

EXELIXIS, INC.
Form 10-Q
July 31, 2014
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 June 27, 2014

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: 0-30235

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 July 24, 2014, there were 195,109,967 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 – June 30, 2014 and December 31, 2013</u>	<u>3</u>
	<u>Condensed Consolidated Statements of Operations – Three and Six Months Ended June 30, 2014 and 2013</u>	<u>4</u>
	<u>Condensed Consolidated Statements of Comprehensive Loss – Three and Six Months Ended June 30, 2014 and 2013</u>	<u>4</u>
	<u>Condensed Consolidated Statements of Cash Flows – Six Months Ended June 30, 2014 and 2013</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>18</u>
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>30</u>
Item 4.	<u>Controls and Procedures</u>	<u>30</u>

PART II - OTHER INFORMATION

Item 1.	<u>Legal Proceedings</u>	<u>32</u>
Item 1A.	<u>Risk Factors</u>	<u>32</u>
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>48</u>
Item 3.	<u>Defaults Upon Senior Securities</u>	<u>48</u>
Item 4.	<u>Mine Safety Disclosures</u>	<u>48</u>
Item 5.	<u>Other Information</u>	<u>49</u>
Item 6.	<u>Exhibits</u>	<u>49</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)

	June 30, 2014 (unaudited)	December 31, 2013*
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 147,340	\$ 103,978
Short-term investments	86,177	138,475
Short-term restricted cash and investments	12,214	12,213
Trade and other receivables	5,034	3,941
Inventory	3,026	2,890
Prepaid expenses and other current assets	4,792	5,112
Total current assets	258,583	266,609
Long-term investments	95,513	144,299
Long-term restricted cash and investments	10,781	16,897
Property and equipment, net	4,052	4,910
Goodwill	63,684	63,684
Other assets	8,022	6,888
Total assets	\$ 440,635	\$ 503,287
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 4,638	\$ 9,345
Accrued clinical trial liabilities	41,367	34,958
Accrued compensation and benefits	9,856	12,797
Other accrued liabilities	15,859	13,116
Current portion of convertible notes	94,207	10,000
Current portion of loans payable	1,077	1,762
Current portion of restructuring	3,726	4,425
Deferred revenue	1,127	1,450
Total current liabilities	171,857	87,853
Long-term portion of convertible notes	173,635	255,147
Long-term portion of loans payable	80,055	80,328
Long-term portion of restructuring	6,743	9,047
Other long-term liabilities	5,102	4,674
Total liabilities	437,392	437,049
Commitments		
Stockholders' equity:		
Preferred stock	—	—
Common stock, \$0.001 par value; 400,000,000 shares authorized; issued and outstanding:		
195,088,645 and 184,533,651 shares at June 30, 2014 and December 31, 2013, respectively	195	184
Additional paid-in capital	1,649,662	1,564,670
Accumulated other comprehensive income	177	146
Accumulated deficit	(1,646,791)	(1,498,762)

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

Total stockholders' equity	3,243	66,238
Total liabilities and stockholders' equity	\$440,635	\$503,287

* The condensed consolidated balance sheet as of December 31, 2013 has been derived from the audited financial statements as of that date.

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

Table of Contents

EXELIXIS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Revenues:				
Net product revenues	\$6,562	\$4,043	\$11,467	\$5,899
License and contract revenues	—	7,813	—	15,626
Total revenues	6,562	11,856	11,467	21,525
Operating expenses:				
Cost of goods sold	477	285	786	565
Research and development	50,976	49,077	105,823	81,812
Selling, general and administrative	16,466	13,180	31,157	23,725
Restructuring charge	331	609	377	728
Total operating expenses	68,250	63,151	138,143	106,830
Loss from operations	(61,688) (51,295) (126,676) (85,305
Other income (expense), net:				
Interest income and other, net	359	373	2,490	711
Interest expense	(12,081) (11,239) (23,843) (22,296
Total other income (expense), net	(11,722) (10,866) (21,353) (21,585
Net loss	\$(73,410) \$(62,161) \$(148,029) \$(106,890
Net loss per share, basic and diluted	\$(0.38) \$(0.34) \$(0.77) \$(0.58
Shares used in computing basic and diluted net loss per share	194,929	183,981	193,323	183,861

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 June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Net loss	\$(73,410) \$(62,161) \$(148,029) \$(106,890
Other comprehensive income (loss) (1)	24	(365) 31	(171
Comprehensive loss	\$(73,386) \$(62,526) \$(147,998) \$(107,061

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

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

Table of Contents

EXELIXIS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Six Months Ended June 30,	
	2014	2013
Cash flows from operating activities:		
Net loss	\$(148,029)	\$(106,890)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,093	1,628
Stock-based compensation expense	7,740	5,605
Accretion of debt discount	14,316	12,793
Changes in the fair value of warrants	(1,854)	—
Other	2,615	3,642
Changes in assets and liabilities:		
Trade and other receivables	(1,093)	(1,458)
Inventory	(136)	(681)
Prepaid expenses and other assets	226	224
Accounts payable, accrued compensation, and other accrued liabilities	(4,905)	379
Clinical trial liabilities	6,409	8,846
Restructuring liability	(3,003)	(3,349)
Other long-term liabilities	(479)	(374)
Deferred revenue	(323)	(14,814)
Net cash used in operating activities	(127,423)	(94,449)
Cash flows from investing activities:		
Purchases of property and equipment	(344)	(1,402)
Proceeds from sale of property and equipment	281	—
Proceeds from maturities of restricted cash and investments	10,777	9,868
Purchase of restricted cash and investments	(4,643)	(3,784)
Proceeds from maturities of investments	181,258	209,889
Purchases of investments	(82,280)	(147,751)
Net cash provided by investing activities	105,049	66,820
Cash flows from financing activities:		
Proceeds from issuance of common stock, net	75,646	—
Proceeds from exercise of stock options and warrants	120	22
Proceeds from employee stock purchase plan	928	894
Principal payments on debt	(10,958)	(11,582)
Net cash provided by (used in) financing activities	65,736	(10,666)
Net increase (decrease) in cash and cash equivalents	43,362	(38,295)
Cash and cash equivalents at beginning of period	103,978	170,069
Cash and cash equivalents at end of period	\$147,340	\$131,774
Supplemental cash flow disclosure - non-cash financing activity:		
Issuance of warrants in connection with amendment to convertible notes	\$2,762	\$—

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 potent, highly selective inhibitor of MEK, which we out-licensed to Genentech (a member of the Roche Group) (“Genentech”). We are evaluating cabozantinib in a broad development program, including five ongoing phase 3 pivotal trials. We currently expect top-line results in 2014 from our two phase 3 pivotal trials of cabozantinib in metastatic castration-resistant prostate cancer, and from the overall survival analysis of our phase 3 EXAM pivotal trial of cabozantinib in progressive metastatic medullary thyroid cancer (“MTC”). Genentech is evaluating cobimetinib in a broad development program. On July 14, 2014, we reported positive top-line results from Genentech’s coBRIM study, a phase 3 pivotal trial evaluating cobimetinib in combination with vemurafenib in previously untreated patients with unresectable locally advanced or metastatic melanoma harboring a BRAF^{V600} mutation.

We are focusing our development and commercialization efforts primarily on cabozantinib. Cabozantinib was approved by the U.S. Food and Drug Administration (“FDA”), on November 29, 2012, for the treatment of progressive, metastatic MTC, in the United States under the brand name COMETRIQ^(R). COMETRIQ became commercially available in the United States 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 the European Committee for Medicinal Products for Human Use (“CHMP”), issued in December 2013.

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 2013, a 52-week year, ended on December 27, 2013, and fiscal year 2014, a 53-week year, will end on January 2, 2015. For convenience, references in this report as of and for the fiscal periods ended June 27, 2014 and June 28, 2013, and as of the fiscal year ended December 27, 2013, are indicated as ended June 30, 2014, June 30, 2013, and December 31, 2013, respectively.

Operating results for the six months ended June 30, 2014 are not necessarily indicative of the results that may be expected for the fiscal year ending January 2, 2015 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, 2013, included in our Annual Report on Form 10-K filed with the SEC on February 20, 2014.

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

Table of Contents

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.

Revenue Recognition

We recognize revenue from the sale of COMETRIQ and 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, 2013 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 six months ended June 30, 2014. 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, 2013 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 shipment of the product to the patient by our distributor. For product sales in Europe, this occurs when our European distribution partner has accepted 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. We have a limited sales history and cannot reliably estimate expected returns of the product nor the discounts and rebates due to payors at the time of shipment to the specialty pharmacy. Accordingly, upon shipment to the specialty pharmacy, we record deferred revenue on our Consolidated Balance Sheets. We recognize revenue when the specialty pharmacy provides the product to a patient based on the fulfillment of a prescription. We record revenue using an analysis of prescription data from our specialty pharmacy to ascertain the date of shipment and the payor mix. This approach is frequently referred to as the “sell-through” revenue recognition model. Once the prescription has been provided to the patient, it is not subject to return unless the product is damaged.

We record revenue at the time our European distribution partner has accepted the product, a method also known as the “sell-in” revenue recognition model.

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 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. Our European distribution partner is entitled to receive a project management fee based upon the achievement of a pre-specified revenue goal which, when deemed probable, is ratably accrued as a reduction to gross revenue. 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, 2013 for a further description of our discounts and allowances.

Cost of Goods Sold

Cost of goods sold is related to our product revenues and consisted primarily of a 3% royalty and indirect labor costs, and to a lesser extent, the cost of manufacturing and other third party logistics costs of our product. A significant 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.

In accordance with our product development and commercialization agreement with GlaxoSmithKline, we are required to pay GlaxoSmithKline a 3% royalty on the Net Sales of any product incorporating cabozantinib, including

COMETRIQ. Net Sales is defined in the product development and commercialization agreement generally as the gross invoiced sales price less customer credits, rebates, chargebacks, shipping costs, customs duties, and sales tax and other similar tax payments we are required to make.

Table of Contents

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. Adoption will be permitted using either a retrospective or modified retrospective approach, and is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016. Early adoption is not permitted. We are currently evaluating the impact of adopting this ASU, inclusive of available transitional methods on our consolidated financial statements and related disclosures.

NOTE 2: RESTRUCTURINGS

Between March 2010 and May 2013, we implemented five restructurings (referred to collectively as the "Restructurings") to manage costs and as a consequence of our decision to focus our proprietary resources and development efforts on the development and commercialization of cabozantinib. The aggregate reduction in headcount from the Restructurings was 429 employees. Charges and credits related to the Restructurings were recorded in periods other than those in which the 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.

We have recorded aggregate restructuring charges of \$53.7 million in connection with the Restructurings, of which \$29.7 million related to facility charges, \$21.7 million related to termination benefits, \$2.2 million related to the impairment of excess equipment and other assets, and an additional minor amount related to legal and other fees. For the six months ended June 30, 2014 and 2013, we recorded restructuring charges of \$0.4 million and \$0.7 million, respectively. The charges for both periods presented were 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 six months ended June 30, 2014, those 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 Restructurings is included in the current and long-term portion of restructuring on the accompanying Consolidated Balance Sheets. The components and changes of these liabilities during the annual periods from inception of the restructuring activities through the year ended December 31, 2013 and during the six months ended June 30, 2014 are summarized in the following table (in thousands):

	Facility Charges	Other	Total
Restructuring liability as of December 31, 2012	\$19,202	\$20	\$19,222
Restructuring charge	662	569	1,231
Cash payments	(6,331)) (434)) (6,765)
Adjustments or non-cash credits including stock compensation expense	(73)) (238)) (311)
Proceeds from sale of assets	—	95	95
Restructuring liability as of December 31, 2013	13,460	12	13,472
Restructuring charge (credit)	490	(113)) 377
Cash payments	(3,496)) (6)) (3,502)
Adjustments or non-cash credits	9	(86)) (77)
Proceeds from sale of assets	—	199	199
Restructuring liability as of June 30, 2014	\$10,463	\$6	\$10,469

We expect to pay accrued facility charges of \$10.5 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. With respect to our Restructurings, we expect to

incur additional restructuring charges of approximately \$1.1 million which relates 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. These charges will be recorded through the end of the building lease terms, the last of which ends in 2017.

Table of Contents

The Restructurings have resulted in aggregate cash expenditures of \$38.7 million, net of \$12.2 million in cash received from subtenants and \$2.9 million in cash received in connection with the sale of excess equipment and other assets. Net cash expenditures for the Restructurings were \$3.3 million and \$4.0 million during the six months ended June 30, 2014 and 2013, respectively.

The restructuring charges that we expect to incur in connection with the Restructurings are subject to a number of assumptions, 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.

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 June 30, 2014 and December 31, 2013 (in thousands):

	June 30, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents	\$147,339	\$2	\$(1)) \$147,340
Short-term investments	86,046	140	(9)) 86,177
Short-term restricted cash and investments	12,143	71	—	12,214
Long-term investments	95,489	47	(23)) 95,513
Long-term restricted cash and investments	10,726	55	—	10,781
Total cash and investments	\$351,743	\$315	\$(33)) \$352,025
	December 31, 2013			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents	\$103,978	\$—	\$—	\$103,978
Short-term investments	138,403	94	(22)) 138,475
Short-term restricted cash and investments	12,173	40	—	12,213
Long-term investments	144,226	106	(33)) 144,299
Long-term restricted cash and investments	16,837	60	—	16,897
Total cash and investments	\$415,617	\$300	\$(55)) \$415,862

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 June 30, 2014 and December 31, 2013 were \$82.8 million and \$83.7 million, respectively, and are reflected on the accompanying 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, 2013, 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 June 30, 2014 and December 31, 2013. The amounts presented exclude cash, but include investments classified as cash equivalents (in thousands):

	June 30, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	\$49,184	\$—	\$—	\$49,184
Commercial paper	97,856	—	—	97,856
Corporate bonds	150,828	178	(32)) 150,974
U.S. Treasury and government sponsored enterprises	26,186	126	(1)) 26,311

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

Municipal bonds	24,246	11	—	24,257
Total investments	\$348,300	\$315	\$(33) \$348,582

9

Table of Contents

	December 31, 2013			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	\$24,813	\$—	\$—	\$24,813
Commercial paper	94,682	—	—	94,682
Corporate bonds	239,937	190	(55) 240,072
U.S. Treasury and government sponsored enterprises	44,284	102	—	44,386
Municipal bonds	6,005	8		6,013
Total investments	\$409,721	\$300	\$(55) \$409,966

There were no realized gains or losses on the sales of investments during the six months ended June 30, 2014 and 2013.

All of our investments are subject to a quarterly impairment review. During the six months ended June 30, 2014 and 2013, we did not record any other-than-temporary impairment charges on our available-for-sale securities. As of June 30, 2014, there were 25 investments in an unrealized loss position with an aggregate fair value \$50.1 million. The investments in an unrealized loss position are primarily 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 June 30, 2014 (in thousands):

	Mature within One Year	After One Year through Two Years	Fair Value
Money market funds	\$49,184	\$—	\$49,184
Commercial paper	97,856	—	97,856
Corporate bonds	111,449	39,525	150,974
U.S. Treasury and government sponsored enterprises	20,215	6,096	26,311
Municipal bonds	24,257	—	24,257
Total investments	\$302,961	\$45,621	\$348,582

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):

	June 30, 2014	December 31, 2013
Raw materials	\$643	\$529
Work in process	1,871	2,280
Finished goods	512	81
Total	\$3,026	\$2,890

We received regulatory approval in the United States for our first product, COMETRIQ, on November 29, 2012. A significant portion of the manufacturing costs for our inventory 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.

Table of Contents

NOTE 5. DEBT

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

	June 30, 2014	December 31, 2013
Convertible Senior Subordinated Notes due 2019	\$173,635	\$165,296
Secured Convertible Notes due 2015	94,207	99,851
Silicon Valley Bank term loan	80,000	80,000
Silicon Valley Bank line of credit	1,132	2,090
Total debt	348,974	347,237
Less: current portion	(95,284)	(11,762)
Long-term debt	\$253,690	\$335,475

See “Note 8 - Debt” to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2013, 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 June 30, 2014, the entire principal balance remains outstanding. The following is a summary of the liability component of the 2019 Notes (in thousands):

	June 30, 2014	December 31, 2013
Net carrying amount of the liability component	\$173,635	\$165,296
Unamortized discount of the liability component	113,865	122,204
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 June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Stated coupon interest	\$3,054	\$3,054	\$6,143	\$6,109
Amortization of debt discount and debt issuance costs	4,397	4,001	8,692	7,910
Total interest expense	\$7,451	\$7,055	\$14,835	\$14,019

The balance of unamortized fees and costs was \$3.6 million and \$4.0 million as of June 30, 2014 and December 31, 2013, 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 June 30, 2014 and December 31, 2013, the remaining outstanding principal balance on the Deerfield Notes was \$104.0 million and \$114.0 million, respectively, which, subject to certain limitations, is payable in cash or in stock at our discretion. The following is a summary of interest expense for the Deerfield Notes (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Stated coupon interest	\$1,495	\$1,496	\$2,975	\$2,975
Amortization of debt discount and debt issuance costs	2,931	2,478	5,626	4,883
Total interest expense	\$4,426	\$3,974	\$8,601	\$7,858

Table of Contents

The balance of unamortized fees and costs was \$2.9 million and \$1.4 million as of June 30, 2014 and December 31, 2013, 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”). Under the terms of the Extension Option, which expires on March 31, 2015, we have the right to require Deerfield Partners, L.P. and Deerfield International Master Fund, L.P. (the “New Deerfield Purchasers”) to acquire \$100 million principal amount of the Deerfield Notes and extend the maturity date to July 1, 2018. If we exercise the Extension Option, 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. We are under no obligation to exercise the Extension Option.

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, which exercise price is subject to change in the event we exercise the Extension Option. See “Note 6 - Common Stock and Warrants” for further information on those warrants. We determined that the amendment resulted in the Deerfield Notes being modified. In connection with the amendment, we recorded a \$2.8 million deferred commitment fee upon the issuance of the 2014 Deerfield Warrants. See “Note 6 - Common Stock and Warrants” for further information on those warrants. The deferred commitment fee is included in Other assets and will be amortized into interest expense as a yield adjustment through the current maturity date of the Deerfield Notes, July 1, 2015. Third-party expenses, comprised primarily of legal and accounting fees, were expensed as of the date of the amendment.

NOTE 6. COMMON STOCK AND WARRANTS**Sale of Shares of Common Stock**

In January 2014 we completed a registered underwritten public offering of 10.0 million shares of our common stock at a price of \$8.00 per share pursuant to a shelf registration statement previously filed with the SEC, which the SEC declared effective on June 8, 2012. We received \$75.6 million in net proceeds from the offering after deducting the underwriting discount and related offering expenses.

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. If we exercise 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 which is included in Other long-term liabilities. The 2014 Deerfield Warrants are recorded at fair value, on a recurring basis, which was \$0.9 million and \$2.8 million as of June 30, 2014 and January 22, 2014, respectively. We recorded an unrealized gain on the warrants of \$0.1 million and \$1.9 million during the three and six months ended June 30, 2014, respectively, which is included in Interest income and other, net. See “Note 7 - Fair Value Measurements” for more information on the valuation of these warrants.

At June 30, 2014, the following warrants to purchase common stock were outstanding and exercisable:

Date Issued	Exercise Price per Share	Expiration Date	Number of Shares
January 22, 2014	\$9.70	January 22, 2016	1,000,000

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

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 June 30, 2014 and December 31, 2013. We did not have any financial liabilities that were measured and recorded on a recurring basis or Level 3 investments as of December 31, 2013. The amounts presented exclude cash, but include investments classified as cash equivalents (in thousands):

	June 30, 2014			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	\$49,184	\$—	\$—	\$49,184
Commercial paper	—	97,856	—	97,856
Corporate bonds	—	150,974	—	150,974
U.S. Treasury and government sponsored enterprises	—	26,311	—	26,311
Municipal bonds	—	24,257	—	24,257
Total financial assets	\$49,184	\$299,398	\$—	\$348,582
Financial liabilities:				
Warrants	\$—	\$—	\$908	\$908
Total financial liabilities	\$—	\$—	\$908	\$908
	December 31, 2013			
	Level 1	Level 2		Total
Money market funds	\$24,813	\$—		\$24,813
Commercial paper	—	94,682		94,682
Corporate bonds	—	240,072		240,072
U.S. Treasury and government sponsored enterprises	—	44,386		44,386
Municipal bonds	—	6,013		6,013
Total financial assets	\$24,813	\$385,153		\$409,966

There were no transfers between any of the fair value hierarchies, as determined at the end of each reporting period. The estimated fair values of our financial instruments that are carried at amortized cost for which it is practicable to determine a fair value were as follows (in thousands):

	June 30, 2014		December 31, 2013	
	Carrying Amount	Fair Value	Carrying Amount	Fair Value
2019 Notes	\$173,635	\$245,640	\$165,296	\$339,883
Silicon Valley Bank term loan	\$80,000	\$79,954	\$80,000	\$79,946
Silicon Valley Bank line of credit	\$1,132	\$1,132	\$2,090	\$2,090

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 and accrued clinical trial liabilities approximate their fair values and are excluded from the tables above.

The following methods and assumptions were used to estimate the fair value of each class of financial instrument for which it is practicable to estimate a value:

When available, we value investments based on quoted prices for those financial instruments, which is a Level 1 input. Our remaining investments are valued using third-party pricing sources, which use observable market prices, interest rates and yield curves observable at commonly quoted intervals of similar assets as observable inputs for pricing, which is a Level 2 input.

Table of Contents

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' equity 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. 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. 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 were estimated using the following assumptions, which, except for risk-free interest rate, are Level 3 inputs (dollars in thousands):

	June 30, 2014	January 22, 2014 (issuance date)		
Fair value of warrants	\$908	\$2,762		
Risk-free interest rate	0.98	% 0.95	%	
Dividend yield	—	% —	%	
Volatility	81	% 57	%	
Average expected life	2.8 years	3.2 years		

NOTE 8. STOCK-BASED COMPENSATION

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Research and development expense	\$1,471	\$1,553	\$3,036	\$2,960
Selling, general and administrative expense	2,511	1,370	4,704	2,638
Total employee stock-based compensation expense	\$3,982	\$2,923	\$7,740	\$5,598

We use the Black-Scholes 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 June 30,		Six Months Ended June 30,			
	2014	2013	2014	2013		
Weighted average grant-date fair value	\$2.33	\$2.56	\$3.65	\$2.52		
Risk-free interest rate	1.75	% 0.98	% 1.66	% 0.92	%	
Dividend yield	—	% —	% —	% —	%	
Volatility	80	% 62	% 81	% 62	%	
Expected life	5.8 years	5.6 years	5.6 years	5.5 years		

Table of Contents

	Employee Stock Purchase Plan			
	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Weighted average grant-date fair value	\$1.32	\$1.65	\$1.44	\$1.63
Risk-free interest rate	0.06	% 0.12	% 0.07	% 0.13
Dividend yield	—	% —	% —	% —
Volatility	67	% 67	% 64	% 67
Expected life	6 months	6 months	6 months	6 months

Of the stock options outstanding as of June 30, 2014, 3,640,752 were granted subject to performance objectives tied to the achievement of 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 June 30, 2014, we expect that achievement of some of those performance objectives is probable and have, therefore, recorded stock-based compensation expense in connection with such awards. We have not included any stock-based compensation expense for stock options with performance objectives for which the achievement of the performance goals is not considered probable; the grant date fair value of such awards outstanding was \$6.7 million.

A summary of all stock option activity for the six months ended June 30, 2014 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, 2013	23,983,275	\$6.48		
Granted	1,120,530	\$5.40		
Exercised	(19,090)) \$6.28		
Forfeited	(166,405)) \$5.52		
Expired	(423,467)) \$7.85		
Options outstanding at June 30, 2014	24,494,843	\$6.41	4.30 years	\$37
Exercisable at June 30, 2014	14,527,591	\$7.05	3.21 years	\$2

As of June 30, 2014, \$16.6 million of total unrecognized compensation expense related to employee stock options was expected to be recognized over a weighted-average period of 2.30 years.

A summary of all restricted stock unit ("RSU") activity for the six months ended June 30, 2014 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, 2013	1,810,521	\$5.56		
Awarded	61,842	\$5.19		
Released	(101,600)) \$6.78		
Forfeited	(62,540)) \$5.52		
Awards outstanding at June 30, 2014	1,708,223	\$5.48	2.96 years	\$5,928

As of June 30, 2014, \$6.2 million of total unrecognized compensation expense related to employee RSUs was expected to be recognized over a weighted-average period of 2.96 years.

Table of Contents

NOTE 9. NET LOSS PER SHARE

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Numerator:				
Net loss	\$ (73,410) \$ (62,161) \$ (148,029) \$ (106,890
Denominator:				
Shares used in computing basic and diluted net loss per share	194,929	183,981	193,323	183,861
Net loss per share, basic and diluted	\$ (0.38) \$ (0.34) \$ (0.77) \$ (0.58

The following table sets forth outstanding potential 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):

	June 30	
	2014	2013
Convertible debt	54,123	54,123
Outstanding stock options, unvested RSUs and ESPP contributions	26,308	18,147
Warrants	1,000	1,441
Total potentially dilutive shares	81,431	73,711

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 June 30, 2014, 78% of our trade and other receivables are with the specialty pharmacy that sells COMETRIQ in the United States and 12% 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 certain 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 ("NPU") 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. The remainder of our revenues were earned in the European Union.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Percentage of revenues earned in the United States	93	% 98	% 96	% 99

Table of Contents

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 during the three and six months ended June 30, 2014 and 2013:

	Three Months Ended June 30,		Six Months Ended June 30,		
	2014	2013	2014	2013	
Collaboration agreement:					
Bristol-Myers Squibb	—	% 66	% —	% 73	%
Product sales:					
Diplomat Specialty Pharmacy	93	% 32	% 96	% 26	%

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," "encouraging," 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, 2013, filed with the Securities and Exchange Commission, or SEC, on February 20, 2014. 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 potent, highly selective inhibitor of MEK, which we out-licensed to Genentech (a member of the Roche Group), or Genentech. We are evaluating cabozantinib in a broad development program, including five ongoing phase 3 pivotal trials. We currently expect top-line results in 2014 from two of our phase 3 pivotal trials of cabozantinib in metastatic castration-resistant prostate cancer, or CRPC, and from the overall survival analysis of our EXAM phase 3 pivotal trial of cabozantinib in progressive, metastatic medullary thyroid cancer, or MTC. Genentech is evaluating cobimetinib in a broad development program. On July 14, 2014, we reported positive top-line results from Genentech's coBRIM study, a phase 3 pivotal trial evaluating cobimetinib in combination with vemurafenib in previously untreated patients with unresectable locally advanced or metastatic melanoma harboring a BRAF^{V600} mutation.

We are focusing our development and commercialization efforts primarily on cabozantinib. Cabozantinib was approved by the U.S. Food and Drug Administration, or FDA, on November 29, 2012, for the treatment of progressive, metastatic MTC in the United States under the brand name COMETRIQ^(R). COMETRIQ became commercially available in the United States 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 the European Committee for Medicinal Products for Human Use, or CHMP, issued in December 2013.

The cabozantinib development program comprises over fifty clinical trials, including two ongoing phase 3 pivotal trials in metastatic CRPC, an ongoing phase 3 pivotal trial in metastatic renal cell cancer, or RCC, and an ongoing phase 3 pivotal trial in advanced hepatocellular cancer, or HCC. We believe cabozantinib has the potential to be a broadly-active and differentiated anti-cancer agent that can make a meaningful difference in the lives of patients. Our objective is to develop cabozantinib into a major oncology franchise, and we believe that the initial regulatory approvals of COMETRIQ for MTC provide us with the opportunity to establish a commercial presence to further this objective. We currently expect top-line results in 2014 from our two phase 3 pivotal trials of cabozantinib in metastatic CRPC, and from the overall survival analysis of our EXAM phase 3 pivotal trial of cabozantinib in progressive, metastatic MTC.

Our Strategy

We believe that the available clinical data demonstrate that cabozantinib has the potential to be a broadly active anti-cancer agent, and our objective is to build cabozantinib into a major 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.

We are focusing our internal efforts on cancers for which we believe cabozantinib has significant therapeutic and commercial potential in the near term, while utilizing 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 to allow 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. Most notable of these is cobimetinib, which is being evaluated by Roche and Genentech in a broad development program, including a phase 3 pivotal trial which has recently yielded positive top-line results. In the aggregate, these partnered compounds could potentially be of significant value to us if their development progresses 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, although in the case of cobimetinib, if the compound is commercialized, we will provide up to 25% of the total sales force for cobimetinib in the United States, under the terms of our co-development agreement with Genentech. 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.

With respect to our partnered compounds, 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.

Our collaboration with Genentech for cobimetinib continues to be of increasing importance to us in 2014 since cobimetinib is our most advanced partnered compound in development and has the greatest near-term commercial potential. On July 11, 2014, Genentech informed us that it received positive top-line results from coBRIM, a phase 3 pivotal trial evaluating cobimetinib in combination with vemurafenib in previously untreated patients with unresectable locally advanced or metastatic melanoma harboring a BRAF^{V600} mutation. Roche has announced that the coBRIM data are planned for presentation at the European Society for Medical Oncology, or ESMO, 2014 Congress taking place in Madrid, Spain, September 26 - 30, 2014. They have also stated that they plan to initiate regulatory filings for the combination before year end.

Preliminary results from BRIM7, an ongoing phase 1b dose escalation study conducted by Roche and Genentech of the BRAF inhibitor vemurafenib in combination with cobimetinib in patients with locally advanced/unresectable or metastatic melanoma carrying a BRAF^{V600} mutation were presented at the 2012 European Society for Medical Oncology Annual Meeting. Final data from BRIM7 reported at the 10th European Association of Dermato-Oncology, or EADO, Congress in May 2014 suggest that the preliminary safety profile and activity of the investigational combination of cobimetinib and vemurafenib are encouraging in BRAF inhibitor-naïve patients. Although the phase 1b dose escalation study was designed to evaluate the safety and tolerability of cobimetinib in combination with vemurafenib, objective responses (comprising complete or partial responses) were observed in 87% of the patients who had not been previously treated with a BRAF inhibitor.

In addition, the following clinical trials of cobimetinib in combination with other agents are ongoing, as disclosed on clinicaltrials.gov:

- A Study of MEHD7945A and Cobimetinib (GDC-0973) in Patients With Locally Advanced or Metastatic Cancers With Mutant KRAS (NCT01986166);
- Safety, Tolerability, and Pharmacokinetics of Onartuzumab Combined With Vemurafenib and/or Cobimetinib in Cancer Patients (NCT01974258);

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); and
A Study Evaluating the Safety, Tolerability, and Pharmacokinetics of GDC-0973 in Combination With GDC-0068 When Administered in Patients With Locally Advanced or Metastatic Solid Tumors (NCT01562275).

Under the terms of our co-development agreement with Genentech for cobimetinib, we are entitled to an initial equal share of U.S. profits and losses for cobimetinib, which will decrease as sales increase, and 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 co-development agreement to co-promote in the United States. As a result of exercising our option to co-promote, we are allowed to provide up to 25% of the total sales force for cobimetinib in the United States if commercialized, and will call on customers and otherwise

Table of Contents

engage in promotional activities using that sales force, consistent with the terms of the co-development agreement and a co-promotion agreement to be entered into by the parties.

In April 2014, we received a notice from GlaxoSmithKline of its intent to terminate the development of foretinib and to return it to us pursuant to the terms and conditions of the product development and commercialization agreement between the parties. We continue to work with GlaxoSmithKline on the transition of the program, which we expect will be completed in the third quarter of 2014. It is contemplated that in connection with the return of foretinib, the product development and commercialization agreement will terminate, although GlaxoSmithKline will continue to be entitled to a 3% royalty on net sales of any product incorporating cabozantinib, including COMETRIQ, and a 4% royalty on net sales of any product incorporating foretinib.

Business Highlights for the Three Months Ended June 30, 2014 and Recent Developments

Positive Top-Line Results for Phase 3 Pivotal Trial of Cobimetinib in Combination with Vemurafenib in Patients with BRAF^{V600} Mutation-Positive Advanced Melanoma

On July 11, 2014, Genentech informed us that the coBRIM study, a phase 3 pivotal trial evaluating cobimetinib in combination with vemurafenib in previously untreated patients with unresectable locally advanced or metastatic melanoma harboring a BRAF^{V600} mutation had met its primary endpoint, delivering a statistically significant increase in progression-free survival for the combination of cobimetinib with vemurafenib as compared to vemurafenib alone. Genentech further informed us that adverse events associated with the coBRIM study were consistent with those observed in a previous study of the combination. Roche has announced that the coBRIM data are planned for presentation at the ESMO 2014 Congress taking place in Madrid, Spain, September 26 - 30, 2014. They have also stated that they plan to initiate regulatory filings for the combination before year end.

Data Presented at the 2014 Annual Meeting of the American Society of Clinical Oncology

In May 2014, clinical data from cabozantinib and cobimetinib was the subject of ten separate data presentations at the 2014 Annual Meeting of the American Society of Clinical Oncology, including, among others, "Trials in Progress" poster presentations describing the trial design of our ongoing phase 3 pivotal trial comparing cabozantinib to placebo in patients with advanced HCC who have previously been treated with sorafenib, and our ongoing phase 3 pivotal trial comparing cabozantinib to everolimus in patients with metastatic RCC who have experienced disease progression following treatment with at least one prior VEGFR tyrosine kinase inhibitor. Additionally, phase 1 and phase 2 data from ongoing trials conducted under the CRADA with NCI-CTEP and our investigator sponsored trial program were presented. Cobimetinib was the subject of one oral presentation highlighting positive data from BRIM7, an ongoing phase 1b clinical trial, conducted by Roche and Genentech of vemurafenib in combination with cobimetinib in patients with locally advanced/unresectable or metastatic melanoma carrying a BRAF^{V600} mutation.

Final Phase 1b Data for Cobimetinib in Combination with Vemurafenib Presented at the 10th European Association of Dermato-Oncology Congress

In May 2014, final data from BRIM7 was reported at the 10th EADO Congress. The final data provide encouraging signs of clinical activity in BRAF inhibitor naïve patients. Although the phase 1b dose escalation study was designed to evaluate the safety and tolerability of cobimetinib in combination with vemurafenib, objective responses (comprising complete or partial responses) were observed in 87% of the patients who had not been previously treated with a BRAF inhibitor.

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.

Limited Sources of Revenues

COMETRIQ was approved by the FDA for the treatment of progressive, metastatic MTC in the United States on November 29, 2012. We commercially launched COMETRIQ in the United States in late January 2013. We currently estimate that there are between 500 and 700 first- and second-line progressive, metastatic MTC patients diagnosed

each year in the United States who will be eligible for COMETRIQ, and as a result we only expect to generate limited revenues from U.S. sales of COMETRIQ in MTC. Effective July 1, 2014, the wholesale acquisition price for COMETRIQ is \$10,915 for a 28-day supply of all dosage strengths. Prior to the approval of COMETRIQ, we had no pharmaceutical product that had received

Table of Contents

marketing approval, and from the commercial launch through June 30, 2014, we generated \$26.5 million in net revenues from the sale of COMETRIQ.

On March 25, 2014, the European Commission approved COMETRIQ for the treatment of adult patients with progressive, unresectable locally advanced or metastatic MTC. We currently believe that the patient population for the approved MTC indication in the European Union who will be eligible for COMETRIQ is similar to that in the United States, and as a result, we only expect to generate limited revenues from European Union sales of COMETRIQ in MTC. Timelines for securing reimbursement in the individual European Union countries can vary considerably, with some countries taking twelve to eighteen months to approve products for reimbursement. In July 2014, Swedish Orphan Biovitrum, or Sobi, our distribution partner, initiated commercialization activities for COMETRIQ in the approved MTC indication in the United Kingdom. We are working with Sobi on activities in preparation for the commercial launch of COMETRIQ in the approved MTC indication in other European Union countries. These activities include preparing submissions for securing reimbursement in such countries, undertaking promotional activities to raise awareness of COMETRIQ as a treatment for the approved MTC indication, and preparing the supply chain for distribution of COMETRIQ.

Prior to the commercialization of COMETRIQ, we derived substantially all of our revenues since inception from collaborative research and development agreements. Revenues from research and development collaborations depend on the achievement of milestones and royalties we earn from any future products developed from the collaborative research. During 2013, we completed the recognition of deferred revenue under our existing collaborative research and development agreements. Any future revenue derived from our existing collaborative research and development agreements will depend on the achievement of milestones and royalties we earn from any future products developed from the collaborations. We do not expect any significant contingent or milestone payments in 2014.

Our collaborative research and development agreements may be terminated or allowed to expire. In April 2014, we received a notice from GlaxoSmithKline of its intent to terminate the development of foretinib and return the compound to us pursuant to the terms and conditions of the product development and commercialization agreement between the parties. Once foretinib is returned to us, we will no longer be eligible to receive milestones or royalties from our collaborative arrangement with GlaxoSmithKline.

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. 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 expect to incur increased expenses for the development of cabozantinib as it advances in clinical development.

The commercial success of COMETRIQ will depend upon the degree of market acceptance of COMETRIQ among physicians, patients, health care payors, 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. We expect to incur increased expenses for the commercialization of COMETRIQ in connection with the approved MTC indication and any future indications for which cabozantinib may be approved.

Liquidity

As of June 30, 2014, we had \$352.0 million in cash and investments, which included short- and long-term restricted cash and investments of \$12.2 million and \$10.8 million, respectively, and short- and long-term unrestricted investments of \$86.2 million and \$95.5 million, respectively. We are required to maintain on deposit with Silicon Valley Bank or one of its affiliates short- and long-term unrestricted investments of \$1.1 million and \$81.7 million,

respectively, pursuant to covenants in our loan and security agreement with Silicon Valley Bank. We anticipate that our current cash and cash equivalents, short- and long-term investments and product revenues will enable us to maintain our operations for a period of at least 12 months following the end of the second quarter of 2014. However, our future capital requirements will be substantial, and we may need to raise additional capital in the future. Our capital requirements will depend on many factors, and we may need to use available capital resources and raise additional capital significantly earlier than we currently anticipate.

Table of Contents

Our minimum liquidity needs are also determined by financial covenants in our loan and security agreement with Silicon Valley Bank as well as other factors, which are described under “– Liquidity and Capital Resources – Cash Requirements.”

Our ability to raise additional funds may be severely impaired if cabozantinib fails to show adequate safety or efficacy in clinical testing.

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 June 30, 2014, we have used \$18.4 million of the amounts held in the escrow account to pay the required semi-annual interest payments. The short- and long-term amounts held in the escrow account as of June 30, 2014 were \$12.2 million and \$6.1 million, respectively, and are included in short- and long-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.

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 June 30, 2014 and December 31, 2013, the remaining outstanding principal balance on the Deerfield Notes was \$104.0 million and \$114.0 million, respectively, 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 six months ended June 30, 2014 and 2013, total interest expense for the Deerfield Notes was \$8.6 million and \$7.9 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 \$5.6 million and \$4.9 million, respectively, during those periods. The balance of unamortized fees and costs was \$2.9 million and \$1.4 million as of June 30, 2014 and December 31, 2013, 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

Table of Contents

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 to July 1, 2018. Under the terms of the extension option, which expires on March 31, 2015, we have the right to require Deerfield Partners, L.P. and Deerfield International Master Fund, L.P., or the New Deerfield Purchasers, to acquire \$100 million principal amount of the Deerfield Notes and extend the maturity date to July 1, 2018. We are under no obligation to exercise the extension option. To exercise the extension option, we must provide a notice of exercise to Deerfield prior to March 31, 2015. If we exercise the extension option, the Deerfield Notes would mature on July 1, 2018 and 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.

In each of January 2014 and 2013, we made mandatory prepayments of \$10.0 million on the Deerfield Notes. We will be required to make an additional mandatory prepayment on the Deerfield Notes in 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 have received no such revenue during the six months ended June 30, 2014. There is no minimum prepayment due in 2015. 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 if we exercise the extension option. However, we will only be obligated to make any such annual mandatory prepayment after exercise of the extension option 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 as amended, 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 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 we exercise the extension option: we may 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 our company, 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, Deerfield may declare all or a portion of the Prepayment Price to be immediately due and payable.

Table of Contents

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. If we exercise the extension option, 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. The 2014 Deerfield Warrants are exercisable for a term of two years, subject to a two year extension if we exercise the extension option, and 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 our company, 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 June 30, 2014, the combined outstanding principal balance due under the lines of credit and term loan was \$81.1 million, compared to \$82.1 million as of December 31, 2013. The principal amount outstanding under the term loan accrues interest at 1.0% per annum, which interest is due and payable monthly. We are required to repay the term loan in one balloon principal payment, representing 100% of the principal balance and accrued and unpaid interest, on May 31, 2017. We are required to repay any advances under an equipment line of credit in 48 equal monthly payments of principal and interest. We have the option to prepay all, but not less than all, of the amounts advanced under the term loan, provided that we pay all unpaid accrued interest thereon that is due through the date of such prepayment and the interest on the entire principal balance of the term loan that would otherwise have been paid after such prepayment date until the maturity date of the term loan. We have the option to prepay without penalty any advance under an equipment line of credit other than advances under a single equipment line of credit, which has a 1.0% prepayment penalty, provided that we pay all unpaid accrued interest thereon that is due through the date of such prepayment. In accordance with the terms of the loan and security agreement, we are required to maintain an amount equal to at least 100%, but not to exceed 107%, of the outstanding principal balance of the term loan and all equipment lines of credit under the loan and security agreement on deposit in one or more investment accounts with Silicon Valley Bank or one of its affiliates as support for our obligations under the loan and security agreement (although we are entitled to retain income earned or the amounts maintained in such accounts). Any amounts outstanding under the term loan during the continuance of an event of default under the loan and security agreement will, at the election of Silicon Valley Bank, bear interest at a per annum rate equal to 6.0%. If one or more events of default under the loan and security agreement occurs and continues beyond any applicable cure period, Silicon Valley Bank may declare all or part of the obligations under the

loan and security agreement to be immediately due and payable and stop advancing money or extending credit to us under the loan and security agreement.

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

Table of Contents

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. Other than the addition of warrant valuation, there have been no significant changes in our critical accounting policies and estimates during the six months ended June 30, 2014, 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, 2013.

Warrant Valuation

Our estimate of the fair value of the 2014 Deerfield Warrants requires us to determine the appropriate fair value model and a number of complex and subjective assumptions. The most significant assumptions are our estimates of the expected volatility and the expected term of the warrant. The value of the warrant is derived from its potential for appreciation. The more volatile the stock, the more valuable the warrant becomes because of the greater possibility of significant changes in stock price. Because there is a market for options on our common stock, we have considered implied volatilities as well as our historical realized volatilities when developing an estimate of expected volatility. The expected term of the warrant also has a significant effect on the value of the warrant. The longer the term, the more time the warrant holder has to allow the stock price to increase without a cash investment and thus, the more valuable the warrant. Further, lengthier warrant terms provide more opportunity to exploit market highs. Based on the terms of the warrant and evidence of warrant holder activity, we estimate the expected term of the warrant to be equal to the underlying contractual term. We are also required to estimate the likelihood of a two year extension that would result from our exercise of the extension option. We remeasure this warrant liability at each reporting date and review our valuation assumptions at each respective valuation date. The assumptions used in calculating the fair value of the warrant represents management’s best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our warrant valuation could be materially different in the future.

Fiscal Year Convention

Exelixis adopted a 52- or 53-week fiscal year that generally ends on the Friday closest to December 31st. Fiscal year 2013, a 52-week year, ended on December 27, 2013, and fiscal year 2014, a 53-week year, will end on January 2, 2015. For convenience, references in this report as of and for the fiscal periods ended June 27, 2014 and June 28, 2013, and as of the fiscal year ended December 27, 2013, are indicated as ended June 30, 2014, June 30, 2013, and December 31, 2013, respectively.

Table of Contents

Results of Operations

Revenues

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Net product revenues	\$6,562	\$4,043	\$11,467	\$5,899
License revenues (1)	—	3,803	—	7,604
Contract revenues (2)	—	4,010	—	8,022
Total revenues	\$6,562	\$11,856	\$11,467	\$21,525
Dollar change	\$(5,294)		\$(10,058)	
Percentage change	(45)%		(47)%	

(1) Includes amortization of upfront payments.

(2) Includes contingent and milestone payments.

Net product revenues relate to the sale of COMETRIQ. The increase in net product revenues reflects the continued ramp up in sales of COMETRIQ following its commercial launch in the United States in January 2013. We estimate our domestic net product revenues by deducting from our gross product revenues (a) trade allowances, such as discounts for prompt payment, (b) estimated government rebates and chargebacks, and (c) estimated costs of patient assistance programs. Discounts and allowances were \$0.3 million and \$0.7 million for the three and six months ended June 30, 2014, respectively, as compared to \$0.2 million and \$0.3 million for the comparable periods in 2013. Our European distribution partner is entitled to receive a project management fee based upon the achievement of a pre-specified revenue goal which, when deemed probable, is ratably accrued as a reduction to gross revenue. The decrease in license and contract revenue reflects our having fully recognized all revenues from our collaboration agreements with Bristol-Myers Squibb in 2013.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Diplomat Specialty Pharmacy	\$6,126	\$3,767	\$10,951	\$5,623
Other	436	276	516	276
Bristol-Myers Squibb	—	7,813	—	15,626
Total revenues	\$6,562	\$11,856	\$11,467	\$21,525
Dollar change	\$(5,294)		\$(10,058)	
Percentage change	(45)%		(47)%	
Cost of Goods Sold				

Cost of goods sold is related to our product revenues and consists primarily of a 3% royalty we are required to pay GlaxoSmithKline, and to a lesser extent, indirect labor costs, the cost of manufacturing and other third party logistics costs for our product. A significant 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 June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Cost of goods sold	\$477	\$285	\$786	\$565
Gross margin	93	% 93	% 93	% 90

Table of Contents

The cost of goods sold increased as a result of our increased sales of COMETRIQ. The cost of goods sold and product gross margins we have experienced in this early stage of our product launch may not be representative of what we may experience going forward.

Research and Development Expenses

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Research and development expenses	\$50,976	\$49,077	\$105,823	\$81,812
Dollar change	\$1,899		\$24,011	
Percentage change	4	%	29	%

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

The increase in research and development expenses for the six months ended June 30, 2014, as compared to the comparable period in 2013, was predominantly driven by an increase in clinical trial costs, which includes services performed by third-party contract research organizations and other vendors who support our clinical trials. The increase in clinical trial costs was \$16.5 million, or 36%, for the six months ended June 30, 2014 as compared to the comparable period in 2013. The increase in clinical trial costs related predominantly to clinical trial activities for METEOR, our phase 3 pivotal trial in metastatic RCC; COMET-2, one of our two our phase 3 pivotal trial in metastatic CRPC; CELESTIAL, our phase 3 pivotal trial in advanced HCC; and a new phase 2 trial of cabozantinib. The increases in costs for those trials was partially offset by lower clinical trial expenses as a result of the continued wind down of various studies for cabozantinib, most notably our randomized discontinuation trial and EXAM, our phase 3 pivotal trial in MTC.

For the three months ended June 30, 2014, as compared to the comparable period in 2013, there was a \$1.6 million, or 5%, decrease in clinical trial costs, predominantly due to a \$6.5 million comparator drug purchase during the second quarter of 2013 for METEOR as well as a decrease in activities for COMET-1 and the continued wind down of various other studies for cabozantinib, including our randomized discontinuation trial and EXAM. The decrease was offset in part by increases in other clinical trial costs for METEOR and COMET-2, our other phase 3 pivotal trial in metastatic CRPC.

There were additional increases in research and development expenses for the three and six months ended June 30, 2014 related to personnel, temporary personnel, and consulting and outside services. Personnel increased by \$1.4 million and \$3.5 million for the three and six months ended June 30, 2014, respectively, as compared to the comparable periods in 2013 primarily due to hiring undertaken as a result of increased clinical trial activities, as well as wage increases. Temporary personnel increased by \$1.3 million and \$2.3 million for the three and six months ended June 30, 2014, respectively, as compared to the comparable periods in 2013 primarily due to increased clinical trial activities. Consulting and outside services increased by \$1.0 million and \$1.8 million for the three and six months ended June 30, 2014, respectively, as compared to the comparable periods in 2013 primarily as a result of the engagement of additional medical science liaisons required to support our increased clinical trial activities.

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 variety of cancer indications through a broad development program, including two ongoing phase 3 pivotal trials in metastatic CRPC, a phase 3 pivotal trial in metastatic RCC, and an ongoing phase 3 pivotal trial in advanced HCC. We also expect to expand the cabozantinib development program to other solid tumor indications,

based on encouraging interim data that have emerged from our phase 2 randomized discontinuation trial, as well as other clinical trials. In addition, postmarketing commitments in connection with the approvals of COMETRIQ in MTC dictate that we conduct additional studies in that indication.

Table of Contents

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

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

Selling, General and Administrative Expenses

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Selling, general and administrative expenses	\$16,466	\$13,180	\$31,157	\$23,725
Dollar change	\$3,286		\$7,432	
Percentage change	25	%	31	%

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

Of the increases for the three and six months ended June 30, 2014, as compared to the comparable period in 2013, \$1.9 million and \$4.0 million, respectively, reflects increased personnel expenses, the majority of which is connected with the expansion of our U.S. sales force. The remaining increases for the three and six months ended June 30, 2014, as compared to the comparable period in 2013, were primarily the result of increases of \$1.1 million and \$2.1 million, respectively, of stock-based compensation expenses related to stock option grants to members of our Board of Directors and two separation agreements, and increases of \$0.4 million and \$1.0 million, respectively, of marketing expenses, including an increase in marketing expenses for cobimetinib under our collaboration agreement with Genentech.

Total Other Income (Expense), Net

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Interest income and other, net	\$359	\$373	\$2,490	\$711
Interest expense	(12,081)	(11,239)	(23,843)	(22,296)
Total other expense, net	\$(11,722)	\$(10,866)	\$(21,353)	\$(21,585)
Dollar change	\$(856)		\$232	
Percentage change	8	%	(1)	%

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 \$7.3 million and \$14.3 million for the three and six months ended June 30, 2014, respectively, as compared to \$6.5 million and \$12.8 million for the same periods in 2013. Interest income and other, net for the three and six months ended June 30, 2014 includes \$0.1 million and \$1.9 million, respectively, in unrealized gain on the revaluation of the 2014 Deerfield Warrants.

Table of Contents

Liquidity and Capital Resources

Sources and Uses of Cash

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

	Six Months Ended June 30,	
	2014	2013
Net loss	\$(148,029)	\$(106,890)
Adjustments to reconcile net loss to net cash used in operating activities	23,910	23,668
Changes in operating assets and liabilities	(3,304)	(11,227)
Net cash used in operating activities	(127,423)	(94,449)
Net cash provided by investing activities	105,049	66,820
Net cash provided by (used in) financing activities	65,736	(10,666)
Net increase (decrease) in cash and cash equivalents	43,362	(38,295)
Cash and cash equivalents at beginning of period	103,978	170,069
Cash and cash equivalents at end of period	\$147,340	\$131,774

To date, we have financed our operations primarily through the sale of equity, payments and loans from collaborators and banks, debt financing arrangements and equipment financing facilities. We have also financed certain of our research and development activities under our agreements with various collaborators. As of June 30, 2014, we had \$352.0 million in cash and investments, which included short- and long-term restricted cash and investments of \$12.2 million and \$10.8 million, respectively, and short- and long-term unrestricted investments of \$86.2 million and \$95.5 million, respectively, compared to \$415.9 million in cash and investments, which included short- and long-term restricted cash and investments of \$12.2 million and \$16.9 million and short- and long-term unrestricted investments of \$138.5 million and \$144.3 million, respectively, as of December 31, 2013. As of June 30, 2014, we are required to maintain on deposit with Silicon Valley Bank or one of its affiliates short- and long-term unrestricted investments of \$1.1 million and \$81.7 million, respectively, pursuant to covenants in our loan and security agreement with Silicon Valley Bank, compared with \$1.8 million and \$81.9 million, respectively, as of December 31, 2013.

Operating Activities

Cash used in operating activities for the six months ended June 30, 2014 related primarily to our \$138.1 million operating expenses for the period, less non-cash expenses for accretion of debt discount totaling \$14.3 million on the Deerfield Notes and the 2019 Notes, stock-based compensation totaling \$7.7 million, investment amortization totaling \$2.1 million, and depreciation and amortization totaling \$1.1 million. Our operating expenses were largely attributable to the development of cabozantinib. In addition, we paid \$3.5 million for restructuring activities and made cash payments that resulted in a \$4.9 million reduction in accounts payable and other accrued expenses during the period. Cash used in operating activities for the six months ended June 30, 2013 related primarily to our \$106.9 million operating expenses for the period, less non-cash expenses for stock-based compensation and depreciation and amortization totaling \$5.6 million and \$1.6 million, respectively. Our operating expenses were largely attributable to the development of cabozantinib. In addition, we paid \$4.0 million for restructuring activities during the period. All of our license and contract revenues during the six months ended June 30, 2013 were non-cash, which was reflected in the \$14.8 million reduction in deferred revenue during the period. Cash paid for interest was significantly lower than our interest expense due to non-cash expenses for accretion of \$12.8 million.

Except for 2011, we have been in a net loss position since inception and our cash used in operating activities has been primarily driven by our net loss. 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. Going forward for at least the next several years, we expect to continue to use cash for operating activities as we incur net losses associated with our research and development activities, primarily with respect to manufacturing and development expenses for cabozantinib.

Investing Activities

Cash provided by investing activities for the six months ended June 30, 2014 was primarily due to the maturity of unrestricted and restricted investments of \$192.0 million, less investment purchases of \$86.9 million.

Table of Contents

Cash provided by investing activities for the six months ended June 30, 2013 was primarily due to the maturity of unrestricted and restricted investments of \$219.8 million, less investment purchases of \$151.5 million.

Financing Activities

Cash provided by our financing activities for the six months ended June 30, 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 \$11.0 million.

Cash used for financing activities for the six months ended June 30, 2013 was primarily due to principal payments on debt of \$11.6 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.

Cash Requirements

We have incurred net losses since inception through the quarter ended June 30, 2014, with the exception of the 2011 fiscal year. We anticipate net losses and negative operating cash flow for the foreseeable future. For the six months ended June 30, 2014, we had a net loss of \$148.0 million; as of June 30, 2014, we had an accumulated deficit of \$1.6 billion. We commercially launched COMETRIQ for the treatment of progressive, metastatic MTC in the United States in late January 2013. From the commercial launch through June 30, 2014, we have generated \$26.5 million in net revenues from the sale of COMETRIQ. We have derived substantially all of our revenues to date from collaborative research and development agreements. Revenues from research and development collaborations depend on research funding, the achievement of milestones, and royalties we earn from any future products developed from the collaborative research. If we are unable to successfully achieve milestones or our collaborators fail to develop successful products, we will not earn the revenues contemplated under such collaborative agreements. The amount of our net losses will depend, in part, on the rate of growth, if any, in our sales of COMETRIQ, license and contract revenues and on the level of our expenses. These losses have had and will continue to have an adverse effect on our stockholders’ equity and working capital. 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. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

We anticipate that our current cash and cash equivalents, short- and long-term investments and product revenues will enable us to maintain our operations for a period of at least 12 months following the end of the second quarter of 2014. However, our future capital requirements will be substantial, and we may need to raise additional capital in the future. Our capital requirements will depend on many factors, and we may need to use available capital resources and raise additional capital significantly earlier than we currently anticipate. These factors include:

- the progress and scope of the development and commercialization activities with respect to cabozantinib;
- repayment of the 2019 Notes;
- repayment of the Deerfield Notes;
- repayment of our loan from Silicon Valley Bank;
- the commercial success of COMETRIQ and the revenues we generate;
- the level of payments received under existing collaboration agreements, licensing agreements and other arrangements;
 - 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;
- 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;

Table of Contents

- the cost and timing of regulatory approvals;
- the cost of clinical and research supplies of our product candidates;
- our obligation to share U.S. marketing and commercialization costs for cobimetinib under our collaboration with Genentech;
- our ability to share the costs of our clinical development efforts with third parties;
- the effect of competing technological and market developments;
- the filing, maintenance, prosecution, defense and enforcement of patent claims and other intellectual property rights; and
- the cost of any acquisitions of or investments in businesses, products and technologies.

We may seek to raise funds through the sale of equity or debt securities or through external borrowings. In addition, we may enter into additional strategic partnerships, collaborative arrangements or other strategic transactions. It is unclear whether any such partnership, arrangement or transaction will occur, on satisfactory terms or at all, or what the timing and nature of such a partnership, arrangement or transaction may be. The sale of equity or convertible debt securities in the future may be 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 may contain other terms that are not favorable to our stockholders or us. If we are unable to obtain adequate funds on reasonable terms, we may be required to curtail operations significantly or obtain funds by entering into financing, supply or collaboration agreements on unattractive terms or we may be required to relinquish rights to technology or product candidates or to grant licenses on terms that are unfavorable to us.

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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our market risks at June 30, 2014 have not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2013, filed with the Securities and Exchange Commission on February 20, 2014.

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio and our long-term debt. As of June 30, 2014, and December 31, 2013, 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 \$8.2 million and \$8.2 million, respectively.

In addition, we have exposure to fluctuations in certain foreign currencies in countries in which we conduct clinical trials. As of June 30, 2014, and December 31, 2013, approximately \$5.4 million and \$4.9 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.

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

Table of Contents

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 December 31, 2013 filed with the Securities and Exchange Commission on February 20, 2014.

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 raise 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 June 30, 2014, we had \$352.0 million in cash and investments, which included short- and long-term restricted cash and investments of \$12.2 million and \$10.8 million, respectively, and short- and long-term unrestricted investments of \$86.2 million and \$95.5 million, respectively. We are required to maintain on deposit with Silicon Valley Bank or one of its affiliates short- and long-term unrestricted investments of \$1.1 million and \$81.7 million, respectively, pursuant to covenants in our loan and security agreement with Silicon Valley Bank. We anticipate that our current cash and cash equivalents, short- and long-term investments and product revenues will enable us to maintain our operations for a period of at least 12 months following the end of the second quarter of 2014. However, our future capital requirements will be substantial, and we may need to raise additional capital in the future. Our capital requirements will depend on many factors, and we may need to use available capital resources and raise additional capital significantly earlier than we currently anticipate. These factors include:

- the progress and scope of the development and commercialization activities with respect to cabozantinib;
- repayment of our \$287.5 million aggregate principal amount of the 2019 Notes, that mature on August 15, 2019, unless earlier converted, redeemed or repurchased;
- repayment of the \$104.0 million principal amount outstanding of the Deerfield Notes, for which we will be required to make a mandatory prepayment in 2015 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, and if we exercise our Extension option, for which we may be subject to similar mandatory prepayment obligations in 2016, 2017 and 2018, in each case unless we are able to repay the Deerfield Notes with our common stock, which we are only able to do under specified conditions;
- repayment of our term loan and line of credit from Silicon Valley Bank, which had an outstanding balance at June 30, 2014, of \$81.1 million;
- the commercial success of COMETRIQ and the revenues we generate;
- the level of payments received under existing collaboration agreements, licensing agreements and other arrangements;

Table of Contents

- 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;
- 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 of our product candidates;
- our obligation to share U.S. marketing and commercialization costs for cobimetinib under our collaboration with Genentech;
- our ability to share the costs of our clinical development efforts with third parties;
- the effect of competing technological and market developments;
- the filing, maintenance, prosecution, defense and enforcement of patent claims and other intellectual property rights; and
- the cost of any acquisitions of or investments in businesses, products and technologies.

We may seek to raise funds through the sale of equity or debt securities or through external borrowings. In addition, we may enter into additional strategic partnerships, collaborative arrangements or other strategic transactions. It is unclear whether any such partnership, arrangement or transaction will occur, on satisfactory terms or at all, or what the timing and nature of such a partnership, arrangement or transaction may be. The sale of equity or convertible debt securities in the future may be 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 may contain other terms that are not favorable to our stockholders or us. If we are unable to obtain adequate funds on reasonable terms, we may be required to curtail operations significantly or obtain funds by entering into financing, supply or collaboration agreements on unattractive terms or we may be required to relinquish rights to technology or product candidates or to grant licenses on terms that are unfavorable to us.

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 annual net losses since inception through the year ended June 30, 2014, with the exception of the 2011 fiscal year. We anticipate net losses and negative operating cash flow for the foreseeable future. For the six months ended June 30, 2014, we had a net loss of \$148.0 million; as of June 30, 2014, we had an accumulated deficit of \$1.6 billion. We commercially launched COMETRIQ for the treatment of progressive, metastatic MTC in the United States in late January 2013. From the commercial launch through June 30, 2014, we have generated \$26.5 million in net revenues from the sale of COMETRIQ. We have derived substantially all of our revenues since inception from collaborative research and development agreements. Revenues from research and development collaborations depend on research funding, the achievement of milestones, and royalties we earn from any future products developed from the collaborative research. If we are unable to successfully achieve milestones or our collaborators fail to develop successful products, we will not earn the revenues contemplated under such collaborative agreements. The amount of our net losses will depend, in part, on the rate of growth, if any, in our sales of

COMETRIQ, license and contract revenues and on the level of our expenses. These losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Our research and development expenditures and 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. 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.

Table of Contents

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 incurred significant additional indebtedness and substantial debt service requirements as a result of our offering of the 2019 Notes in August 2012. As of June 30, 2014, our total consolidated indebtedness through maturity was \$472.6 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 continue to 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 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 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 initiatives to control costs.

Managing costs is a key element of our business strategy. Consistent with this element of our strategy, and as a consequence of our decision to focus our proprietary resources and development efforts on the late-stage development and commercialization of cabozantinib, between March 2010 and May 2013 we implemented five restructurings,

which resulted in an aggregate reduction in headcount of 429 employees. We have recorded aggregate restructuring charges of \$53.7 million from inception through June 30, 2014 in connection with the restructurings and anticipate that we will incur additional

Table of Contents

restructuring charges related to the exit of all or portions of certain of our buildings in South San Francisco, California. These charges will be recorded through the end of the building lease terms, the last of which ends in 2017. As part of these restructurings, we have entered into sublease agreements for certain of our facilities in South San Francisco. We are still assessing our ability to sublease portions of our facilities in light of the workforce reductions as well as the potential for sublease income. Estimates for sublease income 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. If we are able to vacate portions of our facilities, we would need to continue to update our estimate of the lease exit costs in our financial statements until we were able to negotiate an exit to the lease or negotiate a sublease for the remaining term of the lease.

If we experience excessive unanticipated inefficiencies or incremental costs in connection with restructuring activities, such as unanticipated inefficiencies caused by reducing headcount, 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 June 30, 2014, 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 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 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.

Table of Contents

Risks Related to Cabozantinib

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^(R) 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 major oncology franchise. Our ability to realize this objective is contingent on, among other things, successful clinical development, regulatory approval and market acceptance of cabozantinib. If we encounter 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.

The commercial success of cabozantinib will depend upon the degree of market acceptance of cabozantinib among physicians, patients, health care payors, 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 payors 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 or reimbursement.

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

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. 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. 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 cabozantinib and have an adverse impact on our results of operations. If we are unable to establish and 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

Table of Contents

legal and regulatory compliance, of these or other third parties may adversely affect our future profit margins and our ability to supply COMETRIQ to the marketplace on a timely and competitive basis. For example, if our third party logistics provider's warehouse suffers a fire or damage from another type of disaster, the commercial supply of COMETRIQ could be destroyed, resulting in a disruption in our commercialization efforts. These or other third parties may not be able to provide services in the time we require to meet our commercial timelines and objectives or to meet regulatory requirements. We may not be able to maintain or renew our arrangements with third parties, or enter into new arrangements, on acceptable terms, or at all. Third parties could terminate or decline to renew our arrangements based on their own business priorities, at a time that is costly or inconvenient for us. If we are unable to contract for logistics services or distribution of COMETRIQ on acceptable terms, our commercialization efforts may be delayed or otherwise adversely affected.

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

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

- the federal Anti-Kickback Law, which constrains our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, persons 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 payors 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;

- 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 payor, 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 federal and state 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 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, 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 the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA. Although we are not directly subject to HIPAA, we could be subject to criminal penalties if we knowingly obtain

Table of Contents

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 adequate coverage and reimbursement from third-party payors 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 payors, including governmental payors, 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 payors to pay for, or subsidize, their medical needs. If third-party payors do not provide coverage or reimbursement for cabozantinib, our revenues and prospects for profitability will suffer. In addition, even if third-party payors 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 payors are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly-approved health care products. In particular, third-party payors 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 payors 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 Affordability 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 and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, 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 certain financial arrangements with physicians and teaching hospitals, as defined in ACA 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.

As a result of the overall trend towards cost-effectiveness criteria and managed healthcare in the United States, third-party payors 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 payors 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 payors 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 make cabozantinib obsolete.*

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 cabozantinib for the treatment of additional tumor types beyond the approved MTC indication could allow our competitors to bring products to market before us, which would impair our ability to commercialize 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 are highly competitive. Further, our competitors may be more effective at using their technologies to develop commercial products. Many of the organizations competing with us have greater capital resources, larger research and development staff and facilities, more experience in obtaining regulatory approvals and more extensive product manufacturing and commercial capabilities than we do. As a result, our competitors may be able to more easily develop technologies and products that would render our technologies and products, and those of our collaborators, obsolete and noncompetitive. There may also be drug candidates of which we are not aware at an earlier stage of development that may compete with cabozantinib. In addition, cabozantinib may compete with existing therapies that have long histories of use, such as chemotherapy and radiation treatments in cancer indications.

We believe that the principal competing anti-cancer therapy to COMETRIQ in the approved MTC indication is AstraZeneca’s RET, VEGFR and EGFR inhibitor vandetanib, which has been approved by the FDA and the European Commission 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 the approved MTC indication from off-label use of Bayer’s and Onyx Pharmaceuticals’ (a wholly-owned subsidiary of Amgen) multikinase inhibitor sorafenib, Pfizer’s multikinase inhibitor sunitinib, and Ariad Pharmaceutical’s multikinase inhibitor ponatinib.

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:

CRPC (castration-resistant prostate cancer): Bayer's and Algeta's alpha-pharmaceutical radium 223; Janssen Biotech's CYP17 inhibitor abiraterone; Medivation's androgen receptor inhibitor enzalutamide; and chemotherapeutic agents, including Sanofi's cabazitaxel and generic docetaxel;

RCC (renal cell cancer): Pfizer's axitinib, sunitinib and temsirolimus; Novartis' everolimus; Bayer's and Onyx Pharmaceuticals' sorafenib; GlaxoSmithKline's pazopanib; and Genentech's bevacizumab; and

Table of Contents

HCC (hepatocellular cancer): Bayer's and Onyx Pharmaceuticals' sorafenib; Bayer's regorafenib; and ArQule's tivantinib.

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; other MET inhibitors, including Amgen's AMG 208, Pfizer's crizotinib and Genentech's onartuzumab; and immune checkpoint agents such as ipilimumab, nivolumab and pembrolizumab.

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 experience necessary to enable us to produce materials for our clinical trials or for commercial sale of cabozantinib 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. 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.

Our third-party manufacturers may not be able to comply with the cGMP regulations, other applicable FDA regulatory requirements or similar regulations applicable outside of the United States. Additionally, if we are required to enter into new manufacturing or supply arrangements, we may not be able to obtain approval from the FDA of any alternate manufacturer or supplier in a timely manner, or at all, which could delay or prevent the clinical development and commercialization of cabozantinib. Failure of our third party manufacturers or suppliers or us to obtain approval from the FDA or to comply with applicable regulations could result in sanctions being imposed on us, including fines, civil penalties, delays in or failure to grant marketing approval of cabozantinib, injunctions, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products and compounds, operating restrictions and criminal prosecutions, any of which could have a significant adverse effect on our business. In addition, cabozantinib requires precise, high-quality manufacturing. The failure to achieve and maintain these high manufacturing standards, including the incidence of manufacturing errors, could result in patient injury or death, 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 CRPC, 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.

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 CRPC, RCC, 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

Table of Contents

- regulators or institutional review boards may withhold authorization of cabozantinib, or delay, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or their determination that participating patients are being exposed to unacceptable health risks.

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

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

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

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

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

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

We do not have the ability to independently conduct clinical trials for cabozantinib, including our postmarketing 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, or CROs, 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 Marketing Authorization Application to the European Medicines Agency 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.

In December 2011, we initiated COMET-2, our first phase 3 pivotal trial of cabozantinib in patients with metastatic CRPC, with pain response as the primary efficacy endpoint for the trial. We were not able to reach a timely agreement with the FDA for a Special Protocol Assessment, or SPA, on the proposed design and analysis of the COMET-2 trial. We originally submitted the proposed protocol for this trial using primary endpoints of pain reduction and bone scan response to the FDA in June 2011 with a request for a SPA. The FDA's final response prior to our discontinuation of the SPA process, which we

Table of Contents

received in October 2011, raised the following concerns regarding the COMET-2 trial design in the context of its consideration of a SPA for the trial, among other comments:

- a concern about the ability to maintain blinding of the trial due to differences in toxicity profiles between cabozantinib and mitoxantrone;

- a view that the assumed magnitude of pain improvement is modest and could represent a placebo effect or be attained with less toxicity by opioid therapy;

- a view that symptomatic improvement should be supported by evidence of anti-tumor activity, an acceptable safety profile and lack of survival decrement. The FDA also expressed the view that if the effect that we believe cabozantinib will have on pain is mediated by anti-tumor activity, that anti-tumor activity should translate into an improvement in overall survival; and

- a recommendation that if we use pain response as a primary efficacy endpoint, that we conduct two adequate and well-controlled trials to demonstrate effectiveness as, according to the FDA, a conclusion based on two persuasive studies will always be more secure. The FDA advised that for a single randomized trial to support an NDA, the trial must be well designed, well conducted, internally consistent and provide statistically persuasive efficacy findings so that a second trial would be ethically or practically impossible to perform.

In the context of its consideration of a SPA for the COMET-2 trial, the FDA also recommended that overall survival be the primary efficacy endpoint. The final FDA response prior to our discontinuation of the SPA process stated that we could choose to conduct the trial in the absence of a SPA agreement. We elected to proceed with initiation of the COMET-2 trial and the COMET-1 trial, and to discontinue further attempts to secure a SPA agreement with respect to the COMET-2 trial. We initiated the COMET-2 trial with a pain palliation endpoint in December 2011 and the COMET-1 trial with an overall survival endpoint in May 2012.

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 (regardless of prior receipt of a SPA) 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.

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 postmarketing requirements, including a requirement to conduct a phase 2 clinical trial comparing a lower dose of COMETRIQ to the approved dose of 140 mg daily COMETRIQ in progressive, metastatic MTC and to conduct other clinical pharmacology and preclinical studies. These agencies also may 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. We may pursue collaborations for selected unpartnered preclinical and clinical programs and compounds. Our dependence on our relationships with existing collaborators for the development and

commercialization of compounds under the collaborations subjects us to, and our dependence on future collaborators for development and commercialization of additional compounds will subject us to, a number of risks, including:

- we may not be able to control the amount of U.S. marketing and commercialization costs for cobimetinib we are obligated to share under our collaboration with Genentech;

Table of Contents

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;

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 collaborations for selected preclinical and clinical compounds.

We may pursue new collaborations with leading pharmaceutical and biotechnology companies for the development and ultimate commercialization of selected preclinical and clinical programs and compounds, particularly those drug candidates for which we believe that the capabilities and resources of a partner can accelerate development and help to fully realize their therapeutic and commercial potential. 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

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.

43

Table of Contents

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

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

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

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

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

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

Risks Related to Employees and Location

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

We are highly dependent upon the principal members of our management 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

Table of Contents

restructurings we have engaged in could 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 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

Table of Contents

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;
- 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;

Table of Contents

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 reimbursement policies;

disposition of any of our subsidiaries, technologies or compounds; and

general market, economic and political conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

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

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

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

A substantial number of shares of our common stock is reserved for issuance upon conversion of the 2019 Notes, upon the exercise of stock options, upon vesting of restricted stock unit awards, upon sales under our employee stock purchase program, upon exercise of certain warrants issued to Deerfield and upon conversion of the Deerfield Notes. The issuance and sale of substantial amounts of our common stock, including upon conversion of the 2019 Notes or the Deerfield Notes, or the perception that such issuances and sales may occur, could adversely affect the market price of our common stock and impair our ability to raise capital through the sale of additional equity or equity-related securities in the future at a time and price that we deem appropriate. Trading of the 2019 Notes is likely to influence and be influenced by the market for our common stock. For example, the price of our common stock could be affected by possible sales of common stock by investors who view the 2019 Notes as a more attractive means of equity participation in our company and by hedging or arbitrage trading activity that we expect to occur involving our common stock.

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

Under Accounting Standards Codification, or ASC, Subtopic 470-20, issuers of certain convertible debt instruments that have a net settlement feature and may be settled in cash upon conversion, including partial cash settlement, are required to separately account for the liability (debt) and equity (conversion option) components of the instrument. As a result of the

Table of Contents

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, 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 our company, a change in control, or attempts by our stockholders to replace or remove members of our current Board of Directors. Because our Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include:

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

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

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.

48

Table of Contents

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.

49

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.

July 31, 2014
Date

/s/ DEBORAH BURKE
Deborah Burke
Vice President and Interim 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	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 August 14, 2012 by and between Exelixis, Inc. and Wells Fargo Bank, National Association	8-K	000-30235	4.2	8/14/2012	
4.9		8-K	000-30235		8/14/2012	

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

	Form of 4.25% Convertible Senior Subordinated Note due 2019			4.2 (Exhibit A)	
10.1	Exelixis, Inc. 2014 Equity Incentive Plan	8-K	000-30235	10.1	5/29/2014
10.2	Form of Stock Option Agreement under the Exelixis, Inc. 2014 Equity Incentive Plan				X
10.3	Form of Stock Option Agreement (International) under the Exelixis, Inc. 2014 Equity Incentive Plan				X
10.4	Form of Stock Option Agreement (Non-Employee Director) under the Exelixis, Inc. 2014 Equity Incentive Plan				X

51

Table of Contents

Exhibit Number	Exhibit Description	Incorporation by Reference		Exhibit/ Appendix Reference	Filing Date	Filed Herewith
		Form	File Number			
10.5	Form of Restricted Stock Unit Agreement under the Exelixis, Inc. 2014 Equity Incentive Plan					X
10.6	Form of Stock Option Agreement (International) under the Exelixis, Inc. 2011 Equity Incentive Plan					X
10.7	Transition and Consulting Agreement, dated May 7, 2014, between Exelixis, Inc. and Frank Karbe					X
10.8	Offer Letter Agreement, dated May 9, 2005, between Exelixis, Inc. and Deborah Burke					X
10.9	Special One-Time Bonus Memorandum for Deborah Burke dated May 15, 2014					X
10.10*	Collaboration Agreement, dated May 27, 2009, between Exelixis, Inc. and Sanofi					X
12.1	Statement Re Computation of Earnings to Fixed Charges					X
31.1	Certification required by Rule 13a-14(a) or Rule 15d-14(a).					X
31.2	Certification required by Rule 13a-14(a) or Rule 15d-14(a).					X
32.1‡	Certification by the Chief Executive Officer and the Chief Financial Officer of Exelixis, Inc., as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).					X
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					X

* Confidential treatment requested for certain portions of this exhibit.

‡

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