are net of a $1.8 million project management fee payable to our European distribution partner. $1.0 million of the $1.8 million we recorded represents amounts that would have been previously recorded had the cumulative revenue goal been determined to be probable in those periods.

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 we are required to pay GlaxoSmithKline, and to a lesser extent, indirect labor costs, the cost of manufacturing, write-downs related to expiring and excess inventory, and other third party logistics costs for our product. A portion of the manufacturing costs for product sales were incurred prior to regulatory approval of COMETRIQ for the treatment of progressive, metastatic MTC 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,	
	2015	2014	2015	2014
Cost of goods sold	$1,420	$573	$2,872	$1,359
Gross margin	79%	91%	88%	92%

The increase in the cost of goods sold for the three and nine months ended September 30, 2015, as compared to the comparable periods in 2014, was a result of write-downs related to expiring and excess inventory of $0.9 million and $1.1 million for the three and nine months ended September 30, 2015, respectively, increased sales of COMETRIQ, as well as decreases in the amount of product sold that had been expensed as research and development expense prior to regulatory approval. Write-downs related to expiring and excess inventory were nominal for the comparable periods in 2014.

Gross margin is net revenues less cost of goods sold, divided by net revenues. Gross margin decreased for the three and nine months ended September 30, 2015, for the reasons described above. The cost of goods sold and gross margin we have experienced since our 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,	
	2015	2014	2015	2014
Research and development expenses	$26,091	$43,628	$72,879	$149,451
Dollar change	$(17,537)		$(76,572)	
Percentage change	(40)%		(51)%	

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

31

Table of Contents

The decrease in research and development expenses for the three and nine months ended September 30, 2015, as compared to the comparable periods in 2014, was primarily related to a decrease in clinical trial costs, which includes services performed by third-party contract research organizations and other vendors that support our clinical trials. The decrease in clinical trial costs was $16.8 million, or 62%, for the three months ended September 30, 2015 and $52.2 million, or 59%, for the nine months ended September 30, 2015, as compared to the comparable periods in 2014. The decrease in clinical trial costs for both the three and nine months ended September 30, 2015, as compared to the comparable periods in 2014 was predominantly due to decreases in costs related to COMET-1 and COMET-2, our phase 3 pivotal trials in metastatic CRPC which we terminated in September 2014, METEOR, our phase 3 pivotal trial in advanced RCC, and a reduction of general program level costs; the decrease in clinical trial costs for the nine months ended September 30, 2015 included the impact of a $4.9 million decrease in comparator drug purchases for METEOR.

Decreases in research and development expenses for the three and nine months ended September 30, 2015 also related to personnel expenses, consulting and outside services and temporary personnel. Personnel expenses decreased by $2.5 million and $14.4 million for the three and nine months ended September 30, 2015, respectively, as compared to the comparable periods in 2014 primarily due to workforce reductions undertaken as a consequence of the failure of COMET-1. Consulting and outside services decreased by $0.7 million and $4.0 million for the three and nine months ended September 30, 2015, respectively, as compared to the comparable periods in 2014 primarily as a result of decreases in clinical development consulting activities and the use of outside medical safety liaisons. Temporary personnel decreased by $1.2 million and $2.9 million for the three and nine months ended September 30, 2015, respectively, as compared to the comparable periods in 2014 due to a decrease in clinical trial activities performed by those personnel. Those decreases were partially offset by an increase in stock-based compensation, which increased by $6.6 million and $4.9 million for the three and nine months ended September 30, 2015, respectively, as compared to the comparable periods in 2014, primarily due to the vesting of performance-based stock options that have performance goals which were achieved in July 2015 when it was determined that top-line data received from METEOR met its primary endpoint.

Historically, we grouped our research and development expenses into three categories: development, drug discovery and other. As noted under “Overview”, 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 nearly all of our future research and development expenses to relate to the clinical development of cabozantinib. Additionally, as a consequence of our focus on cabozantinib, we have discontinued all of our drug discovery efforts. As a result of this shift in business strategy and the limited relevance of the disclosure with respect to our current operations, we no longer disclose the breakdown of our research and development expenses by category.

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 forty clinical trials across multiple indications, including two ongoing phase 3 pivotal trials focusing on advanced RCC and advanced HCC. In addition, postmarketing commitments in connection with the approvals of COMETRIQ in MTC dictate that we conduct additional studies in that indication.

We anticipate that research and development expenses will increase during the fourth quarter of 2015 as compared to the third quarter of 2015 as a result of our continuing shift from clinical trial activities for METEOR to activities necessary to complete regulatory filings in the U.S. and EU for cabozantinib in the treatment of advanced RCC.

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.

Table of Contents

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,	
	2015	2014	2015	2014
Selling, general and administrative expenses	$17,842	$9,906	$40,162	$41,063
Dollar change	$7,936		$(901)	
Percentage change	80%		(2)%	

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

The change in selling, general and administrative expenses for the three and nine months ended September 30, 2015, as compared to the comparable periods in 2014, was primarily related to increases in marketing costs and stock-based compensation. Marketing expenses increased by $2.5 million and $6.6 million for the three and nine months ended September 30, 2015, respectively, as compared to the comparable periods in 2014, which includes our share of the pre-commercial preparation expenses for cobimetinib under our collaboration agreement with Genentech. Stock-based compensation, increased by $4.7 million and $2.0 million for the three and nine months ended September 30, 2015, respectively, as compared to the comparable periods in 2014, primarily due to the vesting of performance-based stock options that have performance goals which were achieved in July 2015 when it was determined that top-line data received from METEOR met its primary endpoint. Those increases were partially offset by decreases in consulting and outside services, facilities costs and personnel costs. Consulting and outside services decreased by $0.9 million and $3.8 million for the three and nine months ended September 30, 2015, respectively, as compared to the comparable periods in 2014, primarily as a result of decreases in marketing research activities, a reduction in fixed fees paid to Sobi, reductions in outside services for buildings we are no longer occupying and our Board of Directors' decision to receive stock awards in lieu of cash compensation for services rendered during the fourth quarter of 2014 and all of 2015. Facilities costs decreased by $1.1 million and $1.7 million for the three and nine months ended September 30, 2015, respectively, as compared to the comparable periods in 2014, primarily as a result of facilities we have vacated in connection with the 2014 Restructuring. Personnel expenses decreased by $6.6 million for the nine months ended September 30, 2015, as compared to the comparable period in 2014, primarily due to workforce reductions undertaken as a consequence of the failure of COMET-1; personal expenses increased $0.2 million for the three months ended September 30, 2015, as compared to the comparable period in 2014, in part due to a $1.2 million reversal of accrued employee bonuses that occurred in 2014 which offset the impact of workforce reductions described above.

Following the announcement of positive top-line results from the primary analysis of METEOR and the U.S. FDA's approved cobimetinib under the brand name COTELLIC for use in combination with vemurafenib as a treatment for patients with BRAF V600 mutation-positive advanced melanoma, on November 10, 2015, we anticipate selling, general and administrative expenses will increase during the fourth quarter of 2015 as we increase our commercial activities in preparation for the potential launch of cobimetinib and cabozantinib.

Restructuring Charge

On September 2, 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 the 2014 Restructuring to reduce our workforce. Personnel reductions were initiated across our entire organization that resulted in an aggregate reduction in headcount of 143 full-time employees as of September 30, 2015. The principal objective of the 2014 Restructuring was to enable us to focus our financial resources on the phase 3 pivotal trials of cabozantinib in advanced RCC and advanced HCC.

Between March 2010 and May 2013, we implemented five restructurings (referred 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. The aggregate reduction in headcount from the 2010 Restructurings was 429 employees. Charges and recoveries related to the 2010 Restructurings were recorded in periods other than those in which the 2010 Restructurings were implemented as a

result of sublease activities for certain of our buildings in South San Francisco, California, changes in assumptions regarding anticipated sublease activities, the effect of the passage of time on our discounted cash flow computations, previously planned employee terminations, and sales of excess equipment and other assets.

Table of Contents

Total restructuring charge for both for restructurings 2010 Restructurings and 2014 Restructuring was as follows (dollars in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Restructuring charge	$282	$3,758	$1,142	$4,135
Dollar change	$(3,476)		$(2,993)	
Percentage change	(92)%		(72)%	

The charges for each of the periods presented include 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. The restructuring charge for the nine months ended September 30, 2015 also included $2.2 million in additional charges due to the early termination of one of our building leases, the impact of a new sublease executed in June 2015, additional changes in assumptions regarding anticipated sublease activities, and additional facility-related charges related to the decommissioning and exit of certain buildings. The restructuring charge for the nine months ended September 30, 2015 was partially offset by $0.9 million in recoveries recorded in connection with the sale of excess equipment and other assets. The restructuring charge during the three and nine months ended September 30, 2014 includes $2.6 million of employee severance and other benefits from the implementation of the 2014 Restructuring, $0.8 million related to the effect of the passage of time on our discounted cash flow computations for the exit, in prior periods, of certain of our South San Francisco buildings, and $0.7 million of property and equipment write-downs.

Total Other Income (Expense), Net

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Interest income and other, net	$276	$1,296	$146	$3,786
Interest expense	(12,059)	(12,282)	(36,421)	(36,125)
Total other expense, net	$(11,783)	$(10,986)	$(36,275)	$(32,339)
Dollar change	$(797)		$(3,936)	
Percentage change	7%		12%	

Total other income (expense), net consists primarily of interest expense incurred on our debt, partially offset by interest income earned on our cash and investments and gains and losses on derivatives and foreign exchange fluctuations. Interest expense includes aggregate non-cash interest expense on both the 2019 Notes and the Deerfield Notes of $6.9 million and $21.8 million for the three and nine months ended September 30, 2015, respectively, as compared to $7.5 million and $21.8 million for the comparable periods in 2014, respectively. Interest income and other, net for the nine months ended September 30, 2015 and 2014 includes $0.5 million in unrealized losses and $1.9 million in unrealized gains, respectively, on the revaluation of the 2014 Deerfield Warrants. Interest income and other, net for both the three and nine months ended September 30, 2014 also includes an $0.8 million gain for a purchase price adjustment resulting from the resolution of contingencies related to the September 2011 sale of our remaining interest in Artemis Pharmaceuticals GmbH to Taconic Farms, Inc.

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,	
	2015	2014
Net loss	$(126,096)	$(210,589)
Net cash used in operating activities	(106,152)	(185,429)
Net cash provided by investing activities	26,068	116,154
Net cash provided by financing activities	145,331	65,362
Net increase (decrease) in cash and cash equivalents	65,247	(3,913)
Cash and cash equivalents at beginning of period	80,395	103,978
Cash and cash equivalents at end of period	$145,642	$100,065

We commercially launched COMETRIQ for the treatment of progressive, metastatic MTC in the United States in late January 2013, and from the commercial launch through September 30, 2015 we have generated $64.4 million in net revenues from the sale of COMETRIQ. Other than revenues from COMETRIQ, we have derived substantially all of our revenues since inception from collaborative research and development agreements, which depend on research funding, the achievement of milestones, and royalties we earn from any future 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 used cash of $106.2 million for the nine months ended September 30, 2015, compared to $185.4 million for the same period in 2014. Operating cash flows can differ from our consolidated net loss as a result of differences in the timing of cash receipts and earnings recognition and non-cash charges.

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 $20.2 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.

Cash used in operating activities for the nine months ended September 30, 2014 related primarily to our $196.0 million operating expenses for the period, less non-cash expenses for accretion of debt discount totaling $21.8 million on the Deerfield Notes and the 2019 Notes, stock-based compensation totaling $8.5 million, depreciation and amortization totaling $3.0 million and revenues totaling $17.8 million. Our operating expenses were largely attributable to the development of cabozantinib. In addition, we made cash payments that resulted in an $11.6 million reduction in accounts payable and other accrued expenses during the period and paid $5.0 million for restructuring activities; those cash payments were offset by a $10.1 million increase in accrued clinical trial liabilities.

Investing Activities

Our investing activities provided cash of $26.1 million for the nine months ended September 30, 2015, compared to $116.2 million for the same period in 2014.

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.

Cash provided by investing activities for the nine months ended September 30, 2014 was primarily due to the maturity of unrestricted and restricted investments of $232.9 million, less investment purchases of $117.4 million.

Financing Activities

Cash provided by financing activities was $145.3 million for the nine months ended September 30, 2015, compared to $65.4 million for the same period in 2014.

Table of Contents

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.

Cash provided by our financing activities for the nine months ended September 30, 2014 was primarily due to the issuance of 10,000,000 shares of common stock in January 2014 for net proceeds of $75.6 million. The cash provided by the issuance of common stock was partially offset by principal payments on debt of $11.3 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, 2015, with the exception of the 2011 fiscal year. We anticipate net losses and negative operating cash flow for the foreseeable future. For the nine months ended September 30, 2015, we incurred a net loss of $126.1 million and as of September 30, 2015, we had an accumulated deficit of $1.9 billion. These losses have had, and will continue to have, an adverse effect on our stockholders' deficit 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 whether or when we will become profitable, if at all. Our research and development expenditures and selling, general and administrative expenses have exceeded our revenues for each fiscal year other than the 2011 fiscal year, and we expect to spend significant additional amounts to fund the continued development and commercialization of cabozantinib. 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.

We commercially launched COMETRIQ for the treatment of progressive, metastatic MTC in the United States in late January 2013, and from the commercial launch through September 30, 2015 we have generated $64.4 million in net revenues from the sale of COMETRIQ. Other than revenues from COMETRIQ, we have derived substantially all of our revenues since inception from collaborative research and development agreements, which depend on research funding, the achievement of milestones, and royalties we earn from any future products developed from the collaborative research.

The amount of our net losses will depend, in part, on: the rate of growth, if any, in our sales of COMETRIQ; our share of the net profits and losses for the commercialization for cobimetinib in the U.S., if any; the receipt of royalties from cobimetinib sales outside the U.S., if any; partnering activities for cabozantinib; other license and contract revenues; and, the level of expenses primarily with respect to development and commercialization activities for cabozantinib.

As of September 30, 2015, we had $282.1 million in cash and investments, which included $197.8 million available for operations, $81.6 million of compensating balance investments that we are required to maintain on deposit with Silicon Valley Bank, and $2.7 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 end of the third quarter of 2015. While a forecast of future events is inherently uncertain, our ability to sustain our business operations for this time period without additional financing is highly dependent upon the commercial success of COMETRIQ and the revenues we generate, as well as the commercial success of COTELLIC and our share of related net profits and losses and royalties under our collaboration with Genentech. It is also dependent upon whether and when we partner cabozantinib with a global pharmaceutical organization for further development and sales outside the U.S., and the upfront payments and milestones associated with any such transaction. Consistent with the actions we have taken in the past, we will prioritize necessary and appropriate steps to ensure the continued operation of our business and preservation of the value of our assets. However, our future capital requirements will be substantial, and we may need to raise additional capital in the future. 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. These factors include:

- the pace and progress of our current ramping up of sales, marketing, and distribution capabilities in anticipation of obtaining FDA approval for cabozantinib for the potential treatment of advanced RCC patients;

- the commercial success of COMETRIQ and COTELLIC and the revenues we generate;
- the progress and scope of other development and commercialization activities for cabozantinib and our other compounds;
- our obligation to share U.S. sales and marketing costs for cobimetinib under our collaboration with Genentech;

Table of Contents

- the commercial success of cobimetinib and our share of related profits and losses for the commercialization of cobimetinib in the U.S. and receipt of royalties from cobimetinib sales outside the U.S. under our collaboration with Genentech;
- our ability to obtain regulatory approval for cabozantinib for the treatment of advanced RCC and other indications;
- the amount of expenses we incur in the build-out of our sales, marketing and distribution capabilities;
- whether, when and the terms upon which we partner cabozantinib with a global pharmaceutical organization for further development and sales outside the U.S., and the sufficiency of upfront payments and milestones associated with any such transaction to meet our capital needs;
- future clinical trial results, notably the results from CELESTIAL, our phase 3 pivotal trial in patients with advanced HCC;
- repayment of the Deerfield Notes which mature on July 1, 2018, subject to a requirement to make a mandatory prepayment in each of 2016, 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 $287.5 million aggregate principal amount of the 2019 Notes, which mature on August 15, 2019, unless earlier converted, redeemed or repurchased;
- repayment of our term loan and line of credit from Silicon Valley Bank, which had an outstanding balance at September 30, 2015, of $80.0 million;
- 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;
- our need to expand our product and clinical development efforts;
- the cost and timing of regulatory approvals;
- the cost of clinical drug supply for our clinical trials;
- the effect of economic and 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.

In addition, we may need to obtain additional funding in order to stay in compliance with covenants contained in our loan and security agreement with Silicon Valley Bank. This agreement contains covenants or events of default requiring us to maintain specified collateral balances. The failure to comply with these covenants could result in an acceleration of the underlying debt obligations. If we are unable to remain in compliance with such covenants or if we are unable to renegotiate such covenants and the lender exercises its remedies under the agreement, we would not be able to operate under our current operating plan.

Contractual Obligations

We have contractual obligations in the form of debt, loans payable, operating leases, purchase obligations and other long-term liabilities. As a result of our extension of the maturity date of the Deerfield Notes to 2018, the outstanding principal has been reclassified from current to long-term liabilities as of September 30, 2015. There were no other material changes outside of the ordinary course of business in our contractual obligations from those as of December 31, 2014.

Off-Balance Sheet Arrangements

As of September 30, 2015, 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, 2015 have not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2014, filed with the Securities and Exchange Commission on March 2, 2015.

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, 2015, and December 31, 2014, 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 $7.0 million and $7.8 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, 2015, and December 31, 2014, approximately $3.7 million and $5.5 million, respectively, of our clinical accrual balance 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 $0.1 million gain relating to foreign exchange fluctuations for both the nine months ended September 30, 2015 and 2014.

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.

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

We are not a party to any material legal proceedings. We may from time to time become a party to various 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 presently 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 2, 2015 filed with the Securities and Exchange Commission on March 2, 2015. In addition, the risk factors in our Annual Report on Form 10-K for the fiscal year ended January 2, 2015, relating to potentially not achieving the benefits of our cost savings initiatives and the changes to our corporate structure have been removed.

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, or any similar costs we are obligated to fund under collaborations we may enter into in the future.

As of September 30, 2015, we had $282.1 million in cash and investments, which included $197.8 million available for operations, $81.6 million of compensating balance investments that we are required to maintain on deposit with Silicon Valley Bank, and $2.7 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 end of the third quarter of 2015. While a forecast of future events is inherently uncertain, our ability to sustain our business operations for this time period without additional financing is highly dependent upon the commercial success of COMETRIQ and the revenues we generate, as well as the commercial success of COTELLIC and our share of related net profits and losses and royalties under our collaboration with Genentech. It is also dependent upon whether and when we partner cabozantinib with a global pharmaceutical organization for further development and sales outside the U.S., and the upfront payments and milestones associated with any such transaction. Consistent with the actions we have taken in the past, we will prioritize necessary and appropriate steps to ensure the continued operation of our business and preservation of the value of our assets. However, our future capital requirements will be substantial, and we may need to raise additional capital in the future. 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. These factors include:

- the progress and scope of the cabozantinib development and commercialization activities;
- the commercial success of COMETRIQ and the revenues we generate;
- our obligation to share U.S. sales and marketing costs for cobimetinib under our collaboration with Genentech;
- the commercial success of cobimetinib and our share of related profits and losses for the commercialization of cobimetinib in the U.S. and receipt of royalties from cobimetinib sales outside the U.S. under our collaboration with Genentech;

39

Table of Contents

- our ability to obtain regulatory approval for cabozantinib for the treatment of advanced RCC and other indications;
- the amount of expenses we incur in the build-out of our sales, marketing and distribution capabilities;
- whether, when and the terms upon which we partner cabozantinib with a global pharmaceutical organization for further development and sales outside the U.S., and the sufficiency of upfront payments and milestones associated with any such transaction to meet our capital needs;
- future clinical trial results, notably the results from CELESTIAL, our phase 3 pivotal trial in patients with advanced HCC;
- repayment of the Deerfield Notes which mature on July 1, 2018, subject to a requirement to make a mandatory prepayment in each of 2016, 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 $287.5 million aggregate principal amount of the 2019 Notes, which mature on August 15, 2019, unless earlier converted, redeemed or repurchased;
- repayment of our term loan and line of credit from Silicon Valley Bank, which had an outstanding balance at September 30, 2015, of $80.0 million;
- 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;
- our need to expand our product and clinical development efforts;
- the cost and timing of regulatory approvals;
- the cost of clinical and research drug supply for our clinical trials;
- the effect of economic and 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.

In addition, we may need to obtain additional funding in order to stay in compliance with covenants contained in our loan and security agreement with Silicon Valley Bank. This agreement contains covenants or events of default requiring us to maintain specified collateral balances. The failure to comply with these covenants could result in an acceleration of the underlying debt obligations. If we are unable to remain in compliance with such covenants or if we are unable to renegotiate such covenants and the lender exercises its remedies under the agreement, we would not be able to operate under our current operating plan.

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, 2015, with the exception of the 2011 fiscal year. We anticipate net losses and negative operating cash flow for the foreseeable future. For the nine months ended September 30, 2015, we incurred a net loss of $126.1 million and as of September 30, 2015, we had an accumulated deficit of $1.9 billion. These losses have had, and will continue to have, an adverse effect on our stockholders' deficit 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 whether or when we will become profitable, if at all. Our research and development expenditures and selling, general and administrative expenses have exceeded our revenues for each year other than the 2011 fiscal year, and we expect to spend significant additional amounts to fund the continued development and commercialization of cabozantinib. 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. We commercially launched COMETRIQ for the treatment of progressive, metastatic MTC in the United States in late January 2013, and from the commercial launch through September 30, 2015 we have generated $64.4 million in net revenues from the sale of COMETRIQ. Other than revenues from COMETRIQ, we have derived substantially all of our revenues since inception from collaborative research and development agreements, which depend on research funding, the achievement of milestones, and royalties we earn from any future products developed from the

collaborative research. If the amount of research funding we receive from our collaborators decreases, if our collaborators fail to develop successful products, if we are

Table of Contents

unable to successfully achieve the milestones under our collaboration agreements, or if sales of products to which we are entitled to royalties under such agreements are weak, our revenues and financial condition would be materially adversely affected.

The amount of our net losses will depend, in part, on our sales of COMETRIQ, our share of the net profits and losses for the commercialization for cobimetinib in the U.S., if any, the receipt of royalties from cobimetinib sales outside the U.S., if any, partnering activities for cabozantinib, other license and contract revenues, and the level of expenses with respect to development and commercialization activities, including for cabozantinib.

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, our loan and security agreement with Silicon Valley Bank and the 2019 Notes. As of September 30, 2015, our total consolidated indebtedness through maturity was $492.4 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 2019 Notes, the Deerfield Notes, 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;
- preventing us from raising funds necessary to purchase the 2019 Notes in the event we are required to do so following a “Fundamental Change” as specified in the indenture governing the 2019 Notes, or to settle conversions of the 2019 Notes in cash;
- dilution experienced by our existing stockholders as a result of the conversion of the 2019 Notes or 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 2019 Notes, 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 or the Trustee of the 2019 Notes or other indebtedness to accelerate the maturity of such notes or other indebtedness and could cause defaults under the 2019 Notes, the Deerfield Notes, our loan and security agreement with Silicon Valley Bank or our other indebtedness. Any default under the 2019 Notes, 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.

If a Fundamental Change, as defined in the indenture governing the 2019 Notes, occurs, holders of the 2019 Notes may require us to purchase for cash all or any portion of their 2019 Notes at a purchase price equal to 100% of the principal amount of the Notes to be purchased plus accrued and unpaid interest, if any, to, but excluding, the

Fundamental Change purchase date. We may not have sufficient funds to purchase the notes upon a Fundamental Change. In addition, the terms of any borrowing agreements that we may enter into from time to time may require early repayment of borrowings under circumstances similar to those constituting a Fundamental Change. Furthermore, any repurchase of 2019 Notes by us may be considered an event of default under such borrowing agreements.

Table of Contents

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 expenses incurred 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 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, 2015, 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 Cabozantinib and Cobimetinib

In the short-term, our prospects are critically dependent upon our ability to obtain FDA approval for cabozantinib in advanced RCC and then undertake a successful commercial launch of the product in the U.S.*

The success of our business is dependent upon the successful development and commercialization of cabozantinib. Of greatest short-term importance is the development and commercialization of cabozantinib for advanced RCC. On July 20, 2015, we announced that METEOR, a phase 3 pivotal trial comparing cabozantinib to everolimus in patients with advanced RCC who have experienced disease progression following treatment with at least one prior VEGFR TKI, met its primary endpoint of demonstrating a statistically significant increase in PFS for cabozantinib versus everolimus in the first 375 randomized patients as determined by an IRC. Data pertaining to OS in the entire study population of 658 patients, a secondary endpoint of the trial, were immature at the data cutoff, and we cannot be certain that the final analysis of OS anticipated in 2016 will be consistent with the trend in OS favoring cabozantinib that was observed in our interim analysis. In August 2015 the FDA granted Breakthrough Therapy Designation to cabozantinib as a potential treatment for RCC. Although we plan to complete regulatory filings in the United States before the end of 2015 for treatment of advanced RCC, we cannot be certain that this filing will be made when expected, or at all, or that the FDA will ultimately approve cabozantinib for advanced RCC. If we are ultimately unsuccessful in obtaining FDA approval for cabozantinib for advanced RCC we will not have the resources necessary to continue our business in its current form.

In addition, even if such approval is obtained, the commercial potential of cabozantinib for the treatment of advanced RCC remains subject to a variety of factors, including the final analysis of OS expected in 2016, the perceived benefits associated with the median PFS of patients receiving cabozantinib as compared to everolimus, and the availability and benefits of competitive treatments. We believe that if cabozantinib is approved for the treatment of 2nd or later-line advanced RCC, its potential principal competition in this indication could include axitinib and everolimus, which are already approved in this indication, as well as other agents currently approved for 1st-line RCC including sunitinib, sorafenib, pazopanib, temsirolimus, and bevacizumab. Other agents being investigated in 2nd line advanced RCC, including Bristol-Myers Squibb's nivolumab, may also become competitive treatments if they are approved. In particular, on July 20, 2015, Bristol-Myers Squibb announced that the phase 3 trial comparing nivolumab to everolimus in advanced RCC patients who had received previous antiangiogenic therapy (Checkmate 025) had met its primary endpoint of showing an improvement in overall survival for patients treated with nivolumab. We anticipate that nivolumab may be approved for use in 2nd or later-line patients before cabozantinib and, should cabozantinib be approved for a similar indication, nivolumab will provide immediate direct competition for cabozantinib in this

market.

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 assuming cabozantinib's approval in the U.S. and EU for the treatment of advanced RCC, our longer-term success remains contingent upon, among other things, successful clinical development, regulatory approval and

Table of Contents

market acceptance of cabozantinib in additional indications, such as HCC, first-line RCC, 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. These failures demonstrate that cabozantinib will not likely be successful in all future clinical trials. Should we prove unsuccessful in the further development of cabozantinib beyond MTC and advanced RCC, our longer-term prospects, revenues and financial condition would be materially adversely affected.

We are dependent on the successful commercialization and development of cobimetinib, and rely heavily on our partner, Genentech, for achieving that success.*

In 2009, we entered into a worldwide collaboration agreement with Genentech for the development and commercialization of cobimetinib, a compound discovered by Exelixis and licensed to Genentech after determination of the maximum tolerated dose in a phase 1 clinical trial. Genentech is solely responsible for cobimetinib's commercialization and development. Under the terms of the collaboration agreement, we are entitled to an initial equal share of U.S. profits and losses for cobimetinib, with our share decreasing as sales increase, and we will share in the U.S. sales and marketing costs. We have exercised a co-promotion option in the collaboration agreement, and so will provide 25% of the total sales force for cobimetinib in the United States.

Following positive results from coBRIM a phase 3 pivotal trial, on November 10, 2015, cobimetinib was approved in the U.S. by the FDA under the brand name COTELLIC in combination with vemurafenib as a treatment for patients with BRAF V600 mutation-positive advanced melanoma. In Switzerland, cobimetinib in combination with vemurafenib was approved in August 2015 as a treatment for patients with BRAF V600 mutation-positive advanced melanoma. Roche also filed a Marketing Authorization Application for cobimetinib in combination with vemurafenib for the same indication with the European Medicines Agency in late 2014. Roche anticipates a regulatory decision before the end of 2015 following a positive opinion issued by the European Committee for Medicinal Products for Human Use, announced in late September.

Under the terms of our collaboration agreement, we depend upon Genentech's strategic and tactical planning, decision-making, and execution with regard to the worldwide commercialization of cobimetinib and, during the period prior to commercialization, we have been obligated to reimburse half of Genentech's costs for commercializing the drug in the U.S. Genentech, and its parent, the Roche group, may not fund or otherwise resource and prioritize the commercialization of cobimetinib for the indication currently approved in the U.S. and Switzerland and under review in the EU sufficient to achieve the product's full commercial potential. And, regardless of the level of Genentech's investment in cobimetinib, the compound may not be accepted by physicians, patients, health care payers, such as Medicare and Medicaid, and the medical community.

We similarly rely heavily upon Genentech's leadership and expertise to further develop cobimetinib. 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 agreement and result in harm to our business and operations. Genentech has complete financial responsibility for cobimetinib's development program, 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 is currently conducting a phase 1b clinical trial combining cobimetinib with the Genentech PD-L1 antibody (MPDL3280A), we are dependent on Genentech for all future development of cobimetinib in combination with MPDL3280A 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 data supporting product label expansions or approval in additional indications.

The commercial success of cabozantinib, as COMETRIQ capsules for MTC or if approved in a tablet formulation for additional indications in the future, will depend upon the degree of market acceptance for cabozantinib among physicians, patients, health care payers, and the medical community.*

Our ability to commercialize cabozantinib, as COMETRIQ capsules for the approved MTC indication or if approved in a tablet formulation 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 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;
- the existence of any significant side effects of cabozantinib, as well as their severity in comparison to those of any competing products;
- potential advantages or disadvantages in relation to alternative treatments;

Table of Contents

- 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 and distribution support; and
- sufficient third-party coverage and reimbursement.

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. We are currently ramping up our sales, marketing, and distribution capabilities in anticipation of obtaining FDA approval for cabozantinib for the potential treatment for patients with RCC who have received one prior therapy as a result of the positive results obtained in the METEOR trial. We expect to be able to scale up quickly if additional indications for cabozantinib are approved in the future, or to scale down if necessary. Our distribution arrangements with Sobi are also right-sized for the EU MTC opportunity and retain strategic flexibility. 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, should the commercial opportunity for cabozantinib grow over time, we may not correctly judge the proper size and level of and experience of the commercialization team or the scale of distribution necessary to market and sell cabozantinib successfully. Maintaining sales, marketing, and distribution capabilities is expensive and time-consuming. Such expenses may be disproportionate compared to the revenues we may be able to generate on sales of cabozantinib and have an adverse impact on our results of operations. If we are unable to maintain adequate sales, marketing 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 of our commercial supply of COMETRIQ and a single specialty pharmacy to dispense COMETRIQ to patients in fulfillment of prescriptions in the United States. We also rely on a third party, Sobi, to distribute and commercialize COMETRIQ for the treatment of the approved MTC indication primarily in the European Union and potentially other countries in the event that COMETRIQ is approved for commercial sale in those jurisdictions. 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 COMETRIQ to the marketplace on a timely and competitive basis. For example, if our third party logistics provider's warehouse suffers a fire or damage from another type of disaster, the commercial supply of 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 COMETRIQ 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, 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;

Table of Contents

- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal 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.

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

Our ability to successfully commercialize cabozantinib will be 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 cabozantinib 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 cabozantinib, our revenues and prospects for profitability will suffer. In addition, even if third-party payers provide some coverage or reimbursement for cabozantinib, 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.

Table of Contents

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. To obtain reimbursement and/or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of cabozantinib to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in the commercialization of cabozantinib. 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 cabozantinib. Cost-control initiatives could decrease the price we might establish for cabozantinib, 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 cabozantinib 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 cabozantinib 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.

For example, under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively referred to as the PPACA, enacted in March 2010, substantial changes have been made, and may continue to be made, to the way healthcare is financed by both governmental and private insurers, and those changes are significantly impacting the pharmaceutical industry. Provisions of the PPACA relevant to the pharmaceutical industry include the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, not including orphan drug sales;
- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts on 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;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report annually under the federal Open Payments program certain financial arrangements with physicians and teaching hospitals, as defined in PPACA and its implementing regulations, including reporting any payment or "transfer of value" provided to physicians and teaching hospitals and any ownership and investment interests held by physicians and their immediate family members during the preceding calendar year;
- expansion of healthcare fraud and abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research.

The PPACA may change in the future. In August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee on Deficit Reduction did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reductions to

several government programs. These reductions include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013 and will stay in effect through 2024 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from

Table of Contents

three to five years. These laws, and others that may affect our business that have been recently enacted or may in the future be enacted, may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations. Further, under the recently enacted Drug Quality and Security Act, drug manufacturers will be subject to a number of requirements, including, product identification, tracing and verification, among others, that are designed to improve the detection and removal of counterfeit, stolen, contaminated or otherwise potentially harmful drugs from the U.S. drug supply chain. These requirements will be phased in over several years and compliance with this new law will likely increase the costs of the manufacture and distribution of drug products, which could have an adverse effect on our financial condition.

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 cabozantinib by placing it in an expensive tier. They may also refuse to provide any coverage of uses of approved products 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 cabozantinib. We also anticipate pricing pressures in connection with the sale of cabozantinib 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 development of cobimetinib, and cabozantinib for the treatment of additional tumor types, could allow our competitors to bring products to market before us, which would impair the commercialization of cobimetinib or cabozantinib in such tumor types. Our future success will depend upon our ability to maintain a competitive position with respect to technological advances. 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. In addition, cabozantinib and cobimetinib may compete with existing therapies that have long histories of use, such as chemotherapy and radiation treatments in cancer indications.

Competition for cabozantinib

We believe that the principal competing anti-cancer therapy to COMETRIQ in progressive, metastatic MTC is AstraZeneca’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 advanced RCC as a result of positive results from the METEOR trial, we believe its principal competition may include: Pfizer's axitinib, sunitinib and temsirolimus; Novartis' everolimus and pazopanib; Bayer's and Onyx Pharmaceuticals' sorafenib; Genentech's bevacizumab; Eisai's lenvatinib; and Bristol-Myers Squibb's nivolumab. The potential for immediate competition from Bristol-Myers Squibb's nivolumab is particularly significant. On July 20, 2015, Bristol-Myers Squibb announced that the phase 3 trial comparing nivolumab to everolimus in patients who had received previous antiangiogenic therapy for advanced RCC (Checkmate 025) had met its primary endpoint

Table of Contents

of showing an improvement in overall survival for patients treated with nivolumab. Nivolumab is the first drug to show a statistically-significant improvement in overall survival over everolimus, a current standard of care for the treatment of second line RCC patients. Nivolumab also demonstrated an acceptable safety profile. We anticipate that nivolumab may be approved for use in 2nd or later-line patients before cabozantinib and that it may be rapidly adopted by physicians for the treatment of advanced RCC.

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 regorafenib; ArQule's tivantinib; and Eisai's lenvatinib.

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 and Merck's pembrolizumab.

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 and experience 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 or expertise 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, should a tablet formulation be approved for sale, and rely on third party contractors to do so. These third parties must comply with applicable regulatory requirements, including the FDA's current Good Manufacturing Practices, or cGMP 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 ramp up production plans in anticipation of a potential commercial launch in advanced RCC.

The manufacturing process for pharmaceutical products is highly regulated and our third party vendors are subject to cGMP. Our third-party manufacturers may not be able to comply with the cGMP regulations, other applicable FDA regulatory requirements or similar regulations applicable outside of the United States. Additionally, 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, delays, 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 approval. 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.

Table of Contents

Clinical testing of cabozantinib 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 RCC, advanced HCC and a variety of other indications beyond the approved MTC indication. 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 overall survival for patients treated with cabozantinib as compared to prednisone and to demonstrate improvement in pain response for patients 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 RCC, 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 the approved MTC indication.

We do not have the ability to independently conduct clinical trials for cabozantinib, including our post-marketing commitments in connection with the approvals of COMETRIQ in MTC, and we rely on third parties we do not control such as

Table of Contents

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 MTC indication in the United States and European Union.

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.

Cabozantinib, as well as the activities associated with its 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 regulatory approval for cabozantinib would prevent us from promoting its use. 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 or 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 or the process for regulatory review during the development or approval periods of 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 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 Genentech, 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 may not be able to control the amount of U.S. sales and marketing costs for cobimetinib we are obligated to share under our collaboration with Genentech;
- 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;

Table of Contents

- 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;
- 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
- collaborations may be terminated or allowed to expire, which would delay, and may increase the cost of development of our drug candidates.

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 a collaboration for cabozantinib outside of the U.S. or other collaborations for selected preclinical and clinical compounds.*

To enable us to capitalize on a potential indication in advanced RCC and other potential cabozantinib opportunities most effectively, we intend to seek a partner for cabozantinib outside of the U.S. We may also 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 negotiate 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 negotiate additional collaborations, 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

Table of Contents

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. 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 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

Table of Contents

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, clinical and scientific staff, the loss of whose services might adversely impact the achievement of our objectives and the continuation of existing collaborations. Also, we may not have sufficient personnel to execute our business plan. Retaining and, where necessary, recruiting qualified clinical and scientific personnel will be critical to support activities related to advancing our clinical and preclinical development programs, and supporting our collaborative arrangements and our internal proprietary research and development efforts. The restructurings that we have experienced since 2010 have had and may continue to have an adverse impact on our ability to retain and recruit qualified personnel. Competition is intense for experienced clinical personnel, and we may be unable to retain or recruit clinical personnel with the expertise or experience necessary to allow us to pursue collaborations, develop our products and core technologies or expand our operations to the extent otherwise possible. 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

Table of Contents

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 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 product candidates, injury to our reputation, withdrawal of patients from our clinical trials, 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 coverage for our clinical trials and commercial activities for cabozantinib in the amount of $15.0 million per occurrence and $15.0 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 and the 2019 Notes

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 pace and progress of our current ramping up of sales, marketing, and distribution capabilities in anticipation of obtaining FDA approval for cabozantinib for the potential treatment of advanced RCC patients;
- the commercial success of COMETRIQ and the revenues we generate;
- 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;
- 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;
- acceptance of our technologies and platforms;
- 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 amount of expenses we incur in the build-out of our sales, marketing and distribution capabilities;

Table of Contents

- whether, when and the terms upon which we partner cabozantinib with a global pharmaceutical organization for further development and sales outside the U.S., and the sufficiency of upfront payments and milestones associated with any such transaction to meet our capital needs;
- 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;
- the impact of our restructuring activities;
- additions and departures of key personnel;
- 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

A large portion of our expenses, including expenses for facilities, equipment and personnel, are relatively fixed in the short term. If we fail to achieve anticipated levels of revenues, whether due to the expiration or termination of existing contracts, our failure to obtain new contracts, our inability to meet milestones or for other reasons, we may not be able to correspondingly reduce our operating expenses, which could significantly harm our operating results for a particular fiscal period.

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 COMETRIQ and the revenues we generate;
- 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;
- 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;

55

Table of Contents

- 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;
- developments concerning current or future collaborations;
- FDA or international regulatory actions;
- third-party coverage and reimbursement policies;
- disposition of any of our subsidiaries, 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.

Future sales of our common stock or conversion of our convertible 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 conversion of the 2019 Notes, 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 warrants issued to Deerfield and upon conversion of the Deerfield Notes. The issuance and sale of substantial amounts of our common stock, including upon conversion of the 2019 Notes or 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. Trading of the 2019 Notes is likely to influence and be influenced by the market for our common stock. For example, the price of our common stock could be affected by possible sales of common stock by investors who view the 2019 Notes as a more attractive means of equity participation in our company and by hedging or arbitrage trading activity that we expect to occur involving our common stock.

The accounting method for convertible debt securities that may be settled in cash, such as the 2019 Notes, could have a material effect on our reported financial results.

Under Accounting Standards Codification, or 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. As a result of the application of ASC 470-20, we recognized $143.2 million as the initial debt discount with a corresponding increase to paid-in capital, the equity component, for the 2019 Notes. We will be required to record the amortization of this debt discount over the terms of the 2019 Notes, which may adversely affect our reported or future financial results and the market price of our common stock. In addition, if the 2019 Notes become convertible, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the 2019 Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital. Finally, we use the if-converted method to compute earnings per share, which could be more dilutive than using the treasury stock method.

Certain provisions applicable to the 2019 Notes and the Deerfield Notes could delay or prevent an otherwise beneficial takeover or takeover attempt.

Certain provisions applicable to the 2019 Notes and the indenture pursuant to which the 2019 Notes were issued, and 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 Fundamental Change under the indenture for the 2019 Notes or a Major Transaction under the note purchase agreement governing the Deerfield Notes, holders of the 2019 Notes or the Deerfield Notes, as applicable, will have the right to require us to purchase their notes in cash. In addition, if an acquisition event constitutes a Make-Whole Fundamental Change under

the indenture for the 2019 Notes, we may be required to increase the conversion rate for holders who convert their 2019 Notes in connection with such Make-Whole Fundamental Change. In any of these cases, and in other cases, our obligations under the 2019 Notes and the indenture pursuant to which such notes were issued and the Deerfield Notes and the note purchase agreement governing the Deerfield Notes, as well as provisions of our organizational documents and other agreements, could increase the cost of acquiring us or otherwise discourage a third party from acquiring us or removing incumbent management.

Table of Contents

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, 2014, that an ownership change, as defined under Section 382, had not occurred. However, if there is an ownership change in connection with or after our July 2015 public offering under Section 382 of the Code, 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 and anticipate that we will continue to incur significant losses for the foreseeable future; 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 10, 2015	/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	4.1	9/11/2015	
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	4.2	9/11/2015	
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					X
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	Second Amendment to Sublease dated effective July 1, 2015 by and between Exelixis, Inc. and Nodality, Inc.	10-Q	000-30235	10.2	9/11/2015
10.2	First Amendment to Consent to Sublease Agreement dated effective July 1, 2015 by and among Britannia Pointe Grand Limited Partnership, Exelixis, Inc. and Nodality, Inc.	10-Q	000-30235	10.3	9/11/2015

Table of Contents

Exhibit Number	Exhibit Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit/ Appendix Reference	Filing Date	
10.3	Second Amendment to Sublease dated effective July 1, 2015 by and between Exelixis, Inc. and Threshold Pharmaceuticals, Inc.	10-Q	000-30235	10.6	9/11/2015	
10.4	Second Amendment to Consent to Sublease Agreement dated effective July 1, 2015 by and among Britannia Pointe Grand Limited Partnership, Exelixis, Inc. and Threshold Pharmaceuticals, Inc.	10-Q	000-30235	10.7	9/11/2015	
10.5	Offer Letter Agreement, dated June 30, 2015, between Christopher Senner, and Exelixis, Inc.					X
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
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

* Confidential treatment requested for certain portions of this exhibit.

‡ 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.