EXELIXIS, INC.
Form 10-Q
October 30, 2013
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q
(Mark One)
ý QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 27, 2013
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 ý No ¨
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No ¨
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	ý	Accelerated filer	¨
Non-accelerated filer	¨ (Do not check if a smaller reporting company)	Smaller reporting company	¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No ý
As of October 25, 2013, there were 184,204,393 shares of the registrant's common stock outstanding.

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

	September 30, 2013 (unaudited)	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	$92,016	$170,069
Short-term investments	187,203	241,371
Short-term restricted cash and investments	12,211	12,246
Trade and other receivables	5,171	2,751
Inventory	1,764	—
Prepaid expenses and other current assets	7,799	6,104
Total current assets	306,164	432,541
Long-term investments	157,402	182,311
Long-term restricted cash and investments	15,889	27,964
Property and equipment, net	5,520	6,059
Goodwill	63,684	63,684
Other assets	7,300	8,538
Total assets	$555,959	$721,097
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$3,559	$4,398
Accrued clinical trial liabilities	35,042	20,560
Accrued compensation and benefits	9,342	10,375
Other accrued liabilities	13,017	11,795
Current portion of convertible notes	10,000	10,000
Current portion of loans payable	2,127	3,170
Current portion of restructuring	3,776	5,085
Deferred revenue	1,017	16,321
Total current liabilities	77,880	81,704
Long-term portion of convertible notes	248,707	240,476
Long-term portion of loans payable	80,757	82,090
Long-term portion of restructuring	10,126	14,137
Other long-term liabilities	5,726	6,256
Total liabilities	423,196	424,663
Contingencies (Note 10)		
Stockholders' equity:		
Preferred stock	—	—
Common stock, $0.001 par value; 400,000,000 shares authorized; issued and outstanding:		
184,194,124 and 183,697,213 shares at September 30, 2013 and December 31, 2012, respectively	184	183
Additional paid-in capital	1,560,415	1,550,345
Accumulated other comprehensive income (loss)	180	(92)

Accumulated deficit	(1,428,016)	(1,254,002)
Total stockholders' equity	132,763	296,434
Total liabilities and stockholders' equity	$555,959	$721,097

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Revenues:				
License and contract revenues	$695	$13,313	$16,321	$39,636
Net product revenues	4,771	—	10,670	—
Total revenues	5,466	13,313	26,991	39,636
Operating expenses:				
Cost of goods sold	290	—	855	—
Research and development	47,354	30,680	129,166	96,386
Selling, general and administrative	13,598	7,343	37,323	22,008
Restructuring charge	137	733	865	1,704
Total operating expenses	61,379	38,756	168,209	120,098
Loss from operations	(55,913)	(25,443)	(141,218)	(80,462)
Other income (expense), net:				
Interest income and other, net	219	318	930	818
Interest expense	(11,430)	(7,679)	(33,726)	(15,775)
Total other income (expense), net	(11,211)	(7,361)	(32,796)	(14,957)
Loss before income taxes	(67,124)	(32,804)	(174,014)	(95,419)
Income tax provision	—	10	—	33
Net loss	$(67,124)	$(32,814)	$(174,014)	$(95,452)
Net loss per share, basic and diluted	$(0.36)	$(0.20)	$(0.95)	$(0.63)
Shares used in computing basic and diluted net loss per share	184,149	166,354	183,957	152,316

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Net loss	$(67,124)	$(32,814)	$(174,014)	$(95,452)
Other comprehensive income (loss) (1)	443	(23)	272	120
Comprehensive loss	$(66,681)	$(32,837)	$(173,742)	$(95,332)

(1) Other comprehensive income (loss) consisted solely of unrealized gains or losses on available for sale securities arising during the periods presented. There were no reclassification adjustments to net income 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.

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

	Nine Months Ended September 30,	
	2013	2012
Cash flows from operating activities:		
Net loss	$(174,014)	$(95,452)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,382	4,071
Stock-based compensation expense	8,503	6,222
Restructuring credit for property and equipment	—	(141)
Accretion of debt discount	19,445	8,624
Other	5,243	3,450
Changes in assets and liabilities:		
Other receivables	(2,420)	27,082
Inventory	(1,764)	—
Prepaid expenses and other current assets	(1,495)	(1,892)
Other assets	—	(1,983)
Accounts payable and other accrued liabilities	(652)	1,308
Clinical trial liability	14,482	1,972
Restructuring liability	(5,320)	(3,489)
Other long-term liabilities	(530)	(76)
Deferred revenue	(15,304)	(34,106)
Net cash used in operating activities	(151,444)	(84,410)
Cash flows from investing activities:		
Purchases of property and equipment	(2,079)	(1,528)
Proceeds from sale of property and equipment	40	877
Proceeds from maturities of restricted cash and investments	15,968	4,199
Purchase of restricted cash and investments	(3,785)	(40,188)
Proceeds from maturities of investments	251,470	236,323
Purchases of investments	(176,768)	(359,524)
Net cash provided by (used in) investing activities	84,846	(159,841)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net	—	203,479
Proceeds from exercise of stock options and warrants	25	901
Proceeds from employee stock purchase plan	894	828
Proceeds from debt issuance, net	—	277,673
Principal payments on debt	(12,374)	(4,082)
Net cash (used in) provided by financing activities	(11,455)	478,799
Net (decrease) increase in cash and cash equivalents	(78,053)	234,548
Cash and cash equivalents at beginning of period	170,069	74,257
Cash and cash equivalents at end of period	$92,016	$308,805

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

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

NOTE 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization

Exelixis, Inc. ("Exelixis," "we," "our" or "us") is a biotechnology company committed to developing small molecule therapies for the treatment of cancer. We are focusing our proprietary resources and development and commercialization efforts exclusively on COMETRIQ® (cabozantinib), our wholly-owned inhibitor of multiple receptor tyrosine kinases. On November 29, 2012, the U.S. Food and Drug Administration approved COMETRIQ for the treatment of progressive, metastatic medullary thyroid cancer ("MTC"), in the United States, where it became commercially available in late January 2013. Cabozantinib is being evaluated in a variety of other cancer indications through a broad development program, including two ongoing phase 3 pivotal trials in metastatic castration-resistant prostate cancer, an ongoing phase 3 pivotal trial in metastatic renal cell cancer and an ongoing phase 3 pivotal trial in advanced hepatocellular cancer. We believe COMETRIQ has the potential to be a high-quality, broadly-active and differentiated anti-cancer agent that can make a meaningful difference in the lives of patients. Our objective is to develop COMETRIQ into a major oncology franchise, and we believe that the approval of COMETRIQ for the treatment of progressive, metastatic MTC provides us with the opportunity to establish a commercial presence in furtherance of this objective. We have also established a portfolio of other novel compounds that we believe have the potential to address serious unmet medical needs. Many of these compounds are being developed by partners as part of collaborations, at no cost to us but with significant retained economics to us in the event these compounds are commercialized. As disclosed on ClinicalTrials.gov (NCT01689519), a phase 3 clinical trial for one of these compounds, cobimetinib (GDC-0973/XL518), which we out-licensed to Genentech, Inc. (a wholly-owned member of the Roche Group), was initiated on November 1, 2012.

Basis of Consolidation

The consolidated financial statements include the accounts of Exelixis and those of our wholly-owned subsidiaries, including Exelixis International (Bermuda) Ltd. ("Exelixis Bermuda"). In September 2013, Exelixis engaged in intercompany transactions whereby Exelixis Bermuda acquired the existing and future intellectual property rights to exploit cabozantinib in jurisdictions outside of the United States. 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 2012, a 52-week year, ended on December 28, 2012, and fiscal year 2013, a 52-week year, will end on December 27, 2013. For convenience, references in this report as of and for the fiscal quarters ended September 28, 2012 and September 27, 2013, and as of the fiscal year ended December 28, 2012, are indicated as ended September 30, 2012, September 30, 2013, and December 31, 2012, respectively.

Operating results for the three and nine months ended September 30, 2013 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2013 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 fiscal year ended December 31, 2012, included in our Annual Report on Form 10-K filed with the SEC on February 21, 2013.

Segment Information

We operate in one business segment.

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Use of Estimates

The preparation of the consolidated financial statements is in conformity with accounting principles generally accepted in the United States which requires management to make 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, cost of goods sold, valuation of long-lived assets, certain accrued liabilities including clinical trial accruals and restructuring liability, 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 are believed 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.

Inventory

We consider regulatory approval of product candidates to be uncertain and product manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. As such, the manufacturing costs for product candidates incurred prior to regulatory approval are not capitalized as inventory but rather are expensed as research and development costs. When regulatory approval is obtained, we begin capitalization of inventory related costs. We received regulatory approval for our first product, COMETRIQ, on November 29, 2012.

Inventory is valued at the lower of cost or net realizable value. We determine the cost of inventory using the standard-cost method, which approximates actual cost based on a first-in, first-out method. We analyze our inventory levels quarterly and write down inventory that has become obsolete, or has a cost basis in excess of its expected net realizable value and inventory quantities in excess of expected requirements. Expired inventory is disposed of and the related costs are recognized as cost of goods sold in the Consolidated Statements of Operations.

Goodwill

Goodwill amounts have been recorded as the excess purchase price over tangible assets, liabilities and intangible assets acquired based on their estimated fair value, by applying the purchase method. Goodwill is not subject to amortization. We evaluate goodwill for impairment on an annual basis and on an interim basis if events or changes in circumstances between annual impairment tests indicate that the asset might be impaired. When evaluating goodwill for impairment we must determine the reporting units that exist within Exelixis. We have determined that we have one reporting unit, which is consistent with our sole operating segment as of September 30, 2013 and December 31, 2012.

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, 2012 for a description of our policies for revenue recognition on research and collaboration agreements. We did not enter into any new collaboration agreements during the nine months ended September 30, 2013. 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, 2012 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. 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

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the patient, it is not subject to return unless the product is damaged.

Product sales to our European distribution partner are not subject to customer incentives, rights of return or discounts and allowances. 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 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. These discounts and allowances apply only to gross product revenues earned in the United States.

Customer Credits: The United States specialty pharmacy receives a discount of 2% for prompt payment. We expect this specialty pharmacy will earn 100% of its prompt payment discounts and, therefore, we deduct the full amount of these discounts from total product sales when revenues are recognized.

Mandated Rebates: Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program and other government programs. Rebate amounts owed after the final dispensing of the product to a benefit plan participant are based upon contractual agreements or legal requirements with public sector benefit providers, such as Medicaid. The allowance for rebates is based on statutory discount rates and expected utilization. Our estimates for the expected utilization of rebates are based on customer and payor data received from the United States specialty pharmacy. Rebates are generally invoiced by the payor and paid in arrears, such that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter’s shipments to patients, plus an accrual balance for known prior quarter’s unpaid rebates. If actual future rebates vary from estimates, we may need to adjust our accruals, which would affect net revenue in the period of adjustment.

Chargebacks: Chargebacks are discounts that occur when contracted customers purchase directly from a specialty pharmacy. Contracted customers, which currently consist primarily of Public Health Service institutions, non-profit clinics, and Federal government entities purchasing via the Federal Supply Schedule, generally purchase the product at a discounted price. The United States specialty pharmacy, in turn, charges back to us the difference between the price initially paid by the specialty pharmacy and the discounted price paid to the specialty pharmacy by the customer. The allowance for chargebacks is based on sales to contracted customers.

Medicare Part D Coverage Gap: In the United States, the Medicare Part D prescription drug benefit mandates manufacturers to fund 50% of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients. Our estimates for expected Medicare Part D coverage gap are based in part on third party market research data and on customer and payor data received from the United States specialty pharmacy. Funding of the coverage gap is invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's shipments to patients, plus an accrual balance for prior sales. If actual future funding varies from estimates, we may need to adjust our accruals, which would affect net revenue in the period of adjustment.

Co-payment Assistance: Patients who have commercial insurance and meet certain eligibility requirements may receive co-payment assistance. We accrue a liability for co-payment assistance based on actual program participation and estimates of program redemption using customer data provided by our United States specialty pharmacy.

Patient Assistance Program

We provide COMETRIQ at no cost to eligible patients who have no insurance and meet certain financial and clinical criteria through our Patient Assistance Program (“PAP”). We record the cost of the product as a selling, general and administrative expense at the time the product is designated as PAP inventory.

Cost of Goods Sold

Cost of goods sold is related to our product revenues and consists primarily a 3% royalty we are required to pay GlaxoSmithKline and indirect labor costs. A significant portion of the manufacturing costs for current 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 incurred, rather than capitalized as inventory.

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In accordance with our 2002 collaboration 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 collaboration 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.

Recently Adopted Accounting Pronouncements

In February 2013, Accounting Standards Codification Topic 220, Comprehensive Income was amended to require additional information about amounts reclassified out of accumulated other comprehensive income. We adopted this guidance beginning January 1, 2013, and will provide the additional information when such reclassifications occur. The amendment did not have a material effect on our consolidated financial statements.

NOTE 2: RESTRUCTURINGS

Between March 2010 and May 2013, we implemented five restructurings (referred to collectively as the "Restructurings") as a consequence of our decision to focus our proprietary resources and development efforts on the development and commercialization of cabozantinib and strategy to manage costs. 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 $52.9 million in connection with the Restructurings, of which $28.9 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. Asset impairment charges, net were partially offset by cash proceeds of $2.6 million from the sale of such assets.

For the nine months ended September 30, 2013 and 2012, we recorded restructuring charges of $0.9 million and $1.7 million, respectively, which related primarily to termination benefits and facility charges in connection with the exit of portions of certain of our buildings in South San Francisco. Those charges were partially offset by a $0.7 million credit resulting from a new sublease entered into during the three months ended September 30, 2013.

The total outstanding restructuring liability related to the Restructurings is included in current and long-term portion of restructuring on our 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, 2012 and during the nine months ended September 30, 2013 are summarized in the following table (in thousands):

	Employee Severance and Other Benefits	Facility Charges	Asset Impairment	Legal and Other Fees	Total
Restructuring liability as of December 31, 2011	$6	$13,921	$—	$51	$13,978
Restructuring charge (credit)	970	8,276	(47)	(28)	9,171
Cash payments	(965)	(5,299)	—	(3)	(6,267)
Adjustments or non-cash credits including stock compensation expense	(11)	2,304	(891)	—	1,402
Proceeds from sale of assets	—	—	938	—	938
Restructuring liability as of December 31, 2012	—	19,202	—	20	19,222
Restructuring charge (credit)	496	359	25	(15)	865
Cash payments	(424)	(5,608)	—	—	(6,032)
Adjustments or non-cash credits including stock compensation	(55)	(73)	(25)	—	(153)

expense					
Restructuring liability as of September 30, 2013	$17	$13,880	$—	$5	$13,902

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We expect to pay accrued facility charges of $13.9 million, net of cash received from our subtenants, through 2017, or the end of our lease terms of the buildings. With respect to our Restructurings, we expect to incur additional restructuring charges of approximately $1.8 million which relate to 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.

The Restructurings have resulted in aggregate cash expenditures of $34.8 million, net of $9.1 million in cash received from subtenants and $2.6 million in cash received in connection with the sale of excess equipment and other assets. Net cash expenditures for the Restructurings were $2.1 million and $2.2 million during the three months ended September 30, 2013, and 2012, respectively and $6.0 million and $4.5 million during the nine months ended September 30, 2013 and 2012, 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 September 30, 2013 and December 31, 2012 (in thousands):

	September 30, 2013			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
As reported:				
Cash and cash equivalents	$92,016	$—	$—	$92,016
Short-term investments	187,086	141	(24)	187,203
Short-term restricted cash and investments	12,172	39	—	12,211
Long-term investments	157,437	63	(98)	157,402
Long-term restricted cash and investments	15,830	59	—	15,889
Total cash and investments	$464,541	$302	$(122)	$464,721

	December 31, 2012			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
As reported:				
Cash and cash equivalents	$170,070	$—	$(1)	$170,069
Short-term investments	241,391	46	(66)	241,371
Short-term restricted cash and investments	12,242	4	—	12,246
Long-term investments	182,407	28	(124)	182,311
Long-term restricted cash and investments	27,943	21	—	27,964
Total cash and investments	$634,053	$99	$(191)	$633,961

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 and certain other designated financial institutions. The total collateral balances as of September 30, 2013 and December 31, 2012 were $84.5 million and $87.0 million, respectively, and are reflected in our Consolidated Balance Sheets in short- and long-term investments. See “Note 7 - Debt” to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2012, for more information regarding the collateral balance requirements under our Silicon Valley Bank loan and security agreement.

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All of our cash equivalents and investments are classified as available-for-sale. The following table summarizes our cash and cash equivalents and investments by security type as of September 30, 2013 and December 31, 2012 (in thousands):

	September 30, 2013			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and money market funds	$62,645	$—	$—	$62,645
Commercial paper	43,591	1	—	43,592
Corporate bonds	266,700	173	(122)	266,751
U.S. Treasury and government sponsored enterprises	83,323	119	—	83,442
Municipal bonds	8,282	9	—	8,291
Total cash and investments	$464,541	$302	$(122)	$464,721

	December 31, 2012			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and money market funds	$81,744	$2	$—	$81,746
Commercial paper	167,223	8	—	167,231
Corporate bonds	222,106	30	(187)	221,949
U.S. Treasury and government sponsored enterprises	132,933	59	(1)	132,991
Municipal bonds	30,047	—	(3)	30,044
Total cash and investments	$634,053	$99	$(191)	$633,961

All of our investments are subject to a quarterly impairment review. During the three and nine months ended September 30, 2013 and 2012, we did not record any other-than-temporary impairment charges on our available-for-sale securities. As of September 30, 2013, the fair value of investments that were in an unrealized loss position was $106.8 million, including $105.8 million in corporate bonds. There were 53 investments in an unrealized loss position as of September 30, 2013. All 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 September 30, 2013 (in thousands):

	Mature within One Year	After One Year through Two Years	Fair Value
Money market funds	$58,102	$—	$58,102
Commercial paper	43,592	—	43,592
Corporate bonds	168,715	98,036	266,751
U.S. Treasury and government sponsored enterprises	71,279	12,163	83,442
Municipal bonds	2,212	6,079	8,291
Total	$343,900	$116,278	$460,178

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.

During the three and nine months ended September 30, 2013 and 2012, there were no sales of investments, and therefore there were no reclassification adjustments of accumulated other comprehensive income to net income resulting from realized gains or losses on the sale of securities.

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NOTE 4. INVENTORY

Inventory consists of the following (in thousands):

	September 30, 2013	December 31, 2012
Raw materials	$301	$—
Work in process	1,374	—
Finished goods	89	—
Total	$1,764	$—

We received regulatory approval for our first product, COMETRIQ, on November 29, 2012. As of December 31, 2012, our recorded inventory balance was $0 as we did not incur any costs that would be recorded as inventory subsequent to the receipt of regulatory approval and prior to year end.

NOTE 5. DEBT

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

	September 30, 2013	December 31, 2012
Convertible Senior Subordinated Notes due 2019	$161,279	$149,800
Secured Convertible Notes due 2015	97,428	100,676
Silicon Valley Bank term loan	80,000	80,000
Silicon Valley Bank line of credit	2,884	5,260
Total debt	341,591	335,736
Less: current portion	(12,127)	(13,170)
Long-term debt	$329,464	$322,566

See “Note 7 - Debt” to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2012, 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 the 2019 Notes. As of September 30, 2013, the entire principal balance remains outstanding. The following is a summary of the liability component of the 2019 Notes as of September 30, 2013 (in thousands):

	September 30, 2013
Net carrying amount of the liability component	$161,279
Unamortized discount of the liability component	126,221
Face amount of the 2019 Notes	$287,500

The debt discount and debt issuance costs will be amortized as interest expense through August 2019. During the three and nine months ended September 30, 2013, total interest expense for the 2019 Notes was $7.2 million, and $21.2 million, respectively, including stated coupon interest of $3.1 million and $9.2 million, respectively, and the amortization of the debt discount and debt issuance costs of $4.1 million and $12.0 million, respectively. During both the three and nine months ended September 30, 2012, total interest expense for the 2019 Notes was $3.4 million including stated coupon interest of $1.5 million and the amortization of the debt discount and debt issuance costs of $1.9 million. The balance of unamortized fees and costs was $4.1 million and $4.7 million as of September 30, 2013 and December 31, 2012, respectively, which is recorded in the accompanying Consolidated Balance Sheet as Other assets.

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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 initial principal amount of the Deerfield Notes. As of September 30, 2013 and December 31, 2012, the remaining outstanding principal balance on the Deerfield Notes was $114.0 million and $124.0 million, respectively. During the three and nine months ended September 30, 2013, total interest expense for the Deerfield Notes was $4.1 million and $11.9 million, respectively, and during the same periods in 2012, $4.1 million and $11.7 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 were $2.6 million and $7.4 million during the three and nine months ended September 30, 2013, respectively, and $2.5 million and $7.2 million, during the three and nine months ended September 30, 2012, respectively. The balance of unamortized fees and costs was $1.6 million and $2.3 million as of September 30, 2013 and December 31, 2012, respectively, which is recorded in the accompanying Consolidated Balance Sheet as Other assets.

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 parties amended the security agreement to limit the extent to which voting equity interests in any of our foreign subsidiaries shall be secured assets.

NOTE 6. FAIR VALUE MEASUREMENTS

The fair value of our financial instruments reflects the amounts that would be received upon sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). The fair value hierarchy has the following three levels:

Level 1 – quoted prices in active markets for identical assets and liabilities.

Level 2 – observable inputs other than quoted prices in active markets for identical assets and liabilities. These inputs include using prices from independent pricing services based on quoted prices in active markets for similar instruments or on industry models using data inputs, such as interest rates and prices that can be directly observed or corroborated in active markets.

Level 3—unobservable inputs.

A review of the fair value hierarchy classification is conducted on a quarterly basis. Changes in the observability of valuation inputs may result in a reclassification of levels for certain investments within the fair value hierarchy. There were no transfers between any of the fair value hierarchies, as determined at the end of each reporting period.

The following table sets forth the fair value of our financial assets that were measured and recorded on a recurring basis as of September 30, 2013 and December 31, 2012. We did not have any Level 3 investments during the periods presented. The amounts presented exclude cash, but include investments classified as cash equivalents (in thousands):

	September 30, 2013		
	Level 1	Level 2	Total
Money market funds	$58,102	$—	$58,102
Commercial paper	—	43,592	43,592
Corporate bonds	—	266,751	266,751
U.S. Treasury and government sponsored enterprises	—	83,442	83,442
Municipal bonds	—	8,291	8,291
Total	$58,102	$402,076	$460,178

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	December 31, 2012		
	Level 1	Level 2	Total
Money market funds	$76,050	$—	$76,050
Commercial paper	—	167,231	167,231
Corporate bonds	—	221,949	221,949
U.S. Treasury and government sponsored enterprises	—	132,991	132,991
Municipal bonds	—	30,044	30,044
Total	$76,050	$552,215	$628,265

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):

	September 30, 2013		December 31, 2012	
	Carrying Amount	Fair Value	Carrying Amount	Fair Value
2019 Notes	$161,279	$337,928	$149,800	$280,111
Silicon Valley Bank term loan	$80,000	$79,884	$80,000	$79,542
Silicon Valley Bank Line of Credit	$2,884	$2,884	$5,260	$5,253

There is no practicable method 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 and the current non-liquid market in structured notes.

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.
- 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 in the accompanying Consolidated Balance Sheets.
- We have estimated 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.

NOTE 7. 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 September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Research and development expense	$1,415	$970	$4,326	$3,202
Selling, general and administrative expense	1,478	923	4,115	2,970
Restructuring-related stock-based compensation expense	—	—	49	—
Total employee stock-based compensation expense	$2,893	$1,893	$8,490	$6,172

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

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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 September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Weighted average grant-date fair value	$2.99	$3.31	$2.92	$3.27
Risk-free interest rate	1.57%	0.81%	1.47%	0.82%
Dividend yield	—%	—%	—%	—%
Volatility	60%	69%	60%	69%
Expected life	5.6 years	5.6 years	5.6 years	5.7 years

	Employee Stock Purchase Plan			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Weighted average grant-date fair value	$1.74	$1.63	$1.66	$2.13
Risk-free interest rate	0.08%	0.15%	0.12%	0.10%
Dividend yield	—%	—%	—%	—%
Volatility	67%	68%	67%	68%
Expected life	0.5 years	0.5 years	0.5 years	0.5 years

Of the stock options outstanding as of September 30, 2013, 3,720,752 were granted subject to performance objectives tied to the achievement of clinical goals set by the Compensation Committee of our Board of Directors and will vest in full or part based on achievement of such goals. As of September 30, 2013, we expect that achievement of some of those performance objectives is probable and have, therefore, included stock-based compensation for such awards. We have not included any stock-based compensation expense for stock options with performance objectives where the performance goals cannot be reasonably assured of achievement.

A summary of all stock option activity for the nine months ended September 30, 2013 is presented below (dollars in thousands, except per share amounts):

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Options outstanding at December 31, 2012	18,448,550	$6.85		
Granted	5,778,323	$5.38		
Exercised	(4,473)	$4.42		
Forfeited	(712,885)	$6.42		
Options outstanding at September 30, 2013	23,509,515	$6.50	4.71	$5,709
Exercisable at September 30, 2013	13,803,103	$7.23	3.51	$2,376

As of September 30, 2013, $24.4 million of total unrecognized compensation expense related to employee stock options was expected to be recognized over a weighted-average period of 2.92 years.

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A summary of all restricted stock unit ("RSU") activity for the nine months ended September 30, 2013 is presented below (dollars in thousands, except per share amounts):

	Shares	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Awards outstanding at December 31, 2012	1,294,621	$6.07		
Awarded	1,058,668	$5.44		
Released	(230,059)	$7.34		
Forfeited	(72,132)	$5.48		
Awards outstanding at September 30, 2013	2,051,098	$5.62	1.98	$11,855

As of September 30, 2013, $8.0 million of total unrecognized compensation expense related to employee RSUs was expected to be recognized over a weighted-average period of 3.33 years.

NOTE 8. INCOME TAXES

At December 31, 2012, we had federal net operating loss carry-forwards of approximately $1,007 million which expire in the years 2018 through 2032. We also had net operating loss carry-forwards for California of approximately $880 million, which expire in the years 2013 through 2032, and California tax credits of approximately $26 million. During the three months ended September 30, 2013, Exelixis Bermuda acquired the existing and future intellectual property rights to exploit cabozantinib in jurisdictions outside of the United States. The transfer of the existing rights created a taxable gain in the U.S. and state jurisdictions. For tax purposes, that gain is primarily offset by current fiscal year losses and the remainder through the utilization of an insignificant amount of net operating loss carry-forwards for which there is a corresponding reduction to our valuation allowance.

NOTE 9. NET LOSS PER SHARE

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Numerator:				
Net loss	$(67,124)	$(32,814)	$(174,014)	$(95,452)
Denominator:				
Shares used in computing basic and diluted net loss per share	184,149	166,354	183,957	152,316
Net loss per share, basic and diluted	$(0.36)	$(0.20)	$(0.95)	$(0.63)

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):

	September 30	
	2013	2012
Convertible debt	54,123	54,123
Outstanding stock options, unvested RSUs and ESPP contributions	25,694	15,839
Warrants	1,441	1,441
Total potentially dilutive shares	81,258	71,403

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NOTE 10. CONTINGENCIES

Pending Litigation

From time to time, we are party to legal proceedings, claims and investigations in the ordinary course of business, including the matter described below.

In December 2012, a former officer filed a lawsuit against us and our chief executive officer in California state court seeking unspecified monetary damages based on contract and tort claims in connection with the former officer's execution and revocation of a Rule 10b5-1 stock trading plan in December 2010. This matter was settled for an immaterial amount during the three months ended September 30, 2013.

NOTE 11. 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. government agency obligations and U.S. government sponsored enterprises. All investments are maintained with financial institutions that management believes are creditworthy.

Trade and other receivables are unsecured and are concentrated in the pharmaceutical and biotechnology industries. Accordingly, we may be exposed to credit risk generally associated with pharmaceutical and biotechnology companies. We have incurred no bad debt expense since inception. As of September 30, 2013, 55% of our trade receivables are with the specialty pharmacy that sells COMETRIQ in the United States and 14% are with our European distribution partner. Both of these customers pay promptly and within their respective payment terms.

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 three and nine months ended September 30, 2012, 100% of our revenues were earned in the United States. During the 2013, we initiated a Named Patient Use ("NPU") program through our distribution partner, Swedish Orphan Biovitrum, to support the distribution and commercialization of COMETRIQ for metastatic MTC primarily in the European Union and potentially other countries. During the three and nine months ended September 30, 2013, 87% and 96%, respectively, of our revenues were earned in the United States; the remainder of our revenues were earned in the European Union under this NPU program. All of our long-lived assets are located in the United States.

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 nine months ended September 30, 2013 and 2012:

	Nine Months Ended September 30,	
	2013	2012
Collaborator:		
Bristol-Myers Squibb	60 %	59 %
Merck	— %	27 %
Daiichi Sankyo	— %	14 %
Pharmacy:		
Diplomat Specialty Pharmacy	36 %	— %

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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," "e "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, 2012, filed with the Securities and Exchange Commission, or SEC, on February 21, 2013. 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 biotechnology company committed to developing small molecule therapies for the treatment of cancer. We are focusing our proprietary resources and development and commercialization efforts exclusively on COMETRIQ® (cabozantinib), our wholly-owned inhibitor of multiple receptor tyrosine kinases. On November 29, 2012, the U.S. Food and Drug Administration, or FDA, approved COMETRIQ for the treatment of progressive, metastatic medullary thyroid cancer, or MTC, in the United States, where it became commercially available in late January 2013. We have also submitted a Marketing Authorization Application, or MAA, for cabozantinib for the proposed indication of progressive, unresectable, locally advanced, or metastatic MTC to the European Medicines Agency, or EMA, that was accepted for review in November 2012. Cabozantinib is being evaluated in a variety of other cancer indications through a broad development program, including two ongoing phase 3 pivotal trials in metastatic castration-resistant prostate cancer, or 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 COMETRIQ has the potential to be a high-quality, broadly-active and differentiated anti-cancer agent that can make a meaningful difference in the lives of patients. Our objective is to develop COMETRIQ into a major oncology franchise, and we believe that the approval of COMETRIQ for the treatment of progressive, metastatic MTC provides us with the opportunity to establish a commercial presence in furtherance of this objective. We currently expect top-line data from our two phase 3 pivotal trials of cabozantinib in CRPC and the overall survival analysis of EXAM, our phase 3 pivotal trial of cabozantinib in progressive, metastatic MTC, in 2014.

We have also established a portfolio of other novel compounds that we believe have the potential to address serious unmet medical needs. Many of these compounds are being developed by partners as part of collaborations, at no cost to us but with significant retained economics to us in the event these compounds are commercialized. As disclosed on ClinicalTrials.gov (NCT01689519), a phase 3 clinical trial for one of these compounds, cobimetinib (GDC-0973/XL518), which we out-licensed to Genentech, Inc. (a wholly- owned member of the Roche Group), or Genentech, was initiated on November 1, 2012. Roche and Genentech have provided guidance that they expect top-line data from this trial in 2014.

Our Strategy

We believe that the available clinical data demonstrate that COMETRIQ has the potential to be a broadly active anti-cancer agent, and our objective is to build COMETRIQ into a major oncology franchise. The initial regulatory approval of COMETRIQ to treat progressive, metastatic MTC provides a niche market opportunity that allows us to gain commercialization experience at relatively low cost while providing a solid foundation for potential expansion into larger cancer indications.

We intend to advance cabozantinib through an extensive development program investigating its activity in multiple cancer indications including, but not limited to, prostate, renal, hepatocellular and non-small-cell-lung cancers. We

intend to focus 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 personnel and financial resources.

Collaborations

We have established collaborations with leading pharmaceutical and biotechnology companies, including Bristol-Myers Squibb Company, or Bristol-Myers Squibb, Sanofi, Genentech, GlaxoSmithKline, Merck (known as MSD outside of the United States and Canada) and Daiichi Sankyo Company Limited, or Daiichi Sankyo, for various compounds and programs in our portfolio. Pursuant to these collaborations, we have out-licensed compounds or programs to a partner for further development and commercialization, have no further development cost obligations related to such compounds or programs and may be entitled to receive milestones and royalties or a share of profits from commercialization. As disclosed on ClinicalTrials.gov (NCT01689519), a phase 3 clinical trial for one of these compounds, cobimetinib (GDC-0973/XL518), which we out-licensed to Genentech, was initiated on November 1, 2012. In addition, several other out-licensed compounds are in multiple phase 2 studies. These partnered compounds could potentially be of significant value to us if their development progresses successfully.

With respect to our partnered compounds, we are eligible to receive potential milestone payments under our collaborations totaling approximately $2.4 billion in the aggregate on a non-risk adjusted basis, of which 10% are related to clinical development milestones, 41% are related to regulatory milestones and 49% are related to commercial milestones.

Business Highlights for the Three Months Ended September 30, 2013 and Recent Developments

Achievement of Full Patient Enrollment Target for COMET-1

In September 2013, COMET-1 (CabOzantinib MET Inhibition CRPC Efficacy Trial-1), our phase 3 pivotal trial of cabozantinib in patients with metastatic CRPC, with the primary endpoint of overall survival, reached its enrollment target of 960 patients. We currently expect top-line data from COMET-1 and COMET-2, our other phase 3 pivotal trial in metastatic CRPC, in 2014.

Initiation of Phase 3 Pivotal Trial of Cabozantinib in Patients with Advanced Hepatocellular Carcinoma

In September 2013, we initiated CELESTIAL (Cabozantinib Phase 3 Controlled Study In Hepatocellular Carcinoma), a phase 3 pivotal trial comparing cabozantinib with placebo in patients with advanced HCC who have previously been treated with sorafenib. Patients will be randomized 2:1 to receive 60 mg of cabozantinib daily or placebo. The primary endpoint for CELESTIAL is overall survival, and the secondary endpoints include objective response rate and progression-free survival.

Updated Phase 1b Data for Cobimetinib (GDC-0973/XL518) in Combination with Vemurafenib Presented at the European Cancer Congress 2013

In September 2013, data from an ongoing phase 1b clinical trial, conducted by Roche and Genentech, of vemurafenib in combination with cobimetinib (GDC-0973/XL518) in patients with locally advanced/unresectable or metastatic melanoma carrying a $BRAF^{V600}$ mutation was presented at the European Cancer Congress 2013. The data presented suggest that the preliminary safety profile and activity of the investigational combination of cobimetinib (GDC-0973/XL518) 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 (GDC-0973/XL518) in combination with vemurafenib, objective responses (comprising complete or partial responses) were observed in 85% of the patients who had not been previously treated with a BRAF inhibitor.

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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 abilities 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 late January 2013. We currently estimate that there are between 500 and 700 first- and second-line 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 the sale of COMETRIQ in MTC. Prior to the approval of COMETRIQ, we had no pharmaceutical product that had received marketing approval, and from the commercial launch through September 30, 2013, we generated $10.7 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. We do not anticipate any further revenues from our collaborative research and development agreements for the remainder of 2013. Effective October 29, 2013, the wholesale acquisition price for COMETRIQ is $10,395 for a 28-day supply of all dosage strengths.

Clinical Development of Cabozantinib

We have focused our proprietary resources and development efforts on the development of cabozantinib. However, the product candidate may fail to show adequate safety or efficacy in clinical testing. 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.

Liquidity

As of September 30, 2013, we had $464.7 million in cash and investments, which included short- and long-term restricted cash and investments of $12.2 million and $15.9 million, respectively, and short- and long-term unrestricted investments of $187.2 million and $157.4 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 $2.2 million and $82.4 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 third quarter of 2013. 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.

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

On August 14, 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

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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 bankruptcy and insolvency-related events of defaults occur, the principal of, and accrued and unpaid interest on, all of the then outstanding notes shall automatically become due and payable. If an event of default other than certain bankruptcy and insolvency-related events of defaults 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 September 30, 2013, we have used $12.2 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 September 30, 2013 were $12.2 million and $12.2 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

On June 2, 2010, we entered into a note purchase agreement with entities affiliated with Deerfield Management Company, L.P., or Deerfield, pursuant to which, on July 1, 2010, we sold to Deerfield an aggregate of $124.0 million initial principal amount of our secured convertible notes due June 2015, or the Deerfield Notes, for an aggregate purchase price of $80.0 million, less closing fees and expenses of approximately $2.0 million. On August 6, 2012, the parties amended the note purchase agreement to permit the issuance of the 2019 Notes and modify certain optional prepayment rights. The amendment became effective upon the issuance of the 2019 Notes and the payment to Deerfield 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 agreement. The outstanding principal amount of the Deerfield Notes bears interest in the annual amount of $6.0 million, payable quarterly in arrears. In January 2013, we made a mandatory prepayment of $10.0 million on the Deerfield Notes. We will be required to make additional mandatory prepayments on the Deerfield Notes on an annual basis in 2014 and 2015 equal to 15% of specified payments from our collaborative arrangements (other than intercompany arrangements) received during the prior fiscal year, subject to a maximum annual prepayment amount of $27.5 million. There is a required minimum prepayment amount of $10.0 million due in January 2014. There is no minimum prepayment due in 2015. We may also prepay all or a portion (not less than $5.0 million) of the principal amount of the Deerfield Notes at an optional prepayment price based on a discounted principal amount (during the first three years of the term, subject to a prepayment premium) determined as of the date of prepayment, plus accrued and unpaid interest, plus in the case of a prepayment of the full principal amount of the Deerfield Notes (other than prepayments upon the occurrence of specified transactions relating to a change of control or a substantial sale of assets), all accrued interest that would have accrued between the date of such prepayment and the next anniversary of the note purchase agreement. In lieu of making any optional 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 optional prepayment amounts or mandatory prepayment amounts (other than the $10.0 million mandatory prepayment required in January 2014) 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 $400 million or a sale or transfer of more than 50% of our assets, Deerfield may require us to prepay the notes at the optional prepayment price, plus accrued and unpaid interest and any other accrued and reimbursable expenses, or the Put Price. Upon an event of default, Deerfield may declare all or a portion of the Put Price to be immediately due and payable.

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 parties

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amended the security agreement to limit the extent to which voting equity interests in any of our foreign subsidiaries shall be secured assets.

The note purchase agreement 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 September 30, 2013, the combined outstanding principal balance due under the lines of credit and term loan was $82.9 million, compared to $85.3 million as of December 31, 2012. 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.

Restructurings

Between March 2010 and May 2013, we implemented five restructurings, which we refer to collectively as the Restructurings, as a consequence of our decision to focus our proprietary resources and development efforts on the development and commercialization of cabozantinib and strategy to manage costs. 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 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 $52.9 million in connection with the Restructurings, of which $28.9 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. Asset impairment charges, net were partially offset by cash proceeds of $2.6 million from the sale of such assets.

For the nine months ended September 30, 2013 and 2012, we recorded restructuring charges of $0.9 million and $1.7 million, respectively, which related primarily to termination benefits and facility charges in connection with the exit of portions of certain of our buildings in South San Francisco. Those charges were partially offset by a $0.7 million credit resulting from a new sublease entered into during the three months ended September 30, 2013.

We expect to pay accrued facility charges of $13.9 million, net of cash received from our subtenants, through 2017, or the end of our lease terms of the buildings. With respect to our Restructurings, we expect to incur additional

restructuring charges of approximately $1.8 million which relate to 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.

The Restructurings have resulted in aggregate cash expenditures of $34.8 million, net of $9.1 million in cash received from subtenants and $2.6 million in cash received in connection with the sale of excess equipment and other assets. Net cash

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expenditures for the Restructurings were $2.1 million and $2.2 million during the three months ended September 30, 2013, and 2012, respectively and $6.0 million and $4.5 million during the nine months ended September 30, 2013, and 2012, 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.

Critical Accounting Estimates

The preparation of the consolidated financial statements is in conformity with accounting principles generally accepted in the United States which requires management to make 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, cost of goods sold, valuation of long-lived assets, certain accrued liabilities including clinical trial accruals and restructuring liability, 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 are believed 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, cost of goods sold, clinical trial accruals, restructuring liability, share based compensation and convertible debt valuation reflect the more significant estimates and assumptions used in the preparation of our consolidated financial statements.

Other than the addition of inventory, revenue recognition on product sales, and cost of goods sold, there have been no significant changes in our critical accounting policies and estimates during the nine months ended September 30, 2013, 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, 2012.

Inventory

We consider regulatory approval of product candidates to be uncertain and product manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. As such, the manufacturing costs for product candidates incurred prior to regulatory approval are not capitalized as inventory, but rather are expensed as research and development costs. When regulatory approval is obtained, capitalization of inventory may begin. On November 29, 2012, the FDA approved our first product, COMETRIQ, for the treatment of progressive, metastatic MTC in the United States, where it became commercially available in late January 2013.

Inventory is valued at the lower of cost or net realizable value. We determine the cost of inventory using the standard-cost method, which approximates actual cost based on a first-in, first-out method. We analyze our inventory levels quarterly and write down inventory that has become obsolete, or has a cost basis in excess of its expected net realizable value and inventory quantities in excess of expected requirements. Expired inventory is disposed of and the related costs are recognized as cost of goods sold in the Consolidated Statements of Operations.

Revenue Recognition on Product Sales

We recognize revenue when it is both realized or realizable and earned, meaning persuasive evidence of an arrangement exists, delivery has occurred, title has transferred, the price is fixed or determinable, there are no remaining customer acceptance requirements, and collectability of the resulting receivable is reasonably assured. For product sales in the United States, this generally occurs upon shipment of the product to the patient. 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

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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.

Product sales to our European distribution partner are not subject to customer incentives, rights of return or discounts and allowances. 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.

We calculate gross product revenues based on the price that we charge our United States specialty pharmacy and our European distribution partner, Sobi. We estimate our United States 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. These discounts and allowances apply only to gross product revenues earned in the United States.

Cost of Goods Sold

Cost of goods sold is related to our product revenues and consists primarily of indirect labor costs, a 3% royalty we are required to pay GlaxoSmithKline in connection with sales of COMETRIQ and direct logistics costs. A significant portion of the manufacturing costs for current product sales were incurred prior to regulatory approval of COMETRIQ for the treatment of progressive, metastatic MTC and, therefore, are expensed as research and development costs as incurred, rather than capitalized as inventory.

In accordance with our 2002 collaboration 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 collaboration 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.

Exelixis International (Bermuda) Ltd.

In September 2013, Exelixis engaged in intercompany transactions whereby Exelixis Bermuda acquired the existing and future intellectual property rights to exploit cabozantinib in jurisdictions outside of the United States.

Fiscal Year Convention

Exelixis adopted a 52- or 53-week fiscal year that generally ends on the Friday closest to December 31st. Fiscal year 2012, a 52-week year, ended on December 28, 2012, and fiscal year 2013, a 52-week year, will end on December 27, 2013. For convenience, references in this report as of and for the fiscal quarters ended September 28, 2012 and September 27, 2013, and as of the fiscal year ended December 28, 2012, are indicated as ended September 30, 2012, September 30, 2013, and December 31, 2012, respectively.

Results of Operations

Revenues

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
License revenues (1)	$358	$4,012	$8,380	$22,702
Contract revenues (2)	337	9,301	7,941	16,934
Net product revenues	4,771	—	10,670	—
Total revenues	$5,466	$13,313	$26,991	$39,636
Dollar change	$(7,847)		$(12,645)	
Percentage change	(59)%		(32)%	

(1) Includes amortization of upfront payments.

(2) Includes milestone payments.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Bristol-Myers Squibb	695	$7,813	$16,321	$23,439
Diplomat Specialty Pharmacy	4,034	—	9,657	—
Swedish Orphan Biovitrum	737	—	1,013	—
Merck	—	—	—	10,667
Daiichi Sankyo	—	5,500	—	5,500
Other	—	—	—	30
Total revenues	$5,466	$13,313	$26,991	$39,636
Dollar change	$(7,847)		$(12,645)	
Percentage change	(59)%		(32)%	

Revenues for the three and nine months ended September 30, 2013 included net product revenues of $4.8 million and $10.7 million, respectively, from the sale of COMETRIQ, which became commercially available in late January 2013. The decrease in total revenues during the three and nine months ended September 30, 2013 was due to a decrease in contract and license revenues relating to the depletion of deferred revenues from Bristol-Myers Squibb and a $5.5 million milestone payment received from Daiichi Sankyo in August 2012. The decrease in total revenues during the nine months ended September 30, 2013 was also due to $10.7 million in license revenue recognized in 2012 resulting from the completion of the technology transfer under our December 2011 license agreement with Merck for our PI3K-delta program.

Cost of Goods Sold

Cost of goods sold consists primarily of a 3% royalty we are required to pay GlaxoSmithKline in connection with sales of COMETRIQ and indirect labor costs. We began capitalizing COMETRIQ inventory following the regulatory approval for COMETRIQ on November 29, 2012. The cost of product manufactured prior to regulatory approval was expensed as research and development costs as incurred. Cost of goods sold was $0.3 million and $0.9 million for the three and nine months ended September 30, 2013, respectively. 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 September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Research and development expenses	$47,354	$30,680	$129,166	$96,386
Dollar change	$16,674		$32,780	
Percentage change	54%		34%	

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

The increases for the three and nine months ended September 30, 2013, as compared to prior year periods were predominantly driven by increases in clinical trial costs, which include services performed by third-party contract research organizations and other vendors. Those increases in clinical trial costs were $13.9 million, or 101%, for the three months ended September 30, 2013, and $30.4 million, or 71%, for the nine months ended September 30, 2013. The increases in clinical trial costs were primarily related to clinical trial activities for COMET-1, our phase 3 pivotal trial with the primary endpoint of overall survival in metastatic CRPC, as well as costs incurred in connection with the start-up of our phase 3 pivotal trials for metastatic RCC and advanced HCC. The increases in costs for those trials were partially offset by lower clinical trial costs related to the continued wind down of our phase 2 randomized discontinuation trial.

There were additional increases in research and development expenses for the three and nine months ended September 30, 2013, related to personnel, consulting and outside services, and stock-based compensation. Personnel increased primarily due to hiring undertaken as a result of increased clinical trial activities as well as wage increases. Consulting and

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outside services increased primarily as a result of the engagement of additional medical science liaisons required to support our increased clinical trial activities. Stock-based compensation increased primarily as a result of an increase in the number and valuation of new grants as well as an increase in the participation and valuation of purchases under our 2000 Employee Stock Purchase Plan. Those increases were partially offset by decreases in depreciation and amortization expense primarily as a result of the impairment and disposition of assets related to the Restructurings and the impact of additional assets becoming fully depreciated during 2012 and a decrease in the allocation of general corporate costs (such as facility costs, property taxes and insurance) to research and development, primarily due to a decrease in allocable costs.

Historically, we grouped our research and development expenses into three categories: development, drug discovery and other. Our development group leads the development and implementation of our clinical and regulatory strategies and prioritizes disease indications in which our compounds may be studied in clinical trials. Development expenses relate primarily to clinical trial, personnel and general corporate costs. Our drug discovery efforts consisted of the discovery, optimization and characterization of lead compounds for selection of development candidates with the best potential for further evaluation and advancement into clinical development. Drug discovery expenses related primarily to personnel expense, lab supplies and general corporate costs. The other category primarily includes stock-based compensation expense.

As noted under “Overview”, we are focusing our proprietary resources and development efforts exclusively on cabozantinib in order 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, including those previously funded under our ROR collaboration agreement with Bristol-Myers Squibb following the completion of our obligations in July 2013. 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 research and 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, post marketing requirements in connection with the approval of COMETRIQ in progressive, metastatic MTC dictate that we conduct additional studies in that indication.

Selling, General and Administrative Expenses

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Selling, general and administrative expenses	$13,598	$7,343	$37,323	$22,008
Dollar change	$6,255		$15,315	
Percentage change	85 %		70 %	

Selling, general and administrative expenses consist primarily of personnel expenses, consulting and outside services, facility costs, patent costs, employee stock-based compensation expense, marketing and other legal and accounting fees. These expenses also include selling and distribution costs in 2013 as a result of the commercial launch of COMETRIQ in late January 2013.

Approximately half of the increases for the three and nine months ended September 30, 2013, as compared to the prior year periods, were a result of an increase in expenses related to consulting and outside services provided by our U.S. sales force and our European distribution partner for the sale of COMETRIQ. The remaining increases for the three and nine months ended September 30, 2013 were related to legal and accounting fees, wages and benefits, employee stock-based compensation expense, and patent costs and also for the nine months ended September 30, 2013, reduced allocations to research and development. These increases were partially offset by decreases in facilities costs during

both the three and nine months ended September 30, 2013.

Restructuring Charge

Between March 2010 and May 2013, we implemented five restructurings as a consequence of our decision to focus our proprietary resources and development efforts on the development and commercialization of cabozantinib and strategy to

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manage costs. 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.

Total charges from our Restructurings were as follows (dollars in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Restructuring charge	$137	$733	$865	$1,704
Dollar change	$(596)		$(839)	
Percentage change	(81)%		(49)%	

For the three and nine months ended September 30, 2013, we recorded restructuring charges of $0.1 million and $0.9 million, respectively, which related to termination benefits and facility charges in connection with the exit of all or portions of certain of our buildings in South San Francisco. Those charges were partially offset by a $0.7 million credit resulting from a new sublease entered into during the three months ended September 30, 2013.

Total Other Income (Expense), Net

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Interest income and other, net	$219	$318	$930	$818
Interest expense	(11,430)	(7,679)	(33,726)	(15,775)
Total other expense, net	$(11,211)	$(7,361)	$(32,796)	$(14,957)
Dollar change	$(3,850)		$(17,839)	
Percentage change	52%		119%	

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.

The change in total other expense, net for the three and nine months ended September 30, 2013, compared to the same periods in 2012, was primarily due to the increased interest expense as a result of the August 2012 issuance of the 2019 Notes. Interest expense includes aggregate non-cash interest expense on both the 2019 Notes and the Deerfield Notes of $6.7 million and $19.4 million, for the three and nine months ended September 30, 2013, respectively, as compared to $4.5 million and $9.1 million for the three and nine months ended September 30, 2012, respectively.

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Liquidity and Capital Resources

Sources and Uses of Cash

The following table summarizes our cash flow activities for the nine months ended September 30, 2013 and 2012 (in thousands):

	Nine Months Ended September 30,	
	2013	2012
Net loss	$(174,014)	$(95,452)
Adjustments to reconcile net loss to net cash used in operating activities	35,573	22,226
Changes in operating assets and liabilities	(13,003)	(11,184)
Net cash used in operating activities	(151,444)	(84,410)
Net cash provided by (used in) investing activities	84,846	(159,841)
Net cash (used in) provided by financing activities	(11,455)	478,799
Net (decrease) increase in cash and cash equivalents	(78,053)	234,548
Cash and cash equivalents at beginning of period	170,069	74,257
Cash and cash equivalents at end of period	$92,016	$308,805

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 September 30, 2013, we had $464.7 million in cash and investments, which included short- and long-term restricted cash and investments of $12.2 million and $15.9 million, respectively, and short- and long-term unrestricted investments of $187.2 million and $157.4 million, respectively. As of September 30, 2013, we are required to maintain on deposit with Silicon Valley Bank or one of its affiliates short- and long-term unrestricted investments of $2.2 million and $82.4 million, respectively, pursuant to covenants in our loan and security agreement with Silicon Valley Bank.

Operating Activities

Our operating activities used cash of $151.4 million for the nine months ended September 30, 2013, compared to cash used of $84.4 million for the nine months ended September 30, 2012.

Cash used in operating activities for the nine months ended September 30, 2013 related primarily to our $168.2 million in operating expenses for the period, less non-cash expenses for accretion of debt discount totaling $19.4 million, stock-based compensation totaling $8.5 million, investment amortization totaling $5.2 million, and depreciation and amortization totaling $2.4 million. Our operating expenses were largely attributable to the development of cabozantinib. In addition, we paid $6.0 million for restructuring activities during the period. All of our license and contract revenues during the nine months ended September 30, 2013 were non-cash, which was reflected in the $15.3 million reduction in deferred revenue during the period.

Cash used by operating activities for the 2012 period related primarily to our net loss of $95.5 million, which was largely due to the development of cabozantinib and to a $34.1 million reduction in deferred revenue primarily due to non-cash revenue recognized related to our 2007 and 2010 collaboration agreements with Bristol-Myers Squibb. In addition, we paid $4.5 million of our restructuring liability. Uses of cash were partially offset by the receipt of $27.3 million in cash relating to the termination of our 2009 discovery collaboration with Sanofi in December 2011 and the up-front payment received from Merck under our P13K-delta license agreement. In addition, we had non-cash charges totaling $18.9 million relating to stock-based compensation, depreciation and amortization and accretion of implied interest under the Deerfield Notes and the 2019 Notes.

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.

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Investing Activities

Our investing activities provided cash of $84.8 million for the nine months ended September 30, 2013, compared to cash used of $159.8 million for the nine months ended September 30, 2012.

Cash provided by investing activities for the 2013 period was primarily due to the maturity of investments of $251.5 million, less investment purchases of $176.8 million.

Cash used by investing activities for the 2012 period was primarily due to the purchase of $359.5 million of investments, less proceeds from the maturity of investments of $236.3 million.

Financing Activities

Our financing activities used cash of $11.5 million for the nine months ended September 30, 2013, compared to cash provided of $478.8 million for the nine months ended September 30, 2012.

Cash used for financing activities for 2013 was primarily due to principal payments on debt of $12.4 million.

Cash provided by our financing activities for 2012 was primarily due to the issuance of 12.7 million shares of common stock in February 2012 and 34.5 million shares of common stock in August 2012 for total net proceeds of $203.5 million, as well as the issuance and sale of the 2019 Notes for net proceeds of $277.7 million. The cash provided by financing activities was partially offset by cash used for principal payments on notes payable and bank obligations of $4.1 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. In 2010, we amended our loan and security agreement with Silicon Valley Bank to provide for a new seven-year term loan in the amount of $80.0 million. In addition, in 2010 we sold to Deerfield an aggregate $124.0 million initial principal amount of the Deerfield Notes for an aggregate purchase price of $80.0 million, less closing fees and expenses of approximately $2.0 million. In August 2012, we incurred $287.5 million of indebtedness through the issuance of the 2019 Notes. See “--Certain Factors Important to Understanding Our Financial Condition and Results of Operations.”

Cash Requirements

We have incurred net losses since inception through the quarter ended September 30, 2013, with the exception of the fiscal year ended December 31, 2011. In 2011, we had net income primarily as a result of the acceleration of revenue recognized under our 2008 collaboration agreement with Bristol-Myers Squibb that terminated in October 2011 and under our 2009 discovery collaboration agreement with Sanofi that terminated in December 2011. We anticipate net losses and negative operating cash flow for the foreseeable future. For the nine months ended September 30, 2013, we had a net loss of $174.0 million; as of September 30, 2013, we had an accumulated deficit of $1.4 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 September 30, 2013, we have generated $10.7 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, our collaborators fail to develop successful products or research funding we receive from collaborators decreases, 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 for progressive, metastatic MTC, 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 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 third quarter of 2013.

However, our future capital requirements will be substantial, and we may need to raise additional capital in the future. Our capital

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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 COMETRIQ® (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;
- the degree to which we conduct funded development activity on behalf of partners to whom we have out-licensed compounds or programs;
- whether we enter into new collaboration agreements, licensing agreements or other arrangements (including, in particular, with respect to COMETRIQ) 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 (GDC-0973/XL518) 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.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our market risks at September 30, 2013 have not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2012, filed with the Securities and Exchange Commission on February 21, 2013.

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio and our long-term debt. As of September 30, 2013, and December 31, 2012, 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 $10.0 million and $8.7 million, respectively.

In addition, we have exposure to fluctuations in certain foreign currencies in countries in which we conduct clinical trials. As of September 30, 2013, and December 31, 2012, approximately $3.7 million and $1.1 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 have not 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 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.

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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, 2012 filed with the Securities and Exchange Commission on February 21, 2013.

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; and
- commercialize our product candidates, if any such candidates receive regulatory approval for commercial sale.

As of September 30, 2013, we had $464.7 million in cash and investments, which included short- and long-term restricted cash and investments of $12.2 million and $15.9 million, respectively, and short- and long-term unrestricted investments of $187.2 million and $157.4 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 $2.2 million and $82.4 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 third quarter of 2013. 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 COMETRIQ® (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 $114.0 million initial principal amount of the Deerfield Notes, for which we will be required to make mandatory prepayments on an annual basis in 2014 and 2015 equal to 15% of specified payments from our collaborative arrangements (other than intercompany arrangements) received during the prior fiscal year, subject to a maximum annual prepayment amount of $27.5 million and, for the payment due in January 2014, a required minimum prepayment amount of $10.0 million, unless we are able to repay them 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 September 30, 2013, of $82.9 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;
- the degree to which we conduct funded development activity on behalf of partners to whom we have out-licensed compounds or programs;

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- whether we enter into new collaboration agreements, licensing agreements or other arrangements (including, in particular, with respect to COMETRIQ) 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 (GDC-0973/XL518) 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 terms of the agreement contains covenants or events of default requiring us to maintain specified collateral balances. The failure to comply with these covenants could result in an acceleration of the underlying debt obligations. If we are unable to remain in compliance with such covenants or if we are unable to renegotiate such covenants and the lender exercises its remedies under the agreement, we would not be able to operate under our current operating plan.

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

We have incurred net losses since inception through the quarter ended September 30, 2013, with the exception of the fiscal year ended December 31, 2011. In 2011, we had net income primarily as a result of the acceleration of revenue recognized under our 2008 collaboration agreement with Bristol-Myers Squibb that terminated in October 2011 and under our 2009 discovery collaboration agreement with Sanofi that terminated in December 2011. We anticipate net losses and negative operating cash flow for the foreseeable future. For the nine months ended September 30, 2013, we had a net loss of $174.0 million; as of September 30, 2013, we had an accumulated deficit of $1.4 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 September 30, 2013, we have generated $10.7 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, our collaborators fail to develop successful products or research funding we receive from collaborators decreases, 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 for progressive, metastatic MTC, 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 of cabozantinib. As a result, we expect to continue to incur substantial operating expenses, and, consequently, we will need to generate significant

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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.

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 September 30, 2013, our total consolidated indebtedness through maturity was $467.8 million (excluding trade payables). We may also incur additional indebtedness to meet future financing needs. If we raise 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 working capital, capital expenditures, acquisitions 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, we implemented the Restructurings, which resulted in an aggregate reduction in headcount

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of 429 employees. We have recorded aggregate restructuring charges of $52.9 million in connection with the Restructurings and anticipate that we will incur additional 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 the 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 September 30, 2013, no assurance can be given that a deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or investments or our ability to meet our financing objectives.

Risks Related to COMETRIQ™ (cabozantinib)

We are dependent on the successful development and commercialization of COMETRIQ.*

The success of our business is dependent upon the successful development and commercialization of COMETRIQ. As part of our strategy, we are dedicating all of our proprietary resources to advance COMETRIQ as aggressively as possible. On November 29, 2012, the FDA approved COMETRIQ for the treatment of progressive, metastatic MTC in the United States and we commercially launched COMETRIQ in late January 2013. We have also submitted an MAA for cabozantinib for the proposed indication of progressive, unresectable, locally advanced, or metastatic MTC to the EMA that was accepted for review in November 2012. We view the approval of COMETRIQ by the FDA for the treatment of progressive, metastatic MTC as a transitional event towards our objective of developing COMETRIQ into a major oncology franchise. Our ability to realize this objective or the value of our investment is contingent on, among other things, successful clinical development, regulatory approval and market acceptance of COMETRIQ. If we encounter difficulties in the development of COMETRIQ in other indications beyond progressive, metastatic 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 COMETRIQ in progressive, metastatic MTC or such other indications if approved, we will not have the resources necessary to continue our business in its current form.

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.

Our ability to commercialize COMETRIQ for the treatment of progressive, metastatic MTC and potentially other

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indications, if approved, will be highly dependent upon the extent to which COMETRIQ gains market acceptance among: physicians; patients; health care payors, such as Medicare and Medicaid; and the medical community. If COMETRIQ does not achieve an adequate level of acceptance, we may not generate adequate product revenues, if at all, and we may not become profitable. The degree of market acceptance of COMETRIQ will depend upon a number of factors, including:

- the effectiveness, or perceived effectiveness, of COMETRIQ in comparison to competing products;
- the existence of any significant side effects of COMETRIQ, 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 COMETRIQ is approved;
- the ability to offer COMETRIQ 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 COMETRIQ.*

We have established a small commercial organization that we believe is commensurate with the size of the market opportunity for progressive, metastatic MTC. We have also designed our commercial organization to maintain the maximum amount of 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 COMETRIQ. 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. 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 will also rely on a third party, Swedish Orphan Biovitrum, or Sobi, to distribute and commercialize COMETRIQ for the treatment of metastatic MTC in the European Union. Sobi is currently supporting access to cabozantinib under a Named Patient Use program in the European Union and other countries. Our current and anticipated future dependence upon these 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 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 these third parties, or enter into new arrangements, on acceptable terms, or at all. These 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 healthcare programs' 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;

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- 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 efforts;
- the Foreign Corrupt Practices Act, a U.S. law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals);
- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- state and federal government price reporting laws that require us to calculate and report complex pricing metrics to government programs, where such reported priced may be used in the calculation of reimbursement and/or discounts on our marketed drugs (participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our products, increased infrastructure costs, and potentially limit our ability to offer certain marketplace discounts); and
- state and federal marketing expenditure tracking and reporting laws, which generally require certain types of expenditures in the United States to be tracked and reported (compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships, which could potentially have a negative effect on our business and/or increase enforcement scrutiny of our activities).

In addition, certain marketing practices, including off-label promotion, may also violate 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 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 Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology and Clinical Health Act, or HIPAA. Although we are not directly subject to HIPAA, we could be subject to criminal penalties if we knowingly obtain individually identifiable health information from a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect our business, including recently enacted laws in a majority of states requiring security breach notification. These laws could create liability for us or increase our cost of doing business. International laws, such as the EU Data Privacy Directive (95/46/EC) and Swiss Federal Act on Data Protection, regulate the processing of personal data within Europe and between European countries and the United States. Failure to provide adequate privacy protections and maintain compliance with Safe Harbor mechanisms could jeopardize business transactions across borders and result in significant penalties.

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

Our ability to successfully commercialize COMETRIQ 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 COMETRIQ 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 COMETRIQ, our revenues and prospects for profitability will suffer. In addition, even if third-party payors provide some

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coverage or reimbursement for COMETRIQ, the availability of such coverage or reimbursement for prescription drugs under private health insurance and managed care plans often varies based on the type of contract or plan purchased.

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 COMETRIQ to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in the commercialization of COMETRIQ. 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 COMETRIQ. Cost-control initiatives could decrease the price we might establish for COMETRIQ, 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 COMETRIQ profitably.*

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell COMETRIQ 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 of 2010, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, PPACA, substantial changes may be made to the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Among other things, PPACA creates a new system of health insurance “exchanges,” designed to make health policies available to individuals and certain groups though state- or federally-administered marketplaces, beginning in 2014. In connection with such exchanges, certain “essential health benefits” are intended to be made more consistent across plans, setting basically a baseline coverage level. While prescription drugs are broadly considered “essential,” there is some discretion to the plans as to what categories of prescription drug products will be covered (and the scope of coverage in each category). We cannot predict at this time whether COMETRIQ would be covered by the health plans offered in any or all of the exchanges. Failure to be covered by plans offered in the exchanges could have a material adverse impact on our business. We anticipate that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and an additional downward pressure on the price that we receive for COMETRIQ and any subsequently approved product, and could seriously harm our business.

Under the Budget Control Act of 2011, as amended, federal budget “sequestration” became effective in March 2013, automatically reducing payments under various government programs, including, for example, certain Medicare provider and supplier reimbursement payments. Sequestration may have a material adverse effect on our customers and accordingly, our financial operations. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Insurers 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.

We also cannot be certain that COMETRIQ will successfully be placed on the list of drugs covered by particular commercial or government health plan formularies, nor can we predict the negotiated price for COMETRIQ, which will be determined by market factors. Many states have also created preferred drug lists for their Medicaid programs, and include drugs on those lists only when the manufacturers agree to pay a supplemental rebate. If COMETRIQ is not included on these preferred drug lists, physicians may not be inclined to prescribe it to their Medicaid patients, thereby diminishing the potential market for COMETRIQ.

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 our products by placing them 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 COMETRIQ. We also anticipate pricing pressures in connection with the sale of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative

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proposals.

Our competitors may develop products and technologies that make cabozantinib obsolete.*

The biotechnology 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 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 progressive, metastatic MTC 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 progressive, metastatic MTC is AstraZeneca's RET, VEGFR and EGFR inhibitor vandetanib, which has been approved by the FDA and the EMA for the treatment of symptomatic or progressive MTC in patients with unresectable, locally advanced, or metastatic disease. In addition, we believe that COMETRIQ also faces competition as a treatment for progressive, metastatic MTC from off-label use of Bayer's and Onyx Pharmaceuticals' (a wholly-owned subsidiary of Amgen) multikinase inhibitor sorafenib, Pfizer's multikinase inhibitor sunitinib, 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: Bayer's and Algeta's alpha-pharmaceutical alpharadin (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: Pfizer's axitinib, sunitinib and temsirolimus; Novatis' everolimus; Bayer's and Onyx Pharmaceuticals' sorafenib; GlaxoSmithKline's pazopanib; and Genentech's bevacizumab; and
- HCC: Bayer's and Onyx Pharmaceuticals' sorafenib; Bayer's regorafenib; ImClone System's ramucirumab; 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; and other MET inhibitors, including Amgen's AMG 208, Pfizer's crizotinib, ArQule's tivantinib, GlaxoSmithKline's foretinib (XL880), and Genentech's onartuzumab.

We lack the manufacturing capabilities and experience necessary to enable us to produce COMETRIQ 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 COMETRIQ and rely on third party contractors to do so. These third-parties must comply with applicable regulatory requirements, including the FDA's current Good Manufacturing Practices, or GMP. Our current and anticipated future dependence upon these third parties may adversely affect our future profit margins and our ability to develop and commercialize COMETRIQ 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.

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Our third-party manufacturers may not be able to comply with the GMP 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 COMETRIQ. 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 COMETRIQ, 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, COMETRIQ 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 progressive, metastatic MTC. Clinical trials are inherently risky and may reveal that cabozantinib is ineffective or has unacceptable toxicity or other side effects that may significantly decrease the likelihood of regulatory approval in such indications.

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
- regulators or institutional review boards may withhold authorization of, 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 or 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 or the 2019 Notes to decline significantly. Our partners under our collaboration agreements may

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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 progressive, metastatic MTC.

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

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 a New Drug Application, or NDA, or NDA supplement can be submitted to the FDA, or MAA to the EMA or any application or submission to regulatory authorities in other jurisdictions, the product candidate must undergo extensive clinical trials, which can take many years and require substantial expenditures.

In December 2011, we initiated COMET-2, our first phase 3 pivotal trial of cabozantinib in patients with metastatic castration-resistant prostate cancer, 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 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.
- 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

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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 post marketing 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 Bristol-Myers Squibb, Sanofi, Genentech, GlaxoSmithKline, Merck (known as MSD outside of the United States and Canada) and Daiichi Sankyo, for the development and ultimate commercialization of a significant number of 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 our compounds 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 (GDC-0973/XL518) we are obligated to share under our collaboration with Genentech;
- we are not able to control the amount and timing of resources that our collaborators or potential future collaborators will devote to the development or commercialization of drug candidates or to their marketing and distribution;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a drug candidate, repeat or conduct new clinical trials or require a new formulation of a drug candidate for clinical testing;
- disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization of our drug candidates or that result in costly litigation or arbitration that diverts management's attention and resources;
- collaborators may experience financial difficulties;
- collaborators may not be successful in their efforts to obtain regulatory approvals in a timely manner, or at all;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a collaborator's business strategy may adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- a collaborator could independently move forward with a competing drug candidate developed either independently or in collaboration with others, including our competitors;
-

- we may be precluded from entering into additional collaboration arrangements with other parties in an area or field of exclusivity;
- future collaborators may require us to relinquish some important rights, such as marketing and distribution rights; and

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- collaborations may be terminated (as occurred with respect to cabozantinib and XL281, which were previously subject to our 2008 collaboration agreement with Bristol-Myers Squibb, and with respect to our 2009 discovery collaboration with Sanofi, which was terminated in December 2011) or allowed to expire, which would delay, and may increase the cost of development of, our drug candidates.

If any of these risks materialize, our product development efforts could be delayed and otherwise adversely affected, which could adversely impact our business, operating results and financial condition.

If we are unable to continue current collaborations and achieve milestones or royalties, our revenues would suffer.*

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 royalties, or our collaborators fail to develop successful products, we will not earn the revenues contemplated under such collaborative agreements.

If any of these agreements is terminated early (as occurred with respect to cabozantinib and XL281, which were previously subject to our 2008 collaboration agreement with Bristol-Myers Squibb, and with respect to our 2009 discovery collaboration with Sanofi, which was terminated in December 2011), whether unilaterally or by mutual agreement, our revenues could suffer. Most of our collaboration agreements contain early termination provisions. In addition, from time to time we review and assess certain aspects of our collaborations, partnerships and agreements and may amend or terminate, either by mutual agreement or pursuant to any applicable early termination provisions, such collaborations, partnerships or agreements if we deem them to be no longer in our economic or strategic interests. We may not be able to enter into new collaboration agreements on similar or superior financial terms to offset the loss of revenues from the termination or expiration of any of our existing or recently terminated arrangements.

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

Our strategy includes the pursuit of 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 face significant competition in seeking appropriate collaborators, and these collaborations are complex and time consuming to negotiate and document. 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, particularly those drug candidates as to which we believe a broad development program is appropriate or for which we have determined not to continue to utilize our own resources to develop. As a result, our revenues, capital resources and product development efforts could be adversely affected.

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 biotechnology 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 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, there may be 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 these inventions.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign

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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 some of our 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 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. 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 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. 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 Restructurings 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

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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 of 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 trials, substantial monetary awards to trial participants and the inability to commercialize any products that we may develop.

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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 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;
- 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;

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- 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 one or more of our out-licensed programs and 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 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 and adversely impact the trading price of the 2019 Notes.

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

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

Under Accounting Standards Codification, or ASC, Subtopic 470-20, issuers of certain convertible debt instruments that have a net settlement feature and may be settled in cash upon conversion, including partial cash settlement, are required to separately account for the liability (debt) and equity (conversion option) components of the instrument. As a result of the application of ASC 470-20, we recognized $143.2 million as the initial debt discount with a corresponding increase to paid-in capital, the equity component, for the 2019 Notes. We will be required to record the amortization of this debt discount over the terms of the 2019 Notes, which may adversely affect our reported or future

financial results and the market price of our common stock. In addition, if the 2019 Notes become convertible, we could be required under applicable accounting rules to

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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 expect to use the if-converted method to compute earnings per share, which could be more dilutive than using the treasury stock method.

Certain provisions in the 2019 Notes and the indenture pursuant to which such notes were issued could delay or prevent an otherwise beneficial takeover or takeover attempt.

Certain provisions in the 2019 Notes and the indenture pursuant to which such notes were issued 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, holders of the 2019 Notes 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, 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, 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.

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.

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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.

October 30, 2013	/s/ FRANK KARBE
Date	Frank Karbe
	Executive Vice President and Chief Financial Officer
	(Duly Authorized Officer and Principal Financial and Accounting Officer)

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EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit/ Appendix Reference	Filing Date	
3.1	Amended and Restated Certificate of Incorporation of Exelixis, Inc.	10-K	000-30235	3.1	3/10/2010	
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Exelixis, Inc.	10-K	000-30235	3.2	3/10/2010	
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Exelixis, Inc.	8-K	000-30235	3.1	5/25/2012	
3.4	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 Warrant, dated June 10, 2009, to purchase 500,000 shares of Exelixis, Inc. common stock in favor of Symphony Evolution Holdings LLC.	10-Q, as amended	000-30235	4.4	7/30/2009	
4.3	Warrant Purchase Agreement, dated June 9, 2005, between Exelixis, Inc. and Symphony Evolution Holdings LLC.	10-Q	000-30235	4.4	8/5/2010	
4.4*	Form Warrant to Purchase Common Stock of Exelixis, Inc. issued or issuable to Deerfield Private Design Fund, L.P., Deerfield Private Design International, L.P., Deerfield Partners, L.P. and Deerfield International Limited	8-K	000-30235	4.9	6/9/2008	
4.5	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	
4.6	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	
4.7	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,	8-K	000-30235	4.2	8/14/2012	

4.9	National Association Form of 4.25% Convertible Senior Subordinated Note due 2019	8-K	000-30235	4.2 (Exhibit A)	8/14/2012	
10.1	Amendment No. 2 dated August 1, 2013 to Note Purchase Agreement, dated June 2, 2010, by and between Deerfield Private Design Fund, L.P., Deerfield Private Design International, L.P. and Exelixis, Inc.					X
10.2	Sublease, dated August 5, 2013, between Exelixis, Inc. and Sutro Biopharma, Inc.					X

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Exhibit Number	Exhibit Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit/ Appendix Reference	Filing Date	
10.3	Consent to Sublease, dated August 5, 2013, by and among Britannia Pointe Grand Limited Partnership, Exelixis, Inc. and Sutro Biopharma, Inc.					X
10.4	Employment Agreement between Exelixis, Inc. and Pamela A. Simonton					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 granted 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.