

EXELIXIS, INC.  
Form 10-Q  
April 30, 2015  
Table of Contents

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-Q  
(Mark One)

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

For the quarterly period ended April 3, 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  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  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

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

As of April 23, 2015, there were 196,026,599 shares of the registrant's common stock outstanding.

Table of Contents

EXELIXIS, INC.

QUARTERLY REPORT ON FORM 10-Q

INDEX

PART I - FINANCIAL INFORMATION

Item 1.	<u>Financial Statements</u>	<u>3</u>
	<u>Condensed Consolidated Balance Sheets – March 31, 2015 and December 31, 2014</u>	<u>3</u>
	<u>Condensed Consolidated Statements of Operations – Three Months Ended March 31, 2015 and 2014</u>	<u>4</u>
	<u>Condensed Consolidated Statements of Comprehensive Loss – Three Months Ended March 31, 2015 and 2014</u>	<u>4</u>
	<u>Condensed Consolidated Statements of Cash Flows – Three Months Ended March 31, 2015 and 2014</u>	<u>5</u>
	<u>Notes to Condensed Consolidated Financial Statements</u>	<u>6</u>
Item 2.	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>19</u>
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>34</u>
Item 4.	<u>Controls and Procedures</u>	<u>34</u>

PART II - OTHER INFORMATION

Item 1.	<u>Legal Proceedings</u>	<u>35</u>
Item 1A.	<u>Risk Factors</u>	<u>35</u>
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>53</u>
Item 3.	<u>Defaults Upon Senior Securities</u>	<u>53</u>
Item 4.	<u>Mine Safety Disclosures</u>	<u>53</u>
Item 5.	<u>Other Information</u>	<u>53</u>
Item 6.	<u>Exhibits</u>	<u>53</u>

SIGNATURES

EXHIBIT 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)

	March 31, 2015 (unaudited)	December 31, 2014*
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$84,987	\$80,395
Short-term investments	22,258	63,890
Short-term restricted cash and investments	6,108	12,212
Trade and other receivables	3,882	4,882
Inventory	2,593	2,381
Prepaid expenses and other current assets	5,212	3,481
Total current assets	125,040	167,241
Long-term investments	81,597	81,579
Long-term restricted cash and investments	2,684	4,684
Property and equipment, net	2,158	2,432
Goodwill	63,684	63,684
Other assets	7,771	8,340
Total assets	\$282,934	\$327,960
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable	\$1,303	\$6,413
Accrued clinical trial liabilities	30,976	41,545
Accrued compensation and benefits	3,459	3,350
Other accrued liabilities	13,867	12,282
Current portion of convertible notes	3,911	98,880
Current portion of loans payable	164	381
Current portion of restructuring	4,993	6,426
Deferred revenue	7	2,583
Total current liabilities	58,680	171,860
Long-term portion of convertible notes	284,355	182,395
Long-term portion of loans payable	80,000	80,000
Long-term portion of restructuring	3,697	4,365
Other long-term liabilities	2,961	4,169
Total liabilities	429,693	442,789
Commitments		
Stockholders' deficit:		
Preferred stock	—	—
Common stock, \$0.001 par value; 400,000,000 shares authorized; issued and outstanding:		
196,020,856 and 195,895,769 shares at March 31, 2015 and December 31, 2014, respectively	196	196
Additional paid-in capital	1,655,580	1,652,400
Accumulated other comprehensive loss	(61	) (121
Accumulated deficit	(1,802,474	) (1,767,304

Edgar Filing: EXELIXIS, INC. - Form 10-Q

Total stockholders' deficit	(146,759	)	(114,829	)
Total liabilities and stockholders' deficit	\$282,934		\$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 consolidated financial statements.

3

---

Table of Contents

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

	Three Months Ended March 31,	
	2015	2014
Revenues:		
Net product revenues	\$9,388	\$4,905
Operating expenses:		
Cost of goods sold	766	309
Research and development	22,282	54,847
Selling, general and administrative	9,531	14,691
Restructuring (recovery) charge	(431	) 46
Total operating expenses	32,148	69,893
Loss from operations	(22,760	) (64,988
Other income (expense), net:		
Interest income and other, net	(7	) 2,131
Interest expense	(12,403	) (11,762
Total other income (expense), net	(12,410	) (9,631
Net loss	\$(35,170	) \$(74,619
Net loss per share, basic and diluted	\$(0.18	) \$(0.39
Shares used in computing basic and diluted net loss per share	195,904	191,699

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

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

	Three Months Ended March 31,	
	2015	2014
Net loss	\$(35,170	) \$(74,619
Other comprehensive income (1)	60	7
Comprehensive loss	\$(35,110	) \$(74,612

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

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

Table of Contents

EXELIXIS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Three Months Ended March 31,	
	2015	2014
Cash flows from operating activities:		
Net loss	\$(35,170	) \$(74,619
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	297	498
Stock-based compensation expense	1,660	3,758
Accretion of debt discount	7,675	6,988
Gain on sale of equity investment	(95	) —
Change in the fair value of warrants	549	(1,739
Other	637	1,475
Changes in assets and liabilities:		
Trade and other receivables	1,292	(516
Inventory	(212	) 204
Prepaid expenses and other assets	(1,846	) (364
Accounts payable, accrued compensation, and other accrued liabilities	(3,416	) (10,254
Clinical trial liabilities	(10,569	) 4,160
Restructuring liability	(3,024	) (1,241
Other long-term liabilities	(288	) (229
Deferred revenue	(2,576	) (207
Net cash used in operating activities	(45,086	) (72,086
Cash flows from investing activities:		
Purchases of property and equipment	(31	) (384
Proceeds from sale of property and equipment	639	276
Proceeds from sale of equity investment	95	—
Proceeds from maturities of restricted cash and investments	10,748	6,598
Purchase of restricted cash and investments	(2,684	) (504
Proceeds from maturities of investments	54,410	90,311
Purchases of investments	(13,282	) (35,937
Net cash provided by investing activities	49,895	60,360
Cash flows from financing activities:		
Proceeds from issuance of common stock, net	—	75,646
Proceeds from exercise of stock options and warrants	—	120
Principal payments on debt	(217	) (10,479
Net cash (used in) provided by financing activities	(217	) 65,287
Net increase in cash and cash equivalents	4,592	53,561
Cash and cash equivalents at beginning of period	80,395	103,978
Cash and cash equivalents at end of period	\$84,987	\$157,539

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

Table of Contents

EXELIXIS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

NOTE 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization

Exelixis, Inc. (“Exelixis,” “we,” “our” or “us”) is a biopharmaceutical company committed to 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 serine/threonine kinase, which we out-licensed to Genentech (a member of the Roche Group), (“Genentech”).

Our development and commercialization efforts are focused primarily on cabozantinib. We are evaluating cabozantinib in a broad development program comprising over forty-five clinical trials, across multiple indications, including two ongoing phase 3 pivotal trials focusing on metastatic renal cell carcinoma (“mRCC”), and advanced hepatocellular carcinoma (“HCC”). On April 8, 2015, the United States Food and Drug Administration, (“FDA”), granted Fast Track designation to cabozantinib for the treatment of patients with advanced RCC who have received one prior therapy. Cabozantinib is being evaluated in METEOR, our phase 3 pivotal trial in mRCC.

Cabozantinib was approved by the 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.

Our second most advanced oncology asset, cobimetinib, is being evaluated by Genentech in a broad development program, including coBRIM, a phase 3 pivotal trial evaluating cobimetinib in combination with vemurafenib in previously untreated patients with unresectable locally advanced melanoma harboring a BRAF V600 mutation. On September 29, 2014, positive results from this trial were reported at the European Society for Medical Oncology, or ESMO, 2014 Congress. The trial met its primary endpoint of demonstrating a statistically significant increase in investigator-determined progression-free survival (“PFS”). Roche has completed the Marketing Authorization Application for cobimetinib in combination with vemurafenib in the European Union. In the United States, Genentech submitted its New Drug Application (“NDA”) in December 2014, and the FDA has granted the NDA priority review, with a projected action date of August 11, 2015.

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 April 3, 2015 and March 28, 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 March 31, 2015, March 31, 2014, December 31, 2015, and December 31, 2014, respectively.

Operating results for the three months ended March 31, 2015 are not necessarily indicative of the results that may be expected for the fiscal year ending January 1, 2016 or for any future period. These financial statements and notes should be read in conjunction with the consolidated financial statements and notes thereto for the year ended December 31, 2014, included in our Annual Report on Form 10-K filed with the SEC on March 2, 2015.





## Table of Contents

### 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 the three months ended March 31, 2015, with the exception of the 2011 fiscal year. We anticipate net losses and negative operating cash flow for the foreseeable future. For the three months ended March 31, 2015, we incurred a net loss of \$35.2 million and as of March 31, 2015, we had an accumulated deficit of \$1.8 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 2011, 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 March 31, 2015, we have generated \$49.5 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 March 31, 2015, we had \$197.6 million in cash and investments, which included \$107.2 million available for operations, \$6.1 million of short-term restricted investments available for public debt service obligations, \$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. Taking into account our cost saving measures, including the planned effects of the 2014 Restructuring that we initiated on September 2, 2014, and the expected extension of the maturity date of the Deerfield Notes to July 1, 2018, 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 through the first quarter of 2016. While a forecast of future events is inherently uncertain, our ability to sustain our business operations through the first quarter of 2016 is highly dependent on the results of METEOR, the commercial success of COMETRIQ and the revenues we generate as well as the commercial success of cobimetinib and our share of related net profits and losses, and royalties under our collaboration with Genentech. 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 beyond the first quarter of 2016, including but not limited to actions such as further reductions in headcount, additional consolidation of administrative functions, asset sales and additional curtailment of our development activities. However, our future capital requirements will be substantial, and

we may need to access additional capital. We may seek additional capital to support future operations through licensing, partnering or other strategic collaborative arrangements, and we may pursue the issuance of equity or debt securities or external borrowings. It is unclear when any such transactions will occur, on satisfactory terms or at all. Our ability to raise additional capital in the equity and debt markets, should we choose to do so, is dependent on a number of factors, including, but not limited to, the market demand for our common stock, which itself is subject to a number of pharmaceutical

7

---

## Table of Contents

development and business risks and uncertainties, as well as the uncertainty that we would be able to raise such additional capital at a price or on terms that are favorable to us.

### Revenue Recognition

We recognize revenue from the sale of COMETRIQ and have historically recognized revenue from license fees and milestones earned on research and collaboration arrangements. See “Note 1 - Organization and Summary of Significant Accounting Policies” to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 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 three months ended March 31, 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 at 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. During previous periods, 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 net product revenues of \$2.6 million and a nominal amount of cost of goods sold for the three months ended March 31, 2015.

We also utilize the “sell-in” revenue recognition model for sales to our European distribution partner. Once the European distributor 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. We estimate our European net product revenues by deducting from our gross product revenues an estimated credit for product originally delivered with expiry of 18 months or less. European net product revenues for the three months ended March 31, 2015 also included the remaining \$0.1 million of the \$2.4 million project management fee payable to our European distributor upon their achievement of a cumulative revenue goal; no such fees or credits were recognized during the comparable period in 2014. We first determined that the achievement of the revenue goal was probable in the third quarter of 2014 and therefore we recorded project management fees beginning in that period.

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.

### 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 indirect labor costs, the cost of manufacturing and other third party logistics costs of our product. A portion of the manufacturing costs for product sales were incurred prior to

8

---

## Table of Contents

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 April 1, 2015, the FASB proposed deferring 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 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 March 31, 2015, it would have resulted in a reduction of Other assets and total debt by \$4.0 million and \$4.7 million as March 31, 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. We may also incur other material charges not currently contemplated due to events that may occur as a result of, or associated with, the restructurings.

#### 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 to meet its primary endpoint of demonstrating a statistically significant increase in overall survival for patients treated with cabozantinib as compared to prednisone, we initiated the 2014 Restructuring to reduce our workforce. Personnel reductions were initiated across our entire organization and have resulted in an ongoing workforce of approximately 85 full-time employees. 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 mRCC and advanced HCC.

We expect to record an aggregate restructuring charge related to one-time employee termination benefits of approximately \$6.0 million, of which approximately 95% has been recorded from inception of the 2014 Restructuring through March 31, 2015 and the remainder is expected to be recorded during the three months ended June 30, 2015. Although we do not yet have contractual commitments in place, we have made progress towards subleasing our facilities and we currently expect to incur between \$2 million and \$6 million in additional facility-related charges as we exit certain facilities. We expect to record these facility-related charges during the remainder of fiscal year 2015 as they become determinable and as we exit certain facilities. We will not be able to predict our long-term facilities requirements with certainty until top-line results from METEOR become available, and we intend to re-evaluate and update such requirements upon the occurrence of this event.

We have recorded a \$5.2 million restructuring charge for the 2014 Restructuring from inception to date. The restructuring charge includes \$5.8 million of employee severance and other benefits, \$0.7 million in recoveries related to the sale of fully depreciated assets net of asset impairments, and \$0.2 million in other restructuring related charges. Employee severance and other benefits are recognized ratably during the period from the implementation date of the 2014 Restructuring through the employees' termination dates.

Table of Contents

The restructuring liability related to the 2014 Restructuring is included in the current portion of restructuring on the accompanying Consolidated Balance Sheets. The components of and changes to this liability during the three months ended March 31, 2015 are summarized in the following table (in thousands):

	Employee Severance and Other Benefits	Asset Impairment and Other	Total
Restructuring liability as of December 31, 2014	\$1,290	\$47	\$1,337
Restructuring (recovery) charge	5	(853	) (848
Cash (payments) receipts, net	(1,003	) 552	(451
Other non-cash items	—	298	298
Restructuring liability for 2014 Restructuring as of March 31, 2015	\$292	\$44	\$336

## 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 three months ended March 31, 2015 and 2014, we recorded restructuring charges of \$0.4 million and \$46 thousand, 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 three months ended March 31, 2015 we recorded \$0.3 million in additional charges due to changes in assumptions regarding anticipated sublease activities. During the three months ended March 31, 2014, restructuring charges were partially offset by \$0.1 million in recoveries recorded in connection with the sale of excess equipment and other assets. 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 these liabilities during the three months ended March 31, 2015 is summarized in the following table (in thousands):

	Facility Charges
Restructuring liability as of December 31, 2014	\$9,454
Restructuring charge	415
Cash payments	(1,515
Restructuring liability for 2010 Restructurings as of March 31, 2015	\$8,354

We expect to pay accrued facility charges of \$8.4 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 \$0.6 million relating to the effect of accretion expense through to the end of the building lease terms.

Table of Contents

## NOTE 3: CASH AND INVESTMENTS

The following table summarizes cash and cash equivalents, investments, and restricted cash and investments by balance sheet line item as of March 31, 2015 and December 31, 2014 (in thousands):

	March 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents	\$84,988	\$—	\$(1	) \$84,987
Short-term investments	22,274	31	(47	) 22,258
Short-term restricted cash and investments	6,041	67	—	6,108
Long-term investments	81,600	—	(3	) 81,597
Long-term restricted cash and investments	2,684	—	—	2,684
Total cash and investments	\$197,587	\$98	\$(51	) \$197,634
	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 March 31, 2015 and December 31, 2014 were \$81.8 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.

All of our cash equivalents and investments are classified as available-for-sale. The following table summarizes our cash equivalents and investments by security type as of March 31, 2015 and December 31, 2014. The amounts presented exclude cash, but include investments classified as cash equivalents (in thousands):

	March 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	\$36,841	\$—	\$—	\$36,841
Commercial paper	52,724	—	(1	) 52,723
Corporate bonds	98,280	32	(50	) 98,262
U.S. Treasury and government sponsored enterprises	6,041	66	—	6,107
Total investments	\$193,886	\$98	\$(51	) \$193,933



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. Treasury and government sponsored enterprises	12,105	107	—	12,212
Municipal bonds	2,659	3	—	2,662
Total investments	\$238,298	\$145	\$(157	) \$238,286

There were no gains or losses on the sale of investments during the three months ended March 31, 2015 and 2014. All of our investments are subject to a quarterly impairment review. During the three months ended March 31, 2015 and 2014, we did not record any other-than-temporary impairment charges on our available-for-sale securities. As of March 31, 2015, there were 62 investments in an unrealized loss position with an aggregate fair value \$103.3 million. All of our investments in an unrealized loss position are 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 summarizes the fair value of securities classified as available-for-sale by contractual maturity as of March 31, 2015 (in thousands):

	Mature within One Year	After One Year through Two Years	Fair Value
Money market funds	\$36,841	\$—	\$36,841
Commercial paper	52,723	—	52,723
Corporate bonds	95,529	2,733	98,262
U.S. Treasury and government sponsored enterprises	6,107	—	6,107
Total investments	\$191,200	\$2,733	\$193,933

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):

	March 31, 2015	December 31, 2014
Raw materials	\$1,076	\$1,118
Work in process	2,964	2,845
Finished goods	787	559
Total	4,827	4,522
Less: non-current portion included in other assets	(2,234	) (2,141
Inventory	\$2,593	\$2,381

We generally relieve inventory on a first-expiry, first-out basis. Write-downs related to expiring inventory are charged to cost of goods sold. Such write-downs were nominal for three months ended March 31, 2015 and March 31, 2014. The non-current portion of inventory recorded as other assets 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 or excess inventory.



Table of Contents

## NOTE 5. DEBT

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

	March 31, 2015	December 31, 2014
Convertible Senior Subordinated Notes due 2019	\$186,940	\$182,395
Secured Convertible Notes due 2015	101,326	98,880
Silicon Valley Bank term loan	80,000	80,000
Silicon Valley Bank line of credit	164	381
Total debt	368,430	361,656
Less: current portion	(4,075	) (99,261
Long-term debt	\$364,355	\$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 2015 (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 March 31, 2015, the entire principal balance remains outstanding. The following is a summary of the liability component of the 2019 Notes (in thousands):

	March 31, 2015	December 31, 2014
Net carrying amount of the liability component	\$186,940	\$182,395
Unamortized discount of the liability component	100,560	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 March 31, 2015	2014
Stated coupon interest	\$3,055	\$3,089
Amortization of debt discount and debt issuance costs	4,721	4,295
Total interest expense	\$7,776	\$7,384

The balance of unamortized fees and costs was \$3.1 million and \$3.3 million as of March 31, 2015 and December 31, 2014, respectively, which is included in Other assets on the accompanying Consolidated Balance Sheets.

## Secured Convertible Notes due June 2015

In June 2010, we entered into a note purchase agreement with entities affiliated with Deerfield Management Company, L.P. (“Deerfield”), pursuant to which, on July 1, 2010, we sold to Deerfield an aggregate of \$124.0 million in principal amount of the Deerfield Notes. As of both March 31, 2015 and December 31, 2014, the remaining outstanding principal balance on the Deerfield Notes was \$104.0 million which, subject to certain limitations, is payable in cash or in stock at our discretion.

The outstanding principal amount of the Deerfield Notes bears 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 March 31, 2015	2014
Stated coupon interest	\$1,479	\$1,480
Amortization of debt discount and debt issuance costs	2,947	2,695
Total interest expense	\$4,426	\$4,175

Table of Contents

The balance of unamortized fees and costs was \$0.9 million and \$1.4 million as of March 31, 2015 and December 31, 2014, respectively, which is included in Other assets on the accompanying Consolidated Balance Sheets.

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 (the "Extension Option"). Pursuant to the Extension Option, Deerfield Partners, L.P. and Deerfield International Master Fund, L.P. (the "New Deerfield Purchasers") would acquire \$100 million principal amount of the Deerfield Notes, the maturity date of the Deerfield Notes would be extended to July 1, 2018, and the Deerfield Notes would bear interest on and after July 2, 2015 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. On March 4, 2015, we provided Deerfield notice of our election to extend the maturity date of the Deerfield Notes. The acquisition and extension of the Deerfield Notes is expected to occur on July 1, 2015 and will be subject to customary closing conditions, including the absence of an event of default by us and the accuracy of certain of our representations and warranties set forth in the note purchase agreement, each as of July 1, 2015. As a result of our election to extend the maturity date of the Deerfield Notes to 2018, \$97.4 million of the outstanding principal has been classified as long-term debt as of March 31, 2015.

In connection with the amendment to the note purchase agreement, on January 22, 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. Upon 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 will be extended by two years to January 22, 2018. See "Note 6 - Warrants" for further information on the 2014 Deerfield Warrants.

We determined that the January 22, 2014 amendment to the note purchase agreement resulted in the Deerfield Notes being modified. In connection with the amendment, we recorded a \$2.8 million deferred commitment fee as a debt discount upon the issuance of the 2014 Deerfield Warrants. See "Note 6 - Warrants" for further information on those warrants. The deferred commitment fee is included in Other assets. Third-party expenses, comprised primarily of legal and accounting fees, were expensed as of the date of the amendment.

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 upon the March 4, 2015 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 15.26%.

**NOTE 6. WARRANTS**

On January 22, 2014, in connection with the amendment to the note purchase agreement to provide us with the Extension Option, we issued to the New Deerfield Purchasers 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. Under the terms of the Extension Option, the term of the 2014 Deerfield Warrants will be extended by two years and the exercise price will 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 immediately following the date of such extension election. Due to the potential increase in term and decrease of the exercise price, the 2014 Deerfield Warrants were recorded as a liability upon issuance which was included in Other long-term liabilities. The 2014 Deerfield Warrants were recorded at their estimated fair value, on a recurring basis, which was \$1.5 million and \$0.9 million as of March 18, 2015 and December 31, 2014, respectively. Upon 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. Subsequent to our notification of our election to require the New Deerfield Purchasers to acquire the Deerfield Notes and extend the maturity date to July 1, 2018, the terms of the 2014 Deerfield Warrants became fixed on March 18, 2015. 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. We recorded an unrealized loss of \$0.5 million and an unrealized gain of \$1.7 million on the 2014 Deerfield Warrants during the three months ended March 31, 2015 and March 31, 2014, respectively, which is included in Interest income and other, net. See "Note 7 - Fair Value Measurements" for more information on the valuation of 2014 Deerfield Warrants. The 2014 Deerfield Warrants are participating securities. The warrant holders

do not have a contractual obligation to share in our losses.

14

---

Table of Contents

## 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 March 31, 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 March 31, 2015. The amounts presented exclude cash, but include investments classified as cash equivalents (in thousands):

	March 31, 2015		
	Level 1	Level 2	Total
Money market funds	\$36,841	\$—	\$36,841
Commercial paper	—	52,723	52,723
Corporate bonds	—	98,262	98,262
U.S. Treasury and government sponsored enterprises	—	6,107	6,107
Total financial assets	\$36,841	\$157,092	\$193,933

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

The following is a reconciliation of changes in the net 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 warrant 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 March 31, 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):

	March 31, 2015		December 31, 2014	
	Carrying Amount	Fair Value	Carrying Amount	Fair Value
2019 Notes	\$186,940	\$217,034	\$182,395	\$156,889
Silicon Valley Bank term loan	\$80,000	\$79,916	\$80,000	\$79,943
Silicon Valley Bank line of credit	\$164	\$164	\$381	\$381

We believe it is not practicable to determine the fair value of the Deerfield Notes due to the unique structure of the instrument that 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.



Table of Contents

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 Consolidated Balance Sheets.

We estimate the fair value of our other debt instruments, where possible, using the net present value of the payments discounted at an interest rate that is consistent with money-market rates that would have been earned on our non-interest-bearing compensating balances, which is a Level 2 input.

The 2014 Deerfield Warrants are 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	January 22, 2014 (issuance date)
Fair value of warrants	\$1,470	\$921	\$2,762
Risk-free interest rate	0.87	% 1.07	% 0.95
Dividend yield	—	% —	% —
Volatility	95	% 96	% 57
Average expected life	2.8 years	3.1 years	3.2 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 March 31, 2015	2014
Research and development expense	\$627	\$1,565
Selling, general and administrative expense	1,033	2,193
Total employee stock-based compensation expense	\$1,660	\$3,758

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 weighted average fair values:

	Stock Options Three Months Ended March 31,		
	2015	2014	
Weighted average grant-date fair value	\$1.35	\$4.70	
Risk-free interest rate	1.20	% 1.59	%
Dividend yield	—	% —	%
Volatility	95	% 81	%
Expected life	4.5 years	5.5 years	





Table of Contents

	Employee Stock Purchase Plan Three Months Ended March 31,			
	2015	2014		
Weighted average grant-date fair value	\$0.70		\$1.59	
Risk-free interest rate	0.11	%	0.08	%
Dividend yield	—	%	—	%
Volatility	96	%	62	%
Expected life	6 months		6 months	

A summary of all stock option activity for the three months ended March 31, 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	4,235,450	\$1.94		
Forfeited	(291,543 )	\$4.13		
Expired	(3,154,051 )	\$6.06		
Options outstanding at March 31, 2015	28,601,848	\$4.44	4.89 years	\$11,313
Exercisable March 31, 2015	12,737,971	\$6.86	3.02 years	\$—

As of March 31, 2015, a total of 10,190,819 shares were available for grant under our stock option plans.

As of March 31, 2015, \$23.6 million of total unrecognized compensation expense related to employee stock options was expected to be recognized over a weighted-average period of 2.60 years.

Of the stock options outstanding as of March 31, 2015, 13,090,165 were granted subject to performance objectives tied to the achievement of clinical 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 March 31, 2015, we do not consider achievement of those performance objectives to be probable and therefore we have not included any stock-based compensation expense for those stock options. As of March 31, 2015, the grant date fair value of awards outstanding for which we have determined that it is not probable that we will achieve the goals was \$17.2 million.

A summary of all restricted stock unit (“RSU”) activity for the three months ended March 31, 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	65,124	\$2.88		
Released	(111,334 )	\$1.95		
Forfeited	(89,773 )	\$5.29		
Awards outstanding at March 31, 2015	825,486	\$3.84	1.84 years	\$2,196

As of March 31, 2015, \$2.1 million of total unrecognized compensation expense related to employee RSUs was expected to be recognized over a weighted-average period of 1.84 years.

**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 March 31, 2015	2014
--	--------------------------------------	------

Edgar Filing: EXELIXIS, INC. - Form 10-Q

Numerator:

Net loss \$(35,170 ) \$(74,619 )

Denominator:

Shares used in computing basic and diluted net loss per share 195,904 191,699

Net loss per share, basic and diluted \$(0.18 ) \$(0.39 )

17

---

Table of Contents

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):

	March 31,	
	2015	2014
Convertible debt	88,008	54,123
Outstanding stock options, unvested RSUs and ESPP contributions	29,591	26,302
Warrants	1,000	2,186
Total potentially dilutive shares	118,599	82,611

**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 March 31, 2015, 54% of our trade and other receivables are with the specialty pharmacy that sells COMETRIQ in the United States and 31% 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 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 March 31,		
	2015	2014	
Percentage of revenues earned in the United States	86	% 98	%
Percentage of revenues earned in the European Union	14	% 2	%

We recorded a \$0.2 million gain and a \$44 thousand loss relating to foreign exchange fluctuations for the three months ended March 31, 2015 and 2014.

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

	Three Months Ended March 31,		
	2015	2014	
Diplomat Specialty Pharmacy	86	% 98	%
Swedish Orphan Biovitrum	14	% 2	%

## Table of Contents

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

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

This discussion and analysis should be read in conjunction with our financial statements and accompanying notes included in this report and the financial statements and accompanying notes thereto included in our Annual Report on Form 10-K for the fiscal year ended December 31, 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 serine/threonine kinase, which we out-licensed to Genentech (a member of the Roche Group), or Genentech.

Our development and commercialization efforts are focused primarily on cabozantinib. We are evaluating cabozantinib in a broad development program comprising over forty-five clinical trials, across multiple indications, including two ongoing phase 3 pivotal trials focusing on metastatic renal cell carcinoma, or mRCC, and advanced hepatocellular carcinoma, or HCC. On April 8, 2015, the United States Food and Drug Administration, or FDA, granted Fast Track designation to cabozantinib for the treatment of patients with advanced RCC who have received one prior therapy. Cabozantinib is being evaluated in METEOR, our phase 3 pivotal trial in mRCC. We previously announced that we expected top-line results from METEOR to be available in the second quarter of 2015. However, based on the slowing rate at which events associated with the primary endpoint of progression-free survival, or PFS, are occurring, we now expect top-line results to be available late in the second quarter or early in the third quarter of 2015. We also expect top-line results from CELESTIAL, our phase 3 pivotal trial in advanced HCC, in 2017.

Cabozantinib was approved by the 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<sup>(R)</sup>. 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.

Our second most advanced oncology asset, cobimetinib, is being evaluated by Genentech in a broad development program, including coBRIM, a phase 3 pivotal trial evaluating cobimetinib in combination with vemurafenib in previously untreated patients with unresectable locally advanced melanoma harboring a BRAF V600 mutation. On September 29, 2014, positive results from this trial were reported at the European Society for Medical Oncology, or ESMO, 2014 Congress. The trial met its primary endpoint of demonstrating a statistically significant increase in investigator-determined PFS. Roche has completed the Marketing Authorization Application, or MAA, for cobimetinib in combination with vemurafenib in the European Union. In the United States, Genentech submitted its New Drug Application, or NDA, in December 2014 and the FDA has granted the NDA priority review, with a projected action date of August 11, 2015.

#### Our Strategy

We believe that the available clinical data demonstrate that cabozantinib has the potential to be a broadly active anti-cancer agent that can make a meaningful difference in the lives of patients. Our objective is to build cabozantinib into a significant oncology franchise. The initial regulatory approvals of COMETRIQ for MTC in the United States

and European Union provide a niche market opportunity that allows us to gain commercialization experience while providing a solid foundation for potential expansion into larger cancer indications.

Our near-term internal development efforts for cabozantinib are focused on cancers for which we believe cabozantinib has the greatest significant therapeutic and commercial potential. We utilize 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, to generate additional data, allowing us to prioritize future late stage trials in a cost-effective fashion. We believe that this staged approach to building value represents the most rational and effective use of our resources.

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

#### 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 is our most advanced partnered compound in development and has the greatest near-term commercial potential. On September 29, 2014, positive results for coBRIM, a phase 3 pivotal trial evaluating cobimetinib in combination with vemurafenib in previously untreated patients with unresectable locally advanced melanoma harboring a BRAF V600 mutation were reported at the ESMO 2014 Congress. The trial met its primary endpoint of demonstrating a statistically significant increase in investigator-determined progression-free survival, or PFS. On the basis of data from the coBRIM trial, Roche submitted a Marketing Authorization Application, or MAA, for cobimetinib in combination with vemurafenib in previously untreated patients with unresectable locally advanced melanoma harboring a BRAF V600 mutation to the European Medicines Agency in September 2014. On December 15, 2014, Genentech completed the submission of its NDA with the FDA for cobimetinib. The FDA has granted priority review to the NDA, with a PDUFA date of August 11, 2015. Priority Review is granted to a pharmaceutical product that, if approved, would meet an unmet medical need for a serious and life-threatening condition. Cobimetinib previously received Fast Track designation from the FDA for this indication.

In addition, the following clinical trials of cobimetinib in combination with other agents are ongoing, as disclosed on [clinicaltrials.gov](http://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);



## Table of Contents

◆Noadjuvant Vemurafenib + Cobimetinib in Melanoma: NEO-VC (NCT02303951); and

◆Vemurafenib Plus Cobimetinib in Metastatic Melanoma (REPOSIT) (NCT02414750).

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 equally in the U.S. marketing and commercialization 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. We are entitled to low double-digit royalties on ex-U.S. net sales. In November 2013, we exercised an option under the collaboration agreement to co-promote in the United States. As a result of exercising our option to co-promote, we may provide up to 25% of the total sales force for cobimetinib in the United States 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 March 31, 2015 and Recent Developments

#### Cabozantinib Granted Fast Track Designation by the FDA for Advanced Renal Cell Carcinoma

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. Cabozantinib is being evaluated in METEOR, our phase 3 pivotal trial in mRCC. The FDA created the Fast Track process to facilitate the development and expedite the review of drugs to treat serious diseases and address unmet medical needs. Fast Track designation confers important benefits, including the potential eligibility for Priority Review of a NDA, if relevant criteria defined by the FDA are met. We previously announced that we expected top-line results from METEOR to be available in the second quarter of 2015. However, based on the slowing rate at which events associated with the primary endpoint of PFS are occurring, we now expect top-line results to be available late in the second quarter or early in the third quarter of 2015.

#### Enrollment Target Met for Randomized Phase 2 Study of Cabozantinib Versus Sunitinib in the First-Line Setting

In April 2015 The Alliance for Clinical Trials in Oncology, or The Alliance, notified us that CABOSUN, the randomized phase 2 study of cabozantinib versus sunitinib in the first-line RCC setting, being conducted by The Alliance as part of our collaboration with NCI-CTEP, met its enrollment target of 150 patients who were determined to be intermediate or poor risk by the Heng criteria. The primary endpoint of CABOSUN is PFS. Given the historical PFS duration for sunitinib in similar patients in the first-line setting, we anticipate data from the trial in 2016.

#### Top-Line Results for Phase 2 Trial of Cabozantinib Versus Paclitaxel in Patients with Persistent or Recurrent Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cavity Cancer

In April 2015 NCI-CTEP notified us of top-line results from its randomized phase 2 trial (Study GOG-0186K) of cabozantinib versus paclitaxel (1:1) in 111 patients with persistent or recurrent epithelial ovarian, fallopian tube, or primary peritoneal cavity cancer. The trial did not meet its primary endpoint of demonstrating a statistically significant improvement in PFS for patients treated with cabozantinib as compared to paclitaxel. Safety data were consistent with those observed in other trials of cabozantinib. The results of the study are the subject of ongoing analyses and will be submitted by the investigators for presentation at a future medical conference.

#### Exercise of Option to Extend Maturity Date of our Indebtedness Under our Note Purchase Agreement with Deerfield

On March 4, 2015, pursuant to the terms of our note purchase agreement with Deerfield Private Design Fund, L.P. and Deerfield Private Design International, L.P., we provided notice of our election to extend the maturity date of the Deerfield Notes (as defined in "--Certain Factors Important to Understanding Our Financial Condition and Results of Operations - Deerfield Facility") to July 1, 2018. The extension of the Deerfield Notes is expected to occur on July 1, 2015 and will be subject to customary closing conditions. See "--Certain Factors Important to Understanding Our Financial Condition and Results of Operations - Deerfield Facility," for additional information related to our exercise of the extension option.





Table of Contents

Acceptance of New Drug Application for Cobimetinib in Combination with Vemurafenib in Patients with BRAF V600 Mutation-Positive Advanced Melanoma

In February 2015, the FDA accepted for review Genentech's NDA for cobimetinib in combination with vemurafenib in previously untreated patients with unresectable locally advanced melanoma harboring a BRAF V600 mutation. The FDA has granted priority review to the NDA, with a PDUFA date of August 11, 2015. Priority Review is granted to a pharmaceutical product that, if approved, would meet an unmet medical need for a serious and life-threatening condition. Cobimetinib previously received Fast Track designation from the FDA for this indication. See

"--Collaborations - Cobimetinib Collaboration," for additional information related to our collaboration with Genentech.

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 the three months ended March 31, 2015, with the exception of the 2011 fiscal year. We anticipate net losses and negative operating cash flow for the foreseeable future. For the three months ended March 31, 2015, we incurred a net loss of \$35.2 million and as of March 31, 2015, we had an accumulated deficit of \$1.8 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 March 31, 2015, we have generated \$49.5 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 March 31, 2015, we had \$197.6 million in cash and investments, which included \$107.2 million available for operations, \$6.1 million of short-term restricted investments available for public debt service obligations, \$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. Taking into account our cost saving measures, including the planned effects of the 2014 Restructuring that we initiated on September 2, 2014, and the expected extension of the maturity date of the Deerfield Notes to July 1, 2018, 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 through the first quarter of 2016. While a forecast of future events is inherently uncertain, our ability to sustain our business operations through the first quarter of 2016 is highly dependent on the results of METEOR, the commercial success of COMETRIQ and the revenues we generate as well as the commercial success of cobimetinib and our share of related net profits and losses, and royalties under our collaboration with Genentech. 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 beyond the first quarter of 2016, including but not limited to

actions such as further reductions in headcount, additional consolidation of administrative functions, asset sales and additional curtailment of our development activities. However, our future capital requirements will be substantial, and we may need to access additional capital. We may seek additional capital to support future operations through licensing, partnering or other strategic collaborative arrangements, and we may pursue the issuance of equity or debt securities or external borrowings. It is unclear when any such transactions will occur, on satisfactory terms or at all. Our ability to raise additional capital in the equity and debt markets, should we choose to do so, is dependent on a number of factors, including, but not limited to, the market demand for our common stock, which itself is subject to a number of pharmaceutical development and business risks and

## Table of Contents

uncertainties, as well as the uncertainty that we would be able to raise such additional capital at a price or on terms that are favorable to us.

For a description of the factors upon which our capital requirements depend, please see “– Liquidity and Capital Resources – Capital Requirements.”

### Clinical Development and Commercialization of Cabozantinib

Our primary development and commercialization program is focused on cabozantinib, 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 have 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 COMETRIQ depends upon the degree of market acceptance of COMETRIQ among physicians, patients, health care payers, and the medical community. 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 on sales of COMETRIQ and have an adverse impact on our results of operations. Further, if cabozantinib is approved for the treatment of an indication beyond the approved MTC indication, we expect to incur an increase in commercialization expenses in connection with any such approval.

### 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 contains 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 March 31, 2015, we have used \$30.6 million of the amount held in the escrow account to pay the required semi-annual interest payments. The amount held in the escrow account as of March 31, 2015, was \$6.1 million and is included in short-term restricted cash and investments. We have pledged our interest in the escrow account to the Trustee as security for our obligations under the 2019 Notes.

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 Deerfield Notes, for an aggregate purchase price of \$80.0 million, less closing fees and expenses of approximately \$2.0 million. As of both March 31, 2015 and December 31, 2014, the remaining outstanding principal balance on the Deerfield Notes was \$104.0 million which, subject to certain restrictions, is payable in cash or in stock at our discretion. We refer to the Original Deerfield Purchasers and the New Deerfield Purchasers (identified below) collectively as Deerfield.

The outstanding principal amount of the Deerfield Notes bears interest in the annual amount of \$6.0 million, payable quarterly in arrears. During the three months ended March 31, 2015 and 2014, total interest expense for the Deerfield Notes was \$4.4 million and \$4.2 million, respectively, including the stated coupon rate and the amortization of the debt discount and debt issuance costs. The non-cash expense relating to the amortization of the debt discount and debt issuance costs was \$2.9 million and \$2.7 million, respectively, during those periods. The balance of unamortized fees and costs was \$0.9 million and \$1.4 million as of March 31, 2015 and December 31, 2014, respectively, which is included in Other assets on the accompanying Consolidated Balance Sheets.

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 further amended to provide us with an option to extend the maturity date of our indebtedness under the note purchase agreement. Upon our election to extend the maturity date, Deerfield Partners, L.P. and Deerfield International Master Fund, L.P., or the New Deerfield Purchasers, would acquire \$100 million principal amount of the Deerfield Notes, the maturity date of the Deerfield Notes would be extended to July 1, 2018, and, the Deerfield Notes would bear interest on and after July 2, 2015 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. On March 4, 2015, we provided Deerfield notice of our election to extend the maturity date of the Deerfield Notes. The acquisition and extension of the Deerfield Notes is expected to occur on July 1, 2015 and will be subject to customary closing conditions, including the absence of an event of default by us and the accuracy of certain of our representations and warranties set forth in the note purchase agreement, each as of July 1, 2015.

On July 10, 2014, the parties further amended the note purchase agreement to clarify certain provisions of the note purchase agreement.

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. If the expected extension of the Deerfield Notes occurs, our obligation to make annual mandatory prepayments equal to 15% of Development/Commercialization Revenue received by us during the prior fiscal year will 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. 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 Sales (as further described below).

As a result of the January 2014 amendment, 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.

Under the note purchase agreement, we may voluntarily prepay the principal amount of the Deerfield Notes as follows (the amount at which we repay in each case below is referred to as the Prepayment Price):

• Prior to July 1, 2015: we may prepay all of the principal amount of the Deerfield Notes at any time at a prepayment price equal to the outstanding principal amount, plus accrued and unpaid interest through the date of

Table of Contents

such prepayment, plus all interest that would have accrued on the principal amount of the Deerfield Notes between the date of such prepayment and the applicable maturity date of the Deerfield Notes if the outstanding principal amount of the Deerfield Notes had remained outstanding through the applicable maturity date, plus all other accrued and unpaid obligations; and

If the expected extension occurs: 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.

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. Upon our election to extend the maturity date of the Deerfield Notes occurs, 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. 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 in February 2014 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 provide for a new seven-year term loan in the amount of \$80.0 million. As of March 31, 2015, the combined outstanding principal balance due under the lines of credit and term loan was \$80.2 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

## Table of Contents

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, to meet its primary endpoint of demonstrating a statistically significant increase in overall survival for patients treated with cabozantinib as compared to prednisone, we initiated the 2014 Restructuring to reduce our workforce. Personnel reductions were initiated across our entire organization and have resulted in an ongoing workforce of approximately 85 full-time employees. 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 mRCC and advanced HCC. We expect to record an aggregate restructuring charge related to one-time employee termination benefits of approximately \$6.0 million, of which approximately 95% has been recorded from inception of the 2014 Restructuring through March 31, 2015 and the remainder is expected to be recorded during the three months ended June 30, 2015. Although we do not yet have contractual commitments in place, we have made progress towards subleasing our facilities and we currently expect to incur between \$2 million and \$6 million in additional facility-related charges as we exit certain facilities. We expect to record these facility-related charges during the remainder of fiscal year 2015 as they become determinable and as we exit certain facilities. We will not be able to predict our long-term facilities requirements with certainty until top-line results from METEOR become available, and we intend to re-evaluate and update such requirements upon the occurrence of this event.

We have recorded a \$0.4 million restructuring recovery during the three months ended March 31, 2015.

### 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.

25

---

## 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 at 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. During previous periods, 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 net product revenues of \$2.6 million and a nominal amount of cost of goods sold for the three months ended March 31, 2015.

We also utilize the “sell-in” revenue recognition model for sales to our European distribution partner. Once the European distributor 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. We estimate our European net product revenues by deducting from our gross product revenues an estimated credit for product originally delivered with expiry of 18 months or less. European net product revenues for the three months ended March 31, 2015 also included the remaining \$0.1 million of the \$2.4 million project management fee payable to our European distributor upon their achievement of a cumulative revenue goal; no such fees or credits were recognized during the comparable period in 2014. We first determined that the achievement of the revenue goal was probable in the third quarter of 2014 and therefore we recorded project management fees beginning in that period.

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 three months ended March 31, 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 April 3, 2015 and March 28, 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 March 31, 2015, March 31, 2014, December 31, 2015, and December 31, 2014, respectively.



Table of Contents

## Results of Operations – Comparison of Three Month Ended March 31, 2015 and 2014

## Revenues

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

	Three Months Ended March 31,	
	2015	2014
Gross product revenues	\$10,133	\$5,241
Discounts and allowances	(745	) (336
Total revenues	\$9,388	\$4,905
Dollar change	\$4,483	
Percentage change	91	%

Revenues relate to the sale of COMETRIQ. The increase in gross product revenues reflects 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 as well as the continued ramp up in sales of COMETRIQ following its commercial launch in the United States in January 2013.

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 also utilize the “sell-in” method to recognize product revenue.

We estimate our net product revenues by deducting discounts and allowances from our gross product revenues.

Discounts and allowances for domestic sales include (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 three months ended March 31, 2015 included the remaining \$0.1 million of the \$2.4 million one-time project management fee payable to Swedish Orphan Biovitrum (“Sobi”) upon their achievement of a cumulative revenue goal and an estimated credit on product originally delivered within 18 months of expiry; no such fees or credits were recognized during the comparable period in 2014. We first determined that the achievement of the revenue goal was probable in the third quarter of 2014 and therefore we recorded project management fees beginning in that period.

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

	Three Months Ended March 31,	
	2015	2014
Diplomat Specialty Pharmacy	\$8,075	\$4,825
Sobi	1,313	80
Total revenues	\$9,388	\$4,905
Dollar change	\$4,483	
Percentage change	91	%
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, indirect labor costs, the cost of manufacturing 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 March 31,	
	2015	2014
Cost of goods sold	\$766	\$309
Gross margin	92	% 94



Table of Contents

The increase in the cost of goods sold for the three months ended March 31, 2015, as compared to the comparable period in 2014, was a result of increased sales of COMETRIQ and increased period costs as well as decreases in the amount of product sold that had been expensed as research and development expense prior to regulatory approval. 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. Gross margin percentage is net revenues less cost of goods sold, divided by net revenues.

## Research and Development Expenses

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

	Three Months Ended March 31,	
	2015	2014
Research and development expenses	\$22,282	\$54,847
Dollar change	\$(32,565)	)
Percentage change	(59	)%

Research and development expenses consist primarily of clinical trial expenses, personnel expenses, allocation of general corporate costs, consulting and outside services, temporary personnel expenses and stock-based compensation. The decrease in research and development expenses for the three months ended March 31, 2015, as compared to the comparable period in 2014, was primarily related to a \$21.3 million, or 63%, net decrease in clinical trial costs, which includes services performed by third-party contract research organizations and other vendors who support our clinical trials. The decrease in clinical trial costs 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, a reduction of general program level costs, and a \$7.5 million comparator drug purchase that occurred during for the three months ended March 31, 2014 for METEOR, our phase 3 pivotal trial in mRCC; there was no such purchase for the three months ended March 31, 2015. Those decreases were partially offset by increases in other costs related to METEOR for the three months ended March 31, 2015.

Decreases in research and development expenses for the three months ended March 31, 2015 also related to personnel expenses, consulting and outside services and stock-based compensation. Personnel expenses decreased by \$5.8 million for the three months ended March 31, 2015 as compared to the comparable period in 2014 primarily due to workforce reductions undertaken as a consequence of the failure of COMET-1. Consulting and outside services decreased by \$1.4 million for the three months ended March 31, 2015, as compared to the comparable period in 2014 primarily as a result of decreases in clinical development consulting activities and the use of outside medical safety liaisons. Stock-based compensation decreased by \$0.9 million for the three months ended March 31, 2015 as compared to the comparable period in 2014 due to a decrease in outstanding awards and unvested options without performance objectives.

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-five clinical trials, across multiple indications, including two ongoing phase 3 pivotal trials focusing on mRCC 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. It is difficult to predict the magnitude of our research and development expenses as such expenses will be dependent on the outcome of our ongoing phase 3 clinical trials.

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

28

---

Table of Contents

may involve unanticipated additional clinical trials and may not result in receipt of the necessary regulatory approvals. Failure to receive the necessary regulatory approvals would prevent us from commercializing the product candidates affected. In addition, clinical trials of our potential product candidates may fail to demonstrate safety and efficacy, which could prevent or significantly delay regulatory approval.

## Selling, General and Administrative Expenses

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

	Three Months Ended March 31,	
	2015	2014
Selling, general and administrative expenses	\$9,531	\$14,691
Dollar change	\$(5,160)	)
Percentage change	(35	)%

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

The decrease in selling, general and administrative expenses for the three months ended March 31, 2015, as compared to the comparable period in 2014, was primarily related to personnel expenses, consulting and outside services, legal and accounting costs and stock-based compensation. Those decreases were partially offset by an increase in marketing costs. Personnel expenses decreased by \$3.5 million for the three months ended March 31, 2015 as compared to the comparable period in 2014 primarily due to workforce reductions undertaken as a consequence of the failure of COMET-1. Consulting and outside services decreased by \$1.4 million for the three months ended March 31, 2015, as compared to the comparable period 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 facilities we are no longer occupying and our Board of Director's decision to receive stock awards in lieu of cash compensation for services rendered during the fourth quarter of 2014 and all of 2015. Legal and accounting costs decreased by \$1.2 million for the three months ended March 31, 2015 as compared to the comparable period in 2014 primarily due to decreases in activities related to patent filings and defense. Stock-based compensation decreased by \$1.2 million for the three months ended March 31, 2015 as compared to the comparable period in 2014 due to a decrease in outstanding awards and unvested options without performance objectives. Those decreases were partially offset by a \$1.5 million increase in marketing expenses, which include our share of the pre-commercial preparation expenses for cobimetinib under our collaboration agreement with Genentech.

We are unable to predict the magnitude of our selling, general and administrative expenses as such expenses will be dependent on the outcome of our ongoing phase 3 clinical trials.

## 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 mCRPC, to meet its primary endpoint of demonstrating a statistically significant increase in overall survival for patients treated with cabozantinib as compared to prednisone, we initiated the 2014 Restructuring to reduce our workforce. Personnel reductions were initiated across our entire organization and have resulted in an ongoing workforce of approximately 85 full-time employees. 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 mRCC and advanced HCC. We expect to record an aggregate restructuring charge related to one-time employee termination benefits of approximately \$6.0 million, of which approximately 95% has been recorded from inception of the 2014 Restructuring through March 31, 2015 and the remainder is expected to be recorded during the three months ended June 30, 2015. Although we do not yet have contractual commitments in place, we have made progress towards subleasing our facilities and we currently expect to incur between \$2 million and \$6 million in additional facility-related charges as we exit certain facilities. We expect to record these facility-related charges during the remainder of fiscal year 2015 as they become determinable and as we exit certain facilities. We will not be able to predict our long-term facilities requirements with certainty until top-line results from METEOR become available, and we intend to re-evaluate and update such requirements upon the occurrence of this event.



Table of Contents

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

	Three Months Ended March 31,	
	2015	2014
Restructuring (recovery) charge	\$(431	) \$46
Dollar change	\$(477	)
Percentage change	(1,037	)%

The restructuring recovery for the three months ended March 31, 2015 was primarily related to recoveries on the sale of assets removed from service as a result of our restructuring plans. For the three months ended March 31, 2015 and 2014, we recorded restructuring charges of \$0.4 million and \$46 thousand, respectively the 2010 Restructurings 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. During the three months ended March 31, 2015 we also recorded \$0.3 million in additional charges due to changes in assumptions regarding anticipated sublease activities. During the three months ended March 31, 2014, restructuring charges were partially offset by \$0.1 million in recoveries recorded in connection with the sale of excess equipment and other assets.

Total Other Income (Expense), Net

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

	Three Months Ended March 31,	
	2015	2014
Interest income and other, net	\$(7	) \$2,131
Interest expense	(12,403	) (11,762
Total other expense, net	\$(12,410	) \$(9,631
Dollar change	\$(2,779	)
Percentage change	29	%

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 other non-operating gains and losses. Interest expense includes aggregate non-cash interest expense on both the 2019 Notes and the Deerfield Notes of \$7.7 million and \$7.0 million for the three months ended March 31, 2015 and 2014, respectively. Interest income and other, net for the three months ended March 31, 2015 and 2014 includes \$0.5 million in unrealized losses and \$1.7 million in unrealized gains, respectively, on the revaluation of the 2014 Deerfield Warrants.

Liquidity and Capital Resources

Sources and Uses of Cash

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

	Three Months Ended March 31,	
	2015	2014
Net loss	\$(35,170	) \$(74,619
Net cash used in operating activities	(45,086	) (72,086
Net cash provided by investing activities	49,895	60,360
Net cash (used in) provided by financing activities	(217	) 65,287
Net increase in cash and cash equivalents	4,592	53,561
Cash and cash equivalents at beginning of period	80,395	103,978
Cash and cash equivalents at end of period	\$84,987	\$157,539

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 March 31, 2015, we have generated \$49.5 million in net revenues from the sale of COMETRIQ. Other than revenues from COMETRIQ, we have derived substantially all of our revenues since

## Table of Contents

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 \$45.1 million for the three months ended March 31, 2015, compared to \$72.1 million for the same period in 2014.

Cash used in operating activities for the three months ended March 31, 2015 related primarily to our \$32.1 million operating expenses for the period, less non-cash expenses for accretion of debt discount totaling \$7.7 million on the Deerfield Notes and the 2019 Notes and stock-based compensation totaling \$1.7 million. Our operating expenses were largely attributable to the development of cabozantinib. In addition, we made cash payments that resulted in a \$10.6 million reduction in accrued clinical trial liabilities, a \$3.4 million reduction in accounts payable and other accrued expenses, and a \$1.8 million increase in prepaid expenses and other assets during the period. We also paid \$2.0 million for restructuring activities.

Cash used in operating activities for the three months ended March 31, 2014 related primarily to our \$69.9 million operating expenses for the period, less non-cash expenses for accretion of debt discount totaling \$7.0 million and stock-based compensation totaling \$3.8 million. We also made cash payments that resulted in a \$10.3 million reduction in accounts payable and other accrued expenses. In addition, we paid \$1.4 million for restructuring activities during the period.

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

### Investing Activities

Our investing activities provided cash of \$49.9 million for the three months ended March 31, 2015, compared to cash provided of \$60.4 million for the same period in 2014.

Cash provided by investing activities for the three months ended March 31, 2015 was primarily due to the maturity of unrestricted and restricted investments of \$65.2 million, less investment purchases of \$16.0 million.

Cash provided by investing activities for the three months ended March 31, 2014 was primarily due to the maturity of unrestricted and restricted investments of \$96.9 million, less investment purchases of \$36.4 million.

### Financing Activities

Our financing activities used cash of \$0.2 million for the three months ended March 31, 2015, compared to cash provided of \$65.3 million for the same period in 2014.

Cash used for financing activities for the three months ended March 31, 2015 was due to principal payments on debt of \$0.2 million.

Cash provided by our financing activities for 2014 was primarily due to the issuance of 10.0 million 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 \$10.5 million.

Proceeds from common stock and debt issuances are used for general working capital purposes, such as research and development activities and other general corporate purposes. 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 the three months ended March 31, 2015, with the exception of the 2011 fiscal year. We anticipate net losses and negative operating cash flow for the foreseeable future. For the three months ended March 31, 2015, we incurred a net loss of \$35.2 million and as of March 31, 2015, we had an accumulated deficit of \$1.8 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 2011, and we expect to spend significant additional amounts to fund the continued

development and commercialization of cabozantinib. As a result, we

31

---

Table of Contents

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 March 31, 2015, we have generated \$49.5 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 March 31, 2015, we had \$197.6 million in cash and investments, which included \$107.2 million available for operations, \$6.1 million of short-term restricted investments available for public debt service obligations, \$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. Taking into account our cost saving measures, including the planned effects of the 2014 Restructuring that we initiated on September 2, 2014, and the expected extension of the maturity date of the Deerfield Notes to July 1, 2018, 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 through the first quarter of 2016. While a forecast of future events is inherently uncertain, our ability to sustain our business operations through the first quarter of 2016 is highly dependent on the results of METEOR, the commercial success of COMETRIQ and the revenues we generate as well as the commercial success of cobimetinib and our share of related net profits and losses, and royalties under our collaboration with Genentech. 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 beyond the first quarter of 2016, including but not limited to actions such as further reductions in headcount, additional consolidation of administrative functions, asset sales and additional curtailment of our development activities. However, our future capital requirements will be substantial, and we may need to access additional capital. We seek additional capital to support future operations through licensing, partnering or other strategic collaborative arrangements, and we may pursue the issuance of equity or debt securities or external borrowings. It is unclear when any such transactions will occur, on satisfactory terms or at all. Our ability to raise additional capital in the equity and debt markets, should we choose to do so, is dependent on a number of factors, including, but not limited to, the market demand for our common stock, which itself is subject to a number of pharmaceutical development and business risks and uncertainties, as well as the uncertainty that we would be able to raise such additional capital at a price or on terms that are favorable to us.

Our capital requirements will depend on many factors including but not limited to:

- the progress and scope of the development and commercialization activities with respect to cabozantinib;
- the commercial success of COMETRIQ and the revenues we generate;
- our obligation to share U.S. marketing and commercialization 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;
- repayment of the \$104.0 million principal amount outstanding of the Deerfield Notes, which mature on July 1, 2015, unless the expected extension occurs, in which case we will also be required 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 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;

- whether we enter into new collaboration agreements, licensing agreements or other arrangements (including, in particular, with respect to cabozantinib) that provide additional capital;

• 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;



Table of Contents

the amount of our cash and cash equivalents, short- and long-term investments that serve as collateral for bank lines of credit;

future clinical trial results;

our need to expand our product and clinical development efforts;

the cost and timing of regulatory approvals;

the cost of clinical and research supplies for our clinical trials;

the effect of competing technological and market developments; and

the filing, maintenance, prosecution, defense and enforcement of patent claims and other intellectual property rights.

We may need to obtain additional funding in order to stay in compliance with financial covenants contained in our loan and security agreement with Silicon Valley Bank. The loan and security agreement requires that we 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 at all times 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. If the balance on our deposit account(s) falls below the required level for more than 10 days, 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. If we are unable to remain in compliance with our financial 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 election to extend the maturity date of the Deerfield Notes to 2018, \$97.4 million the outstanding principal has been reclassified from current to long-term liabilities as of March 31, 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 March 31, 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 March 31, 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 both March 31, 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 \$7.8 million.

In addition, we have exposure to fluctuations in certain foreign currencies in countries in which we conduct clinical trials. As of March 31, 2015, and December 31, 2014, approximately \$4.3 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 \$0.2 million gain and a \$44 thousand loss relating to foreign exchange fluctuations for the three months ended March 31, 2015 and 2014, respectively.

Item 4. Controls and Procedures.

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

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.

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;
- commercialize cabozantinib or any other future product candidates, if any such candidates receive regulatory approval for commercial sale; and
- fund the U.S. marketing and commercialization costs for cobimetinib we are obligated to share 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 March 31, 2015, we had \$197.6 million in cash and investments, which included \$107.2 million available for operations, \$6.1 million of short-term restricted investments available for public debt service obligations, \$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. Taking into account our cost saving measures, including the planned effects of the 2014 Restructuring that we initiated on September 2, 2014, and the expected extension of the maturity date of the Deerfield Notes to July 1, 2018, 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 through the first quarter of 2016. While a forecast of future events is inherently uncertain, our ability to sustain our business operations the first quarter of 2016 is highly dependent on the results of METEOR, the commercial success of COMETRIQ and the revenues we generate as well as the commercial success of cobimetinib and our share of related net profits and losses, and royalties under our collaboration with Genentech. 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 beyond the first quarter of 2016, including but not limited to actions such as further reductions in headcount, additional consolidation of administrative functions, asset sales and additional curtailment of our development activities. However, our future capital requirements will be substantial, and we may need to access additional capital. We may seek additional capital to support future operations through licensing, partnering or other strategic collaborative arrangements, and we may pursue the issuance of equity or debt securities or external borrowings. It is unclear when any such transactions will occur, on satisfactory terms or at all. Our ability to raise additional capital in the equity and debt markets, should we choose to do so, is dependent on a number of factors, including, but not limited to, the market demand for our common stock, which itself is subject to a number of pharmaceutical development and business risks and uncertainties, as well as the uncertainty that we would be able to raise such additional capital at a price or on terms that are favorable to us.

The sale of equity or convertible debt securities in the future may be substantially dilutive to our stockholders, and debt-financing arrangements may require us to pledge certain assets and enter into covenants that would restrict

certain business activities or our ability to incur further indebtedness, and could contain other terms that are not favorable to our stockholders or us.

Table of Contents

Our capital requirements will depend on many factors including but not limited to:

- the progress and scope of the development and commercialization activities with respect to cabozantinib;
  - the commercial success of COMETRIQ and the revenues we generate;
  - our obligation to share U.S. marketing and commercialization 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;
  - repayment of the \$104.0 million principal amount outstanding of the Deerfield Notes, which mature on July 1, 2015, unless the expected extension occurs, in which case we will also be required 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 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;
  - whether we enter into new collaboration agreements, licensing agreements or other arrangements (including, in particular, with respect to cabozantinib outside of the U.S.) that provide additional capital;
  - our ability to control costs;
  - our ability to remain in compliance with, or amend or cause to be waived, financial covenants contained in agreements with third parties;
  - the amount of our cash and cash equivalents, short- and long-term investments that serve as collateral for bank lines of credit;
  - future clinical trial results;
  - 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 competing technological and market developments; and
  - the filing, maintenance, prosecution, defense and enforcement of patent claims and other intellectual property rights.
- We may need to obtain additional funding in order to stay in compliance with financial 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 the three months ended March 31, 2015, with the exception of the 2011 fiscal year. We anticipate net losses and negative operating cash flow for the foreseeable future. For the three months ended March 31, 2015, we incurred a net loss of \$35.2 million and as of March 31, 2015, we had an accumulated deficit of \$1.8 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 2011, 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 March 31, 2015, we have generated \$49.5 million in net

revenues from

36

---

Table of Contents

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. 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 amount of additional 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 March 31, 2015, our total consolidated indebtedness through maturity was \$471.7 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 financial and other restrictive 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 which we may enter into from time to time may require early repayment of borrowings under

37

---



Table of Contents

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.

We may not realize the expected benefits of our cost-saving initiatives.\*

Reducing costs is a key element of our current business strategy. 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, to meet its primary endpoint of demonstrating a statistically significant increase in overall survival for patients treated with cabozantinib as compared to prednisone, we initiated the 2014 Restructuring to reduce our workforce. Personnel reductions were initiated across our entire organization and have resulted in an ongoing workforce of approximately 85 full-time employees. 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 mRCC and advanced HCC.

We expect to record an aggregate restructuring charge related to one-time employee termination benefits of approximately \$6.0 million, of which approximately 95% has been recorded from inception of the 2014 Restructuring through March 31, 2015 and the remainder is expected to be recorded during the three months ended June 30, 2015. Although we do not yet have contractual commitments in place, we have made progress towards subleasing our facilities and we currently expect to incur between \$2 million and \$6 million in additional facility-related charges as we exit certain facilities. We expect to record these facility-related charges during the remainder of fiscal year 2015 as they become determinable and as we exit certain facilities. We will not be able to predict our long-term facilities requirements with certainty until top-line results from METEOR become available, and we intend to re-evaluate and update such requirements upon the occurrence of this event.

As a consequence of the workforce reductions as well as potential for sublease income and/or rent relief, we are actively marketing portions of our facilities for sublease. Estimates for sublease income and/or rent relief would require significant assumptions regarding the time required to contract with subtenants, the amount of idle space we would be able to sublease and potential future sublease rates. Until we were able to negotiate an exit to the lease or negotiate a sublease for the remaining term of the lease for our vacant buildings, we will need to continue to update our estimate of the lease exit costs in our financial statements.

If we experience excessive unanticipated inefficiencies or incremental costs in connection with restructuring activities, such as unanticipated inefficiencies caused by reducing headcount or failure to find acceptable subtenants, we may be unable to meaningfully realize cost savings and we may incur expenses in excess of what we anticipate. Either of these outcomes could prevent us from meeting our strategic objectives and could adversely impact our results of operations and financial condition.

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

Most of our foreign expenses incurred are associated with establishing and conducting clinical trials for cabozantinib. The amount of 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 March 31, 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.

We may not achieve expected benefits as a result of changes to our corporate structure.

During 2013, we engaged in intercompany transactions with a newly established wholly-owned foreign subsidiary pursuant to which such subsidiary acquired the existing and future intellectual property rights to exploit cabozantinib in jurisdictions outside of the United States, and we may establish additional wholly-owned foreign subsidiaries in the future. We

38

---

Table of Contents

established this structure in anticipation of an increase in the international nature of our business activities and to reduce our overall effective tax rate through changes in how we develop and use our intellectual property and the structure of our international procurement and sales, including by entering into transfer-pricing arrangements that establish transfer prices for our intercompany transactions. One of our objectives is to achieve a reduction in our overall effective tax rate in the future as a result. There can be no assurance that the taxing authorities of the jurisdictions in which we determine to operate or to which we will otherwise be deemed to have sufficient tax nexus will not challenge the tax benefits that we expect to realize as a result of the new structure. In addition, future changes to U.S. or non-U.S. tax laws, including proposed legislation to reform U.S. taxation of international business activities would negatively impact the anticipated tax benefits of the new structure. Any benefits to our tax rate will also depend on our ability and decision to operate our business in a manner consistent with the new structure of our corporate organization and applicable taxing provisions, including by eliminating the amount of cash distributed to us by our subsidiaries. If the intended tax treatment is not accepted by the applicable taxing authorities, changes in tax law negatively impact the structure or we do not operate our business consistent with the new structure and applicable tax provisions, we may fail to achieve the financial efficiencies that we anticipate as a result of the changes to our corporate structure, and our future operating results and financial condition may be negatively impacted.

**Risks Related to Cabozantinib and Cobimetinib**

We are dependent on the successful development and commercialization of cabozantinib.

The success of our business is dependent upon the successful development and commercialization of cabozantinib. As part of our strategy, we are dedicating substantially all of our proprietary resources to advance cabozantinib as aggressively as possible. On November 29, 2012, the FDA approved cabozantinib for the treatment of progressive, metastatic MTC in the United States under the brand name COMETRIQ<sup>(R)</sup>, and we commercially launched COMETRIQ in late January 2013. 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. The European Commission granted conditional marketing authorization following a positive opinion from CHMP, issued in December 2013. We view the approvals of COMETRIQ by the FDA and European Commission for MTC as transitional events towards our objective of developing cabozantinib into a significant oncology franchise. Our ability to realize this objective is contingent on, among other things, successful clinical development, regulatory approval and market acceptance of cabozantinib. The failure of COMET-1 and COMET-2, our two phase 3 pivotal trials of cabozantinib in mCRPC, to meet their respective primary endpoints has impacted our ability to achieve our development and commercialization goals for cabozantinib. If we encounter additional difficulties in the development of cabozantinib in other indications beyond MTC due to any of the factors discussed in this “Risk Factors” section or otherwise, or we do not receive regulatory approval in such indications or are unable to successfully commercialize cabozantinib in such other indications, if approved, we will not have the resources necessary to continue our business in its current form.

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

We have entered into a worldwide collaboration agreement with Genentech for the development and commercialization of cobimetinib, a compound discovered by Exelixis and licensed to Genentech in 2009 after determination of the maximum tolerated dose in a phase 1 clinical trial. Genentech is responsible for cobimetinib’s clinical development and, if cobimetinib is approved, for worldwide commercialization. Under the terms of our 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 equally in the U.S. marketing and commercialization costs. Pursuant to our collaboration agreement, we may provide up to 25% of the total sales force for cobimetinib in the United States, if cobimetinib is commercialized.

On September 29, 2014, positive results from coBRIM, a phase 3 pivotal trial evaluating cobimetinib in combination with vemurafenib in previously untreated patients with unresectable locally advanced melanoma harboring a BRAF V600 mutation, were reported at the ESMO 2014 Congress. The trial met its primary endpoint of demonstrating a statistically significant increase in investigator-determined PFS. On the basis of data from the coBRIM trial, Roche submitted a MAA for cobimetinib in combination with vemurafenib in the European Union in September 2014.

In the United States, Genentech submitted its NDA in December 2014 and the FDA has granted the NDA priority review, with a projected action date of August 11, 2015.

Under the terms of our collaboration agreement, we 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

## Table of Contents

significance are Genentech's development efforts with respect to the combination of cobimetinib with immune-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 immune-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.

We are similarly dependent upon Genentech's strategic and tactical planning and decision-making with regard to the commercialization of cobimetinib; and, in addition, during the period prior to commercialization, we are obligated to reimburse half of Genentech's costs for commercializing the drug in the U.S. 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.

The commercial success of COMETRIQ for MTC and any other potential approvals of cabozantinib in additional indications in the future will depend upon the degree of market acceptance of cabozantinib among physicians, patients, health care payers, and the medical community.

Our ability to commercialize cabozantinib for the approved MTC indication and potentially other indications, if approved, 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 cabozantinib 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;
- 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 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 established a small internal commercial organization that we believe is commensurate with the size of the market opportunity for the applicable approved MTC indication in the United States and European Union. We have also designed our commercial organization to maintain flexibility, and to enable us to quickly scale up if additional indications are approved in the future or scale down if we are not successful in gaining approval of additional indications. We believe we have created an efficient commercial organization, taking advantage of outsourcing options where prudent to maximize the effectiveness of our commercial expenditures. However, we may not be able to correctly judge the size and experience of the sales and marketing force and the scale of distribution necessary to successfully market and sell cabozantinib. Maintaining sales, marketing, and distribution capabilities is expensive and time-consuming. Such expenses may be disproportional 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

Table of Contents

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;

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 prices 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 COMETRIQ 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,

41

---



Table of Contents

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.

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 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;

Table of Contents

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 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 industry is highly fragmented and is 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 cobimetinib and cabozantinib. In addition, cobimetinib and cabozantinib may compete with existing therapies that have long histories of use, such as chemotherapy and radiation treatments in cancer indications.

## Table of Contents

### 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. 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.

We believe that if cabozantinib is approved for the treatment of the indications for which we currently have ongoing phase 3 pivotal trials, its potential principal competition in such indications may include the following:

**RCC:** 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; and

**HCC:** 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 immune-oncology agents such as Bristol-Myers Squibb's ipilimumab and nivolumab and Merck's pembrolizumab.

### Competition for cobimetinib

We believe that if cobimetinib is approved for the treatment of advanced melanoma, its potential principal competition amongst targeted agent's may include Novartis' trametinib and dabrafenib, and Array's ecorafenib and binimetinib; and within the class of immune-oncology agents, Bristol-Myers Squibb's ipilimumab and nivolumab and Merck's pembrolizumab. The second category, immune-oncology agents, 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 COMETRIQ 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.

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,

## Table of Contents

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.

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 RCC, 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 mRCC, 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

45

---



## Table of Contents

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 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

## Table of Contents

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. marketing and commercialization 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; 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 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 the 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 maintain sensitive data on our networks, including our intellectual property and proprietary or confidential business information relating to our business and that of our customers and business partners. 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, all ranging in sophistication from an individual hacker to a state-sponsored attack. Cyber threats may be generic, or they may be custom-crafted against our information systems. Over the past year, cyber-attacks

Table of Contents

have become more prevalent and much harder to detect and defend against. Our network and storage applications may be subject to unauthorized access by hackers or breached due to operator error, malfeasance or other system disruptions. It is often difficult to anticipate or immediately detect such incidents and the damage caused by such incidents. These data breaches and any unauthorized access or disclosure of our information or intellectual property could compromise our intellectual property and expose sensitive business information. A data security breach could also lead to public exposure of personal information of our clinical trial patients, customers and others. Cyber-attacks could cause us to incur significant remediation costs, result in product development delays, disrupt key business operations and divert attention of management and key information technology resources. 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

## Table of Contents

infringement is brought against us, we may be required to pay damages and obtain one or more licenses from third parties. We may not be able to obtain these licenses at a reasonable cost, or at all. Defense of any lawsuit or failure to obtain any of these licenses could adversely affect our ability to develop and commercialize products.

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

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

### Risks Related to Employees and Location

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

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

Our network security and data recovery measures may not be adequate to protect against computer viruses, break-ins, and similar disruptions from unauthorized tampering with our computer systems. The misappropriation, theft, sabotage or any other type of security breach with respect to any of our proprietary and confidential information that is electronically stored, including research or clinical data, could subject us to liability and have a material adverse impact on our business, operating results and financial condition. Additionally, 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



## Table of Contents

clinical data, or that results in damage to our research and development equipment and assets, could subject us to liability and have a material adverse impact on our business, operating results and financial condition.

### Risks Related to Environmental and Product Liability

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

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

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

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

We may be held liable if any product we or our collaborators develop 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 progress and scope of our development and commercialization activities;
- the commercial success of COMETRIQ and the revenues we generate;
- 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;
- our ability to enter into new collaborative relationships;
- the termination or non-renewal of existing collaborations;

the timing and amount of expenses incurred for clinical development and manufacturing of cabozantinib;

50

---

Table of Contents

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; and  
 general and industry-specific economic conditions that may affect our collaborators' research and development expenditures.

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;
- 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.



## Table of Contents

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 Exelixis 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.

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;

Table of Contents

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.

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.

April 30, 2015  
Date

/s/ DEBORAH BURKE  
Deborah Burke  
Senior 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		Exhibit/ Appendix Reference	Filing Date	Filed Herewith
		Form	File Number			
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-Cepto 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	
3.4	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	Form of Note, dated July 1, 2010, in favor of Deerfield Private Design International, L.P.	10-Q	000-30235	10.1 (Exhibit A-1)	8/5/2010	
4.3	Form of Note, dated July 1, 2010, in favor of Deerfield Private Design Fund, L.P.	10-Q	000-30235	10.1 (Exhibit A-2)	8/5/2010	
4.4	Form of Amended and Restated Secured Convertible Note issuable to entities affiliated with Deerfield Management Company, L.P.	8-K	000-30235	10.1 (Exhibit A)	1/22/2014	
4.5	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	
4.6	Form of Warrant to Purchase Common Stock of Exelixis, Inc. issued to Deerfield Partners, L.P. and Deerfield International Master Fund, L.P.	8-K	000-30235	4.1	1/22/2014	
4.7	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	
4.8	First Supplemental Indenture dated August 14, 2012 to Indenture dated	8-K	000-30235	4.2	8/14/2012	

Edgar Filing: EXELIXIS, INC. - Form 10-Q

August 14, 2012 by and between  
Exelixis, Inc. and Wells Fargo Bank,  
National Association

4.9	Form of 4.25% Convertible Senior Subordinated Note due 2019	8-K	000-30235	4.2 (Exhibit A)	8/14/2012
10.1	Compensation Information for Named Executive Officers	8-K	000-30235	5.02 Disclosure	2/11/2015
10.2	Compensation Information for Non-Employee Directors	8-K	000-30235	10.2	10/16/2014

55

---

Table of Contents

Exhibit Number	Exhibit Description	Incorporation by Reference		Exhibit/ Appendix Reference	Filing Date	Filed Herewith
		Form	File Number			
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

‡ 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.