

EXELIXIS, INC.  
Form 10-Q  
November 07, 2012  
Table of Contents

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

FORM 10-Q

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

For the quarterly period ended September 28, 2012  
Or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission File Number: 000-30235

Exelixis, Inc.  
(Exact Name of Registrant as Specified in Its Charter)

Delaware  
(State or Other Jurisdiction of  
Incorporation or Organization)  
210 East Grand Ave.  
South San Francisco, CA 94080  
(Address of Principal Executive Offices) (Zip Code)  
(650) 837-7000  
(Registrant's Telephone Number, Including Area Code)

04-3257395  
(I.R.S. Employer  
Identification No.)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days). Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of November 2, 2012, there were 183,596,930 shares of the registrant's common stock outstanding.

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Table of Contents

EXELIXIS, INC.

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 28, 2012

INDEX

<u>Part I. Financial Information</u>	<u>3</u>
Item 1. <u>Financial Statements</u>	<u>3</u>
<u>Condensed Consolidated Balance Sheets – September 30, 2012 and December 31, 2011</u>	<u>3</u>
<u>Condensed Consolidated Statements of Operations – Three and Nine Months Ended September 30, 2012 and 2011</u>	<u>5</u>
<u>Consolidated Statements of Other Comprehensive Loss – Three and Nine Months Ended September 30, 2012 and 2011</u>	<u>5</u>
<u>Condensed Consolidated Statements of Cash Flows – Nine Months Ended September 30, 2012 and 2011</u>	<u>6</u>
<u>Notes to Condensed Consolidated Financial Statements</u>	<u>7</u>
Item 2. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>19</u>
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>34</u>
Item 4. <u>Controls and Procedures</u>	<u>34</u>
<u>Part II. Other Information</u>	<u>35</u>
Item 1A. <u>Risk Factors</u>	<u>35</u>
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>52</u>
Item 6. <u>Exhibits</u>	<u>53</u>
<u>SIGNATURES</u>	<u>54</u>
EXHIBITS	
Exhibit 31.1	
Exhibit 31.2	
Exhibit 32.1	

Table of Contents

## PART I. FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

## EXELIXIS, INC.

## CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)

	September 30, 2012 (unaudited)	December 31, 2011 (1) (unaudited)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 308,805	\$ 74,257
Marketable securities	163,542	120,005
Short-term restricted cash and investments	12,242	—
Other receivables	2,708	30,190
Prepaid expenses and other current assets	6,098	4,372
Total current assets	493,395	228,824
Restricted cash and investments	27,946	4,199
Long-term investments	162,173	85,260
Property and equipment, net	6,292	8,506
Goodwill	63,684	63,684
Other assets	9,123	2,789
Total assets	\$ 762,613	\$ 393,262
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 3,246	\$ 1,957
Accrued clinical trial liabilities	23,701	21,729
Accrued compensation and benefits	8,255	8,943
Other accrued liabilities	8,882	8,423
Current portion of notes payable and bank obligations	3,164	4,870
Current portion of convertible loans	10,000	—
Current portion of restructuring	4,033	4,483
Deferred revenue	24,134	41,920
Total current liabilities	85,415	92,325
Long-term portion of notes payable and bank obligations	82,885	85,260
Long-term portion of convertible loans	239,244	91,385
Long-term portion of restructuring	6,456	9,495
Other long-term liabilities	7,768	7,844
Deferred revenue	—	16,321
Total liabilities	\$ 421,768	\$ 302,630
Commitments		
Stockholders' equity:		
Common stock, \$0.001 par value; 400,000,000 and 200,000,000 shares authorized at September 30, 2012 and December 31, 2011, respectively; issued and outstanding: 183,489,026 and 135,563,735 shares at September 30, 2012 and December 31, 2011, respectively:	183	135
Additional paid-in-capital	1,542,489	1,196,992
Accumulated other comprehensive income (loss)	(18	) (138 )

Accumulated deficit	(1,201,809 )	(1,106,357 )
Total stockholders' equity	340,845	90,632
Total liabilities and stockholders' equity	\$762,613	\$ 393,262

The condensed consolidated balance sheet at December 31, 2011 has been derived from the audited consolidated (1) financial statements at that date but does not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements.

Table of Contents

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

4

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Table of Contents

## EXELIXIS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Revenues:				
Contract	\$9,301	\$5,024	\$16,934	\$25,761
License	4,012	122,703	22,702	167,984
Collaboration reimbursement	—	545	—	2,583
Total revenues	13,313	128,272	39,636	196,328
Operating expenses:				
Research and development	30,680	37,465	96,386	126,058
General and administrative	7,343	8,171	22,008	26,119
Restructuring charge	733	2,937	1,704	6,190
Total operating expenses	38,756	48,573	120,098	158,367
(Loss) income from operations	(25,443	) 79,699	(80,462	) 37,961
Other income (expense), net:				
Interest income and other, net	318	98	818	1,479
Interest expense	(7,679	) (4,142	) (15,775	) (12,249
Gain on sale of business	—	2,210	—	2,210
Total other income (expense), net	(7,361	) (1,834	) (14,957	) (8,560
(Loss) income before income taxes	(32,804	) 77,865	(95,419	) 29,401
Income tax provision	(10	) —	(33	) —
Net (loss) income	\$(32,814	) \$77,865	\$(95,452	) \$29,401
Net (loss) income per share, basic	\$(0.20	) \$0.60	\$(0.63	) \$0.24
Net (loss) income per share, diluted	\$(0.20	) \$0.59	\$(0.63	) \$0.23
Shares used in computing basic (loss) income per share amounts	166,354	129,145	152,316	123,426
Shares used in computing diluted (loss) income per share amounts	166,354	131,344	152,316	129,430

## EXELIXIS, INC.

## CONSOLIDATED STATEMENTS OF OTHER COMPREHENSIVE LOSS

(in thousands)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Net (loss) income	\$(32,814	) \$77,865	\$(95,452	) \$29,401
Net unrealized (losses) gains on available-for-sale securities	(23	) (236	) 120	(261
Comprehensive (loss) income	\$(32,837	) \$77,629	\$(95,332	) \$29,140

Accumulated other comprehensive income consisted solely of unrealized gains (losses) on available for sale securities for the periods presented.

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





Table of Contents

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

	Nine Months Ended September	
	30,	2011
	2012	2011
Cash flows from operating activities:		
Net (loss) income	\$(95,452	) \$29,401
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Depreciation and amortization	4,071	5,035
Stock-based compensation expense	6,222	9,409
Restructuring (credit) charge for property and equipment	(141	) 379
Gain on sale of business	—	(2,210
Accretion of debt discount	8,624	5,900
Other	3,450	3,637
Changes in assets and liabilities:		
Other receivables	27,082	1,242
Prepaid expenses and other current assets	(1,892	) (1,522
Other assets	(1,983	) 701
Accounts payable and other accrued expenses	3,280	(2,225
Restructuring liability	(3,489	) (3,886
Other long-term liabilities	(76	) (758
Deferred revenue	(34,106	) (175,162
Net cash used in operating activities	(84,410	) (130,059
Cash flows from investing activities:		
Purchases of property and equipment	(1,528	) (712
Proceeds from sales of property and equipment	877	—
Proceeds on sale of business	—	3,010
(Increase) decrease in restricted cash and investments	(35,989	) 2,200
Proceeds from maturities of marketable securities	236,323	117,244
Purchases of marketable securities	(359,524	) (210,580
Net cash used in investing activities	(159,841	) (88,838
Cash flows from financing activities:		
Proceeds from issuance of common stock, net	203,479	179,377
Proceeds from convertible notes, net	277,673	—
Proceeds from exercise of stock options and warrants	901	11,705
Proceeds from employee stock purchase plan	828	987
Proceeds from note payable and bank obligations	—	2,589
Principal payments on notes payable and bank obligations	(4,082	) (6,990
Net cash provided by financing activities	478,799	187,668
Net increase (decrease) in cash and cash equivalents	234,548	(31,229
Cash and cash equivalents, at beginning of period	74,257	97,440
Cash and cash equivalents, at end of period	\$308,805	\$66,211

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



Table of Contents

EXELIXIS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2012

(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 efforts exclusively on cabozantinib (formerly known as XL184), our most advanced product candidate, in order to maximize the therapeutic and commercial potential of this compound. We believe cabozantinib has the potential to be a high-quality, broadly active, differentiated pharmaceutical product that can make a meaningful difference in the lives of patients. We have also established a portfolio of other novel compounds that we believe have the potential to address serious unmet medical needs, many of which are being advanced by partners as part of collaborations.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and pursuant to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (“SEC”). Accordingly, they do not include all of the information and footnotes required by U.S. generally accepted accounting principles (“GAAP”) for complete financial statements. In our opinion, all adjustments (consisting 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 ends on the Friday closest to December 31<sup>st</sup>. Fiscal year 2011, a 52-week year, ended on December 30, 2011, and fiscal year 2012, a 52-week year, will end on December 28, 2012. For convenience, references in this report as of and for the fiscal quarters ended September 30, 2011 and September 28, 2012, and as of the fiscal year ended December 30, 2011, are indicated as ended September 30, 2011 and 2012, and as ended December 31, 2011, respectively.

Operating results for the three and nine months ended September 30, 2012 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2012 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, 2011 included in our Annual Report on Form 10-K filed with the SEC on February 22, 2012.

Basis of Consolidation

The consolidated financial statements include the accounts of Exelixis and those of our wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated.

Use of Estimates

The preparation of the consolidated financial statements is in conformity with GAAP, 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 revenue recognition, clinical trial accruals, restructuring and stock option valuation. 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.

Cash and Investments

We consider all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. We invest in high-grade, short-term commercial paper and money market funds, which are subject to minimal credit and market risk.



Table of Contents

Historically, all marketable securities were classified as available-for-sale, were carried at fair value and were viewed as available for use in current operations. Therefore, we had classified certain investments as short-term marketable securities, even though their stated maturity dates may have been one year or more beyond the balance sheet date. As of September 30, 2012, we continue to classify all marketable securities as available-for-sale; however, due to the increase in our cash balances as a result of the financing activities we conducted during the three months ended September 30, 2012, we no longer require these marketable securities for use in current operations, and have accordingly classified those securities that mature in more than 12 months as Long-term investments on our Condensed Consolidated Balance Sheets. Certain investments that collateralize loan balances that extend over 12 months have been classified as Long-term investments, in association with the loan arrangement; they are not restricted to withdrawal. Unrealized gains and losses on available-for-sale investments are reported as a separate component of stockholders' equity. Realized gains and losses, net, and interest and dividends on available-for-sale securities are recorded in our Condensed Consolidated Statement of Operations as Interest income and other, net. The cost of securities sold is based on the specific identification method.

All our marketable securities are subject to quarterly reviews for impairment that is deemed to be other-than-temporary. An investment is considered other-than-temporarily impaired when its fair value is below its amortized cost and (1) we intend to sell the security, (2) it is "more likely than not" that we will be required to sell the security before recovery of its amortized cost basis or (3) the present value of expected cash flows from the investment is not expected to recover the entire amortized cost basis.

The following summarizes available-for-sale securities as of September 30, 2012 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	\$ 139,645	\$7	\$(4)	\$ 139,648
Commercial paper	258,942	17	—	258,959
Corporate bonds	162,787	44	(94)	162,737
U.S. Government sponsored enterprises	81,787	16	(2)	81,801
Municipal bonds	31,566	—	(3)	31,563
Total	\$674,727	\$84	\$(103)	\$674,708
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
As reported:				
Cash and cash equivalents	\$308,804	\$1	\$—	\$308,805
Marketable securities	163,543	64	(66)	163,541
Restricted cash and investments	40,185	7	(4)	40,188
Long-term investments	162,195	12	(33)	162,174
Total	\$674,727	\$84	\$(103)	\$674,708

As of September 30, 2012, all securities that were in an unrealized loss position have been so for less than one year and the unrealized losses were due to market conditions and were not attributed to credit risk. Based on the scheduled maturities of our marketable securities, 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.

Table of Contents

The following summarizes available-for-sale securities as of December 31, 2011 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	\$81,986	\$—	\$—	\$81,986
Commercial paper	29,079	2	(1	) 29,080
Corporate bonds	116,068	22	(169	) 115,921
U.S. Government sponsored enterprises	37,237	12	—	37,249
Municipal bonds	19,488	—	(3	) 19,485
Total	\$283,858	\$36	\$(173	) \$283,721
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
As reported:				
Cash and cash equivalents	\$74,256	\$1	\$—	\$74,257
Marketable securities	120,143	35	(173	) 120,005
Restricted cash and investments	4,199	—	—	4,199
Long-term investments	85,260	—	—	85,260
Total	\$283,858	\$36	\$(173	) \$283,721

The following summarizes available-for-sale securities as of September 30, 2012 by contractual maturity (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Mature in less than one year	\$555,899	\$65	\$(67	) \$555,897
Mature in one to two years	118,828	19	(36	) 118,811
Total	\$674,727	\$84	\$(103	) \$674,708

The following summarizes available-for-sale securities as of December 31, 2011 by contractual maturity (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Mature in less than one year	\$259,209	\$24	\$(151	) \$259,082
Mature in one to two years	24,649	12	(22	) 24,639
Total	\$283,858	\$36	\$(173	) \$283,721

**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.

Level 3—unobservable inputs.

Our Level 1 investments and liabilities are valued using quoted prices in active markets or based upon other observable inputs. Our Level 2 inputs were determined 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. There were no transfers between Level 1 and Level 2 of the fair value hierarchy, as determined at the end of each reporting period. The following table sets forth the fair value of our financial assets that were measured on a recurring basis as of September 30, 2012 and December 31, 2011, respectively (in thousands):

9

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Table of Contents

As of September 30, 2012:

	Level 1	Level 2	Level 3	Total
Money market funds	\$ 139,648	\$—	\$—	\$ 139,648
Commercial paper	—	258,959	—	258,959
Corporate bonds	—	162,737	—	162,737
U.S. Government sponsored agencies	—	81,801	—	81,801
Municipal bonds	—	31,563	—	31,563
Total	\$ 139,648	\$ 535,060	\$—	\$ 674,708

As of December 31, 2011:

	Level 1	Level 2	Level 3	Total
Money market funds	\$ 81,986	\$—	\$—	\$ 81,986
Commercial paper	—	29,080	—	29,080
Corporate bonds	—	115,921	—	115,921
U.S. Government sponsored agencies	—	37,249	—	37,249
Municipal bonds	—	19,485	—	19,485
Total	\$ 81,986	\$ 201,735	\$—	\$ 283,721

Silicon Valley Bank loan and Deerfield facility

We have estimated the fair value of our long-term 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. However, due to the unique structure of our 2010 financing with entities affiliated with Deerfield Management Company L.P. (“Deerfield”) and the current non-liquid market in structured notes, there is no practicable method to determine the fair value of this instrument. The fair value of our debt will fluctuate with movements of interest rates, increasing in periods of declining rates of interest, and declining in periods of increasing rates of interest. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Certain Factors Important to Understanding Our Financial Condition and Results of Operations—Deerfield Facility” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Cash Requirements” for details on the structure and terms of our 2010 financing with Deerfield.

Convertible Senior Subordinated Notes due 2019

On August 14, 2012, we issued and sold \$287.5 million aggregate principal amount of 4.25% convertible senior subordinated notes due 2019 (the “2019 Notes”). The fair value of the 2019 Notes at September 30, 2012 is based on the average trading prices, a level 1 input. The 2019 Notes are not marked-to-market and are shown at their original issuance value net of the unamortized discount; the portion of the value allocated to the conversion option is included in stockholders’ equity in the accompanying unaudited Condensed Consolidated Balance Sheets at September 30, 2012. See Note 6 to the Condensed Consolidated Financial Statements for further information regarding the 2019 Notes.

The estimated fair value of our outstanding debt, excluding our 2010 financing with Deerfield, was as follows (in thousands):

	September 30, 2012	December 31, 2011
Equipment lines of credit	\$ 6,006	\$ 10,066
Silicon Valley Bank loan	77,981	77,835
Convertible senior subordinated notes due 2019 (face value \$287,500)	305,900	—
Total	\$ 389,887	\$ 87,901

Our payment commitments associated with these debt instruments are fixed during the corresponding terms and comprise interest payments, principal payments or a combination thereof.





Table of Contents

## Long-Lived Assets

The carrying value of our long-lived assets is reviewed for impairment whenever events or changes in circumstances indicate that the asset may not be recoverable. An impairment loss would be recognized when estimated future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount.

Long-lived assets include property and equipment and identified intangible assets. In the nine months ended September 30, 2011, we recorded impairment charges associated with our property and equipment in the amount of approximately \$0.3 million in connection with our 2010 and 2011 restructurings. The charges related to the 2010, 2011 and 2012 restructurings (collectively, the "Restructurings") recorded during the nine months ended September 30, 2012 were \$0.3 million. See Note 4 to the Condensed Consolidated Financial Statements for further information on the restructurings.

## Concentration of Credit Risk

Financial instruments that potentially subject us to concentrations of credit risk are primarily cash and cash equivalents, accounts receivable and investments in marketable securities. Cash equivalents and marketable securities consist of money market funds, taxable commercial paper, corporate bonds with high credit quality, obligations of U.S. government sponsored enterprises and municipal bonds. All cash and cash equivalents and marketable securities are maintained with financial institutions that management believes are creditworthy. Other receivables are typically 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.

## Net (Loss) income Per Share

Basic net (loss) income per share is computed by dividing net (loss) income for the period by the weighted average number of shares of common stock outstanding during the period. Diluted net (loss) income per share gives effect to potential incremental common shares issuable (1) upon the exercise of stock options and warrants, (2) in connection with vesting of restricted stock units ("RSUs"), (3) pursuant to our employee stock purchase plan, and (4) upon conversion of our loan with GlaxoSmithKline, which was fully repaid in October 2011, and of the 2019 Notes (both of which were calculated using an as-if-converted method).

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Numerator:				
Net (loss) income	\$(32,814)	\$77,865	\$(95,452)	\$29,401
Denominator:				
Shares used in computing basic (loss) income per share amounts	166,354	129,145	152,316	123,426
Add effect of dilutive securities:				
Shares issuable upon conversion of our GlaxoSmithKline loan	—	449	—	1,568
Shares issuable upon the exercise of outstanding stock options	—	1,444	—	3,471
Shares issuable pursuant to the issuance of vested RSUs	—	144	—	558
Shares issuable pursuant to the exercise of warrants	—	48	—	281
Shares issuable upon the purchase of ESPP	—	114	—	126
Shares used in computing diluted net (loss) income per common share	—	2,199	—	6,004
Shares used in computing diluted (loss) income per share amounts	166,354	131,344	152,316	129,430
Net (loss) income per share, basic	\$(0.20)	\$0.60	\$(0.63)	\$0.24
Net (loss) income per share, diluted	\$(0.20)	\$0.59	\$(0.63)	\$0.23

For the three and nine months ended September 30, 2012, 71.9 million total potential common shares were excluded from the total number of dilutive shares because their effect is antidilutive. Of these excluded shares, 54.1 million potential common shares related to the 2019 Notes and the remaining 17.7 million potential common shares related to RSUs, common stock options, our employee stock purchase plan and warrants. The total number of antidilutive outstanding potential common shares excluded from the net income per share computation of RSUs, common stock options, warrants and shares related to our GlaxoSmithKline convertible debt were 15.5 million and 7.4 million for the three and nine months ended September 30, 2011, respectively.

Table of Contents

## Collaboration Arrangements

Collaborative agreement reimbursement revenues or collaboration cost-sharing expenses are recorded as earned or owed based on the performance requirements by both parties under the respective contracts. There were no such reimbursements for the three and nine months ended September 30, 2012, and we do not expect to record any further collaboration reimbursement revenues under our current collaborations.

## Foreign Currency Translation and Remeasurement

Assets and liabilities denominated in currencies other than the functional currency are remeasured using exchange rates in effect at the end of the period and related gains or losses are recorded in Interest income and other, net. Gains and losses on the remeasurement of foreign currency assets and liabilities were not material for the periods presented.

## Recently Adopted Accounting Pronouncements

In December 2011, Accounting Standards Codification Topic 350, Testing Goodwill for Impairment was amended to allow the option of performing a qualitative assessment in evaluating goodwill for impairment. We adopted this guidance beginning January 1, 2012, and it did not have a material effect on our consolidated financial statements. In May 2011, Accounting Standards Codification Topic 820, Fair Value Measurement was amended to converge U.S. and international accounting standards and provide more detailed disclosure. We adopted this guidance beginning January 1, 2012 and added additional disclosure as required. The amendment did not have a material effect on our consolidated financial statements.

## Recently Issued Accounting Pronouncements

In December 2011, Accounting Standards Codification Topic 210, Balance Sheet was amended to converge U.S. and international accounting standards, and requires additional disclosure about offsetting of financial instruments. This guidance will be effective January 1, 2013 and we are evaluating the effect on our consolidated financial statements.

## NOTE 2. Stock-Based Compensation

We recorded and allocated employee stock-based compensation expenses as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Research and development expense	\$970	\$1,378	\$3,202	\$4,557
General and administrative expense	923	1,401	2,970	4,102
Restructuring-related stock-based compensation expense	—	176	—	625
Total employee stock-based compensation expense	\$1,893	\$2,955	\$6,172	\$9,284

We use the Black-Scholes option pricing model to value our stock options. The expected life computation is based on historical exercise patterns and post-vesting termination behavior. We considered implied volatility as well as our historical volatility in developing our estimate of expected volatility. The fair value of employee share-based payments awards was estimated using the following assumptions and weighted average fair values:

Table of Contents

	Stock Options Three Months Ended September 30,		Employee Stock Purchase Plan Three Months Ended September 30,		
	2012	2011	2012	2011	
Weighted average grant date fair value	\$3.31	\$3.28	\$1.63	\$4.24	
Risk-free interest rate	0.81	% 0.97	% 0.15	% 0.10	%
Dividend yield	0	% 0	% 0	% 0	%
Volatility	69	% 70	% 68	% 70	%
Expected life	5.6 years	5.4 years	0.5 years	0.5 years	

  

	Stock Options Nine Months Ended September 30,		Employee Stock Purchase Plan Nine Months Ended September 30,		
	2012	2011	2012	2011	
Weighted average grant date fair value	\$3.27	\$3.52	\$2.13	\$3.05	
Risk-free interest rate	0.82	% 1.05	% 0.10	% 0.13	%
Dividend yield	0	% 0	% 0	% 0	%
Volatility	69	% 70	% 68	% 68	%
Expected life	5.7 years	5.5 years	0.5 years	0.5 years	

A summary of all stock option activity for the nine months ended September 30, 2012 is presented below:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Options outstanding at December 31, 2011	17,436,378	\$ 7.16		
Granted	3,300,546	5.49		
Exercised	(175,708 )	5.12		
Cancelled	(1,399,526 )	7.92		
Options outstanding at September 30, 2012	19,161,690	\$ 6.84	4.64 years	\$287,800
Exercisable at September 30, 2012	13,559,920	\$ 7.32	3.80 years	\$239,408

As of September 30, 2012, \$16.0 million of total unrecognized compensation expense related to employee stock options was expected to be recognized over a weighted-average period of 3.09 years.

Table of Contents

A summary of all RSU activity for the nine months ended September 30, 2012 is presented below:

	Shares	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
RSUs outstanding at December 31, 2011	1,391,691	\$ 6.92		
Awarded	711,575	5.53		
Released	(459,416 )	7.33		
Forfeited	(201,987 )	6.74		
RSUs outstanding at September 30, 2012	1,441,863	\$ 6.13	1.84 years	\$6,956,995

As of September 30, 2012, \$6.8 million of total unrecognized compensation expense related to employee RSUs was expected to be recognized over a weighted-average period of 3.06 years.

## NOTE 3. Collaborations

## Merck

On December 21, 2011, we entered into an agreement with Merck & Co., Inc., known as MSD outside of the United States and Canada (“Merck”), pursuant to which we granted to Merck an exclusive worldwide license to our phosphoinositide-3 kinase delta (“PI3K-delta”) program, including XL499 and other related compounds. Pursuant to the terms of the agreement, Merck will have sole responsibility to research, develop, and commercialize compounds from our PI3K-delta program. As a result we recognized \$1.3 million in revenue in December 2011.

Merck was required to pay us an up-front cash payment of \$12.0 million in connection with the agreement, which we received on January 19, 2012. Under the terms of the agreement, we completed the transfer of the license and associated knowledge within ninety days of the effective date of the agreement and accordingly recognized the remaining unrecognized up-front payment of \$10.7 million during the three months ended March 31, 2012. We will be eligible to receive potential development and regulatory milestone payments for multiple indications of up to \$239.0 million. We will also be eligible to receive combined sales performance milestones of up to \$375.0 million and royalties on net sales of products emerging from the agreement. Milestones and royalties are payable on compounds emerging from our PI3K-delta program or from certain compounds that arise from Merck’s internal discovery efforts targeting PI3K-delta during a certain period.

Merck may at any time, upon specified prior notice to us, terminate the license. In addition, either of us may terminate the agreement for the other party’s uncured material breach. In the event of termination by Merck at will or by us for Merck’s uncured material breach, the license granted to Merck would terminate. In the event of a termination by us for Merck’s uncured material breach, we would receive a royalty-free license from Merck to develop and commercialize certain joint products. In the event of termination by Merck for our uncured material breach, Merck would retain the licenses from us, and we would receive reduced royalties from Merck on commercial sales of products.

## Bristol-Myers Squibb Company

## 2007 Cancer Collaboration

In December 2006, we entered into a worldwide collaboration with Bristol-Myers Squibb Company (“Bristol-Myers Squibb”), which became effective in January 2007, to discover, develop and commercialize novel targeted therapies for the treatment of cancer. We were responsible for discovery and preclinical development of small molecule drug candidates directed against mutually selected targets. In January 2007, Bristol-Myers Squibb made an up-front payment of \$60.0 million to us for which we granted Bristol-Myers Squibb the right to select up to three investigational new drug (“IND”) candidates from six future Exelixis compounds. We recognized the up-front payment as revenues over the estimated research term.

For each IND candidate selected, we were entitled to receive a \$20.0 million selection milestone from Bristol-Myers Squibb. Once selected, Bristol-Myers Squibb became responsible for leading the further development and commercialization of the selected IND candidates. In addition, we had the right to opt in to co-promote the selected IND candidates, in which case we would equally share all development costs and profits in the United States. In January 2008 and November 2008, Bristol-Myers Squibb exercised its option under the collaboration to develop and

commercialize XL139 (BMS-833923), a Hedgehog inhibitor, and XL413 (BMS-863233), a CDC7 inhibitor, respectively. Under the terms of the collaboration agreement, the selection of XL139 and XL413 by Bristol-Myers Squibb entitled us to milestone payments of \$20.0 million each, which we received in February 2008 and December 2008, respectively. In addition, we exercised our option under the collaboration agreement to co-develop and co-commercialize each of XL139 and XL413 in the United States.

## Table of Contents

In September 2010, we and Bristol-Myers Squibb terminated the XL413 program due to an unfavorable pharmacological profile observed in phase 1 clinical evaluation. Additionally, in connection with an amendment to the collaboration, which became effective in November 2010, we exercised our right to opt-out of further co-development of XL139 in consideration for a payment of \$20.0 million. This opt-out payment and the remaining deferred revenue balance as of the effective date of the opt-out, November 2010, were combined with and recognized in conjunction with the up-front fees received related to our TGR5 license agreement and ROR collaboration agreement entered into with Bristol-Myers Squibb in 2010, and will be recognized over the agreement with the longest term. Please refer to “2010 Collaboration Agreements” within this note.

The collaboration agreement was amended and restated in April 2011 in connection with an assignment of patents to one of our wholly-owned subsidiaries. We have no further responsibility for conducting new activities or funding new development or commercialization activities with respect to XL139 and will therefore no longer be eligible to share profits on sales of any commercialized products under the collaboration. We will continue to be eligible to receive regulatory and commercial milestones as well as double-digit royalties on any future sales of any products commercialized under the collaboration. As a result of the November 2010 amendment to the collaboration, the research term has ended, and we have no further obligation to deliver to Bristol-Myers Squibb a third IND candidate under the collaboration.

### 2010 Collaboration Agreements

#### TGR5 License Agreement

In October 2010, we entered into a global license agreement with Bristol-Myers Squibb for XL475 (and any potential backups), a preclinical compound that modulates the metabolic target known as TGR5 (the “TGR5 License Agreement”). Pursuant to the terms of the TGR5 License Agreement, Bristol-Myers Squibb received a worldwide exclusive license to XL475 and has sole control and responsibility for all subsequent research, development, commercial and manufacturing activities. The TGR5 License Agreement became effective in November 2010 following clearance under the Hart-Scott-Rodino Antitrust Improvement Act of 1976, as amended. The license agreement was amended and restated in April 2011 in connection with an assignment of patents to one of our wholly-owned subsidiaries.

Under the license agreement, Bristol-Myers Squibb received a worldwide exclusive license to XL475 and sole control and responsibility for all research, development, commercial and manufacturing activities. In November 2010 we received a nonrefundable up-front cash payment of \$35.0 million from Bristol-Myers Squibb. Additionally, for each product developed by Bristol-Myers Squibb under the license, we will be eligible to receive development and regulatory milestones of up to \$250.0 million and commercial milestones of up to \$150.0 million, as well as royalties on commercial sales of any such products. As of September 30, 2012, we have recognized aggregate license revenue of \$24.1 million under this agreement.

#### ROR Collaboration Agreement

In October 2010, we entered into a worldwide collaboration with Bristol-Myers Squibb pursuant to which each party granted to the other certain intellectual property licenses to enable the parties to discover, optimize and characterize ROR antagonists that may subsequently be developed and commercialized by Bristol-Myers Squibb. In November 2010, we received a nonrefundable up-front cash payment of \$5.0 million from Bristol-Myers Squibb. Additionally, for each product developed by Bristol-Myers Squibb under the collaboration, we will be eligible to receive development and regulatory milestones of up to \$255.0 million and commercial milestones of up to \$150.0 million, as well as royalties on commercial sales of any such products. The collaboration agreement was amended and restated in April 2011 in connection with an assignment of patents to one of our wholly-owned subsidiaries. In July 2011, we achieved a development preclinical milestone of \$2.5 million. As of September 30, 2012, we have recognized aggregate license revenue of \$5.3 million under this agreement.

#### NOTE 4: Restructurings

During 2010, we implemented two restructurings that resulted in an overall reduction in our workforce of 386 employees. As a consequence of our decision to focus our proprietary resources and development efforts on the development and commercialization of cabozantinib, we implemented additional restructurings in both March 2011



and May 2012, resulting in further reductions to our workforce. The aggregate reduction in headcount from the Restructurings is 422 employees.

Table of Contents

We have recorded aggregate restructuring charges of \$44.6 million in connection with the Restructurings, of which \$21.3 million related to termination benefits and \$23.3 million related to facility charges and the impairment of various assets. For the nine months ended September 30, 2012 and 2011, we recorded restructuring charges of approximately \$1.7 million and \$6.2 million, respectively. The charge for the nine months ended September 30, 2012, was primarily related to termination benefits and facility related charges in connection with the exit of all or portions of three of our South San Francisco buildings. The total outstanding restructuring liability related to the Restructurings is included in current and long-term portion of restructuring on our Condensed Consolidated Balance Sheets. As of September 30, 2012, the components of these liabilities are summarized in the following table (in thousands):

	Employee Severance And Other Benefits	Facility Charges	Asset Impairment, net of sales	Legal and Other Fees	Total
Ending accrual balance as of December 31, 2011	\$ 6	\$13,921	\$—	\$51	\$13,978
Restructuring charge (credit)	1,046	866	(180 )	(28 )	1,704
Cash payments	(909 )	(4,451 )	—	(3 )	(5,363 )
Adjustments or non-cash credits	(10 )	—	(697 )	—	(707 )
Proceeds from sale of assets	—	—	877	—	877
Ending accrual balance as of September 30, 2012	\$ 133	\$10,336	\$—	\$20	\$10,489

We expect to incur additional restructuring charges of approximately \$1.3 million, primarily related to the exit of all or portions of three of our South San Francisco buildings and will be recorded through the end of the building lease terms, the last of which ends in 2017.

## NOTE 5. Sales of Shares of Common Stock

In March 2011, we completed a public offering of 17.3 million shares of our common stock pursuant to a shelf registration statement previously filed with the SEC, which the SEC declared effective on May 8, 2009. We received approximately \$179.3 million in net proceeds from the offering after deducting the underwriting discount and related offering expenses.

In February 2012, we completed a public offering of 12.7 million shares of our common stock pursuant to a shelf registration statement previously filed with the SEC, which the SEC declared effective on May 8, 2009. We received approximately \$65 million in net proceeds from the offering after deducting the underwriting discount and related offering expenses.

## NOTE 6. Concurrent Debt and Equity Offerings

On August 14, 2012, we completed concurrent registered underwritten public offerings in which we sold \$287.5 million aggregate principal amount of the 2019 Notes and 34.5 million shares of common stock at a price of \$4.25 per share, generating aggregate net proceeds of \$416.1 million.

The convertible debt offering resulted in net proceeds of \$277.7 million after deducting the underwriting discount and offering expenses of \$9.3 million and \$0.5 million, respectively. The equity offering resulted in net proceeds of \$138.4 million after deducting the underwriting discount of \$7.7 million and other expenses of \$0.5 million.

The 2019 Notes were issued pursuant to an indenture, as supplemented by a supplemental indenture with Wells Fargo Bank, National Association, as trustee (the "Trustee"), and mature on August 15, 2019, unless earlier converted, redeemed or repurchased. The 2019 Notes bear interest at the rate of 4.25% per annum, payable semi-annually in arrears on February 15 and August 15 of each year, beginning February 15, 2013. Subject to certain terms and conditions, at any time on or after August 15, 2016, we may redeem for cash all or a portion of the 2019 Notes. The redemption price will equal 100% of the principal amount of the 2019 Notes to be redeemed, plus accrued and unpaid interest, if any, to, but excluding, the redemption date.

Upon the occurrence of certain circumstances, holders may convert their 2019 Notes prior to the close of business on the business day immediately preceding May 15, 2019. On or after May 15, 2019, until the close of business on the second trading day immediately preceding August 15, 2019, holders may surrender their 2019 Notes for conversion at any time. Upon conversion, we will pay or deliver, as the case may be, cash, shares of our common stock or a

combination of cash and shares

16

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Table of Contents

of our common stock, at our election. The initial conversion rate of 188.2353 shares of common stock per \$1,000 principal amount of 2019 Notes is equivalent to a conversion price of approximately \$5.31 per share of common stock. The conversion rate is subject to adjustment upon the occurrence of certain events.

In connection with the convertible debt offering, \$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. The amount held in the escrow account is classified on our Condensed Consolidated Balance Sheets as Short-term restricted cash and investments and Restricted cash and investments of \$12.2 million and \$24.3 million, respectively, as of September 30, 2012. We have pledged our interest in the escrow account to the Trustee as security for our obligations under the 2019 Notes.

The 2019 Notes are accounted for in accordance with ASC Subtopic 470-20, Debt with Conversion and Other Options. Under ASC Subtopic 470-20, issuers of certain convertible debt instruments that have a net settlement feature and may be settled in cash upon conversion, including partial cash settlement, are required to separately account for the liability (debt) and equity (conversion option) components of the instrument. The carrying amount of the liability component of any outstanding debt instrument is computed by estimating the fair value of a similar liability without the conversion option. The amount of the equity component is then calculated by deducting the fair value of the liability component from the principal amount of the convertible debt instrument. The effective interest rate used in determining the liability component of the 2019 Notes was approximately 10%. This resulted in initial recognition of \$149.2 million as the liability component and the residual \$138.3 million as the debt discount with a corresponding increase to paid-in capital, the equity component, for the 2019 Notes. The underwriting discount of \$9.3 million and offering expenses of \$0.5 million were allocated between debt issuance costs and equity issuance costs in proportion to the allocation of the proceeds. Debt issuance costs of \$5.1 million are included in Other long term assets on our Condensed Consolidated Balance Sheets as of September 30, 2012. Equity issuance costs of \$4.7 million related to the convertible debt offering were recorded as an offset to additional paid-in capital.

The following is a summary of the liability component of the 2019 Notes as of September 30, 2012 (in thousands):

	September 30, 2012
Net carrying amount of the liability component	\$ 151,024
Unamortized discount of the liability component	\$ 136,476
Face Value of the 2019 Notes	\$ 287,500

The debt discount and debt issuance costs are amortized as interest expense through August 2019. For the three and nine months ended September 30, 2012, total interest expense related to the 2019 Notes was \$3.2 million, relating to the 4.25% 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 for the three and nine months ended September 30, 2012 was \$1.8 million.

#### NOTE 7. Deerfield Financing

On June 2, 2010, we entered into a note purchase agreement with 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 (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 which is included in Other long term assets on our Condensed Consolidated Balance Sheets and will be amortized through June 2015, the remaining life of the Deerfield Notes. The outstanding principal amount of the Deerfield Notes bears interest in the annual amount of \$6.0 million, payable quarterly in arrears. We will be required to make mandatory prepayments on the notes on an annual basis in 2013, 2014 and 2015 equal to 15% of certain revenues from our collaborative arrangements received during the prior fiscal year, subject to a maximum annual prepayment amount of \$27.5 million and, for payments due in January 2013 and 2014, a minimum prepayment amount of \$10.0 million. 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. Pursuant to the amendment of the note purchase

Table of Contents

agreement, any optional prepayment of the Deerfield Notes made on or prior to July 2, 2013 will be determined as if such prepayment occurred as of July 3, 2013. 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 first \$10.0 million of mandatory prepayments required in 2013 and 2014 and any optional prepayments made prior to July 3, 2013) 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 \$400.0 million or a sale or transfer of more than 50% of our assets, Deerfield may require us to prepay the Deerfield Notes at the optional prepayment price, plus accrued and unpaid interest and any other accrued and reimbursable expenses (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. In connection with the amendment of the note purchase agreement, the security agreement was also amended to exclude any escrowed proceeds from the issuance of 2019 Notes from the collateral pledged to Deerfield. 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. The balance of unamortized closing fee and expenses of \$1.1 million is included in Other long term assets on our Condensed Consolidated Balance Sheets. The carrying value of the loan as of September 30, 2012 is \$98.2 million.

**NOTE 8: Income Taxes**

We recorded an income tax provision of \$0.01 million and \$0.03 million for the three and nine months ended September 30, 2012, respectively, for tax-related interest associated with the audit by the Internal Revenue Service of our 2008, 2009 and 2010 tax years.

During the three months ended September 30, 2012, we recognized a deferred tax liability of \$54.4 million related to the 2019 Notes (see Note 6 of the Notes to our Consolidated Financial Statements for further discussion regarding the 2019 Notes). Under ASC 470-20 we are required to bifurcate our convertible debt instrument into two separate components: a liability component and an equity component, resulting in a basis difference between financial reporting and tax amounts associated with the liability component. This difference creates a temporary difference for purposes of applying ASC 740, Income Taxes. The deferred tax liability was primarily offset by a reduction in our tax valuation allowance. The resulting allocation of valuation allowance required a deferred tax liability of \$0.4 million included in Other long-term liabilities and a deferred tax asset of \$0.4 million in Prepaid expenses and other current assets in our Condensed Consolidated Balance Sheets as of September 30, 2012.

Table of Contents

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis contains forward-looking statements. These statements are based on our 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," "plan," "focus," "goal," "objective," "will," "may," "could," "would," "estimate," "predict," "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, 2011, filed with the Securities and Exchange Commission, or SEC, on February 22, 2012. 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 efforts exclusively on cabozantinib, formerly known as XL184, our most advanced product candidate, in order to maximize the therapeutic and commercial potential of this compound. We believe cabozantinib has the potential to be a high-quality, broadly-active, differentiated pharmaceutical product that can make a meaningful difference in the lives of patients.

We have also established a portfolio of other novel compounds that we believe have the potential to address serious unmet medical needs, many of which are being advanced by partners as part of collaborations. As disclosed on [clinicaltrials.gov](http://clinicaltrials.gov) (NCT01689519), a phase 3 clinical trial for one of these compounds, GDC-0973 (XL518), which we out-licensed to Genentech, Inc. (a wholly-owned member of the Roche Group), was recruiting participants as of November 1, 2012.

Cabozantinib

Cabozantinib inhibits MET, VEGFR2 and RET, proteins that are key drivers of tumor growth, vascularization, and/or metastasis. Cabozantinib has shown novel and differentiated activity in multiple cancer indications. The current clinical program for cabozantinib is focused on the treatment of metastatic castration-resistant prostate cancer, or CRPC, and progressive, unresectable, locally advanced, or metastatic medullary thyroid cancer, or MTC, but also includes the evaluation of other tumor types.

Exelixis has implemented a strategy to investigate cabozantinib in a comprehensive development program for CRPC to potentially generate a product that could effectively compete in the CRPC marketplace. Two phase 3 pivotal trials, COMET-1 (CabOzantinib MET Inhibition CRPC Efficacy Trial-1, formerly known as XL184-307) and COMET-2 (formerly known as XL184-306), were designed to provide an opportunity to commercially differentiate cabozantinib as an oncology agent with a potentially beneficial impact on overall survival, pain palliation and narcotic usage. 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. We currently believe that the top-line results from the COMET-1 and COMET-2 trials will be available in 2014.

In May 2012, we completed the submission of our rolling new drug application, or NDA, with the United States Food and Drug Administration, or FDA, for cabozantinib as a treatment for MTC. On July 30, 2012, we announced that the FDA accepted our NDA for filing and granted a Priority Review designation with a stated action date of November 29, 2012. The NDA submission was based on the data from our phase 3 clinical trial of cabozantinib as a potential treatment for medullary thyroid cancer, known as the EXAM trial (Efficacy of XL184 (Cabozantinib) in Advanced Medullary Thyroid Cancer), with progression-free survival, or PFS, as the trial's primary endpoint. The EXAM trial has been conducted under a special protocol assessment, or SPA, with the FDA, which allows for full approval on the

basis of PFS if the data are supportive. We announced in October 2011 that the primary endpoint of the EXAM trial had been met. Data from the EXAM trial were reported at the American Society of Clinical Oncology Annual Meeting, or ASCO, in June 2012. Assuming approval of our NDA by the FDA, we currently anticipate a potential U.S. commercial launch of cabozantinib for the treatment of MTC in late 2012 or early 2013. We recently submitted our marketing authorization application, or MAA, to the European Medicines Agency, or EMA, and the MAA is currently subject to the EMA's validation process.



## Table of Contents

We expect to expand the cabozantinib development program to other solid tumor indications, based on encouraging interim data that have emerged from our randomized discontinuation trial, or RDT, as well as other clinical trials. Objective tumor responses have been observed in patients treated with cabozantinib in 12 of 13 individual tumor types investigated to date, reflecting the broad potential clinical activity and commercial opportunity of this product candidate. Interim data suggest that cabozantinib has shown novel activity against bone and soft tissue lesions in patients with CRPC. In addition, interim data demonstrated that CRPC patients with bone metastases and bone pain at baseline experienced alleviation of pain, were able to reduce or discontinue narcotic medication and experienced a reduction in circulating tumor cell count. We have also observed resolution of metastatic bone lesions on bone scan in patients with metastatic breast cancer, renal cell carcinoma, thyroid cancer and melanoma.

Lower starting doses of cabozantinib are being evaluated in a cohort of CRPC patients in a non-randomized expansion cohort, or NRE, of the RDT treated at a daily dose of 40 mg, and in a dose-ranging study in CRPC patients conducted through an investigator-sponsored trial, or IST. Interim data from the NRE reported at the European Society for Medical Oncology, or ESMO, 2012 Annual Meeting in September 2012 suggest that the 40 mg daily dose has similar clinical activity to the 100 mg daily dose used in the RDT for key parameters, including reduction of metastatic bone and soft tissue disease, and reduction of bone pain and narcotic use, with apparent improvement in tolerability compared to the 100 mg dose cohort. Interim data from the 40 mg cohort of the dose-ranging IST reported at ASCO in June 2012 had also demonstrated clinical activity.

We believe that cabozantinib's clinical profile is compelling and will allow commercial differentiation, assuming regulatory approval. Accordingly, it is a priority for us to generate additional data from the RDT as well as other ongoing exploratory clinical trials for cabozantinib in a broad range of tumor types, including ovarian cancer, melanoma, breast cancer, non-small cell lung cancer, hepatocellular cancer, renal cell carcinoma, and differentiated thyroid cancer, to support further prioritization of our clinical and commercial options. We currently are evaluating the initiation of phase 3 pivotal trials of cabozantinib in hepatocellular cancer, renal cell carcinoma and potentially other indications. We believe the initiation of such pivotal trials potentially will increase the value of the cabozantinib franchise and spread the development and commercialization risk for cabozantinib across multiple opportunities. We have launched two initiatives to expand the cabozantinib development program beyond our internal development efforts: our Cooperative Research and Development Agreement, or CRADA, with the National Cancer Institute's Cancer Therapy Evaluation Program, or NCI-CTEP, and our IST program.

We entered into our CRADA with NCI-CTEP in November 2011. The proposed clinical trials approved to date under the CRADA include the following:

Phase 2 clinical trials in disease settings where there is substantial unmet medical need and in which cabozantinib has previously demonstrated clinical activity, consisting of randomized phase 2 clinical trials in first line renal cell carcinoma, platinum-resistant or refractory ovarian cancer, ocular melanoma, second line non-small cell lung cancer, and second line/third line non-small cell lung cancer. We believe that data from these phase 2 clinical trials will help prioritize future phase 3 pivotal trials of cabozantinib.

Additional phase 2 clinical trials to explore cabozantinib's potential utility in other tumor types, consisting of trials in endometrial cancer, bladder cancer, sarcoma and second line differentiated thyroid cancer. Positive results in these indications could lead to further study in randomized phase 2 or phase 3 clinical trials.

Additional phase 1 clinical trials, consisting of a trial evaluating cabozantinib in combination with docetaxel in CRPC patients, a trial exploring the utility of combining cabozantinib with vemurafenib, a BRAF inhibitor, in patients with BRAF-mutated melanoma, and a trial to evaluate the safety and pharmacokinetics of cabozantinib in pediatric patients. Commencement of each of the proposed trials approved under the CRADA is subject to protocol development and satisfaction of certain other conditions. The proposed trials approved under the CRADA will be conducted under an investigational new drug application held by NCI-CTEP. We believe our CRADA reflects a major commitment by NCI-CTEP to support the broad exploration of cabozantinib's potential in a wide variety of cancers that have substantial unmet medical needs. Since NCI-CTEP provides funding for as many as 20 active clinical trials each year for a five year period, we believe the agreement will enable us to broadly expand the cabozantinib development program in a cost-efficient manner.

We launched the IST program in October 2010, and it has already provided important interim data through the dose-ranging study in CRPC patients described above. These data were important for dose selection in the COMET pivotal trial program, and we believe they will guide dose selection for a potential future trial to evaluate the ability of cabozantinib to prevent bone metastases in men with prostate cancer. Cabozantinib currently is being evaluated in a variety of other ISTs and we expect to continue to consider additional IST proposals for the foreseeable future.

Table of Contents

## 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, generally have no further unfunded cost obligations related to such compounds or programs and may be entitled to receive research funding, milestones and royalties or a share of profits from commercialization. As disclosed on [clinicaltrials.gov](http://clinicaltrials.gov) (NCT01689519), a phase 3 clinical trial for one of these compounds, GDC-0973 (XL518), which we out-licensed to Genentech, was recruiting participants as of November 1, 2012. In addition, several other out-licensed compounds are in multiple phase 2 studies. These partnered compounds potentially could 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 \$3.1 billion in the aggregate on a non-risk adjusted basis, of which 9% are related to clinical development milestones, 45% are related to regulatory milestones and 46% are related to commercial milestones.

## GDC-0973 (XL518) Collaboration with Genentech

Preliminary results from BRIM7, an ongoing phase 1b trial dose escalation study conducted by Roche and Genentech, our collaboration partner, of the BRAF inhibitor (BRAFi) vemurafenib in combination with the MEK inhibitor GDC-0973 (XL518) in patients with locally advanced/unresectable or metastatic melanoma carrying a BRAFV600 mutation were presented at the 2012 ESMO Annual Meeting. As disclosed on [clinicaltrials.gov](http://clinicaltrials.gov) (NCT01689519), a multicenter, randomized, double-blind, placebo-controlled phase 3 clinical trial evaluating the combination of vemurafenib with GDC-0973 (XL518) versus vemurafenib in previously untreated BRAFV600 mutation positive patients with unresectable locally advanced or metastatic melanoma was recruiting participants as of November 1, 2012.

GDC-0973 (XL518) is a potent, highly selective inhibitor of MEK, a serine/threonine kinase that is a component of the RAS/RAF/MEK/ERK pathway. This pathway mediates signaling downstream of growth factor receptors, and is prominently activated in a wide variety of human tumors. In preclinical studies, oral dosing of GDC-0973 (XL518) resulted in potent and sustained inhibition of MEK in RAS- or BRAF-mutant tumor models. Exelixis discovered GDC-0973 (XL518) internally and advanced the compound to investigational new drug, or IND, status. In late 2006, we entered into a worldwide co-development agreement with Genentech, under which Exelixis received initial upfront and milestone payments for signing the agreement and submitting the IND. We were responsible for development of GDC-0973 (XL518) through the end of phase 1, at which point Genentech exercised its option to further develop the compound.

Under the terms of our agreement with Genentech, we are entitled to an initial equal share of U.S. profits and losses for GDC-0973 (XL518), which will decrease as sales increase, and will share equally in the U.S. marketing and commercialization costs. The profit share has multiple tiers--we are entitled to 50% of profits from the first \$200 million of U.S. actual sales, decreasing to 30% of profits from U.S. actual sales in excess of \$400 million. We are entitled to low double-digit royalties on ex-U.S. net sales. We also have the option to co-promote in the United States. The co-promotion option would allow us to provide up to 25% of the total sales force for GDC-0973 (XL518) in the United States. We must exercise the co-promotion option within 12 months of receiving notification of first patient dosed in first phase 3 clinical trial of GDC-0973 (XL518). As a condition to exercise the co-promotion option, we must have the capability to co-promote, including an adequate internal sales and promotional infrastructure, and an experienced internal oncology sales force.

## 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, often for products that fail during the research and development process. Our long-term prospects depend upon our ability, particularly with respect to cabozantinib, and the ability of our partners to successfully commercialize new therapeutics in highly competitive areas such as cancer treatment. Our

financial performance is driven by many factors, including those described below.

21

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Table of Contents

Clinical Development and Commercialization Efforts for Cabozantinib and Other Product Candidates

We are focusing our proprietary resources and development and commercialization efforts on cabozantinib. However, cabozantinib 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, as well as commercialization expenses in the event cabozantinib receives regulatory approval. In addition to expenses related to cabozantinib, we will be obligated to share U.S. marketing and commercialization expenses related to GDC-0973 (XL518) in order to maintain our U.S. profit share.

With the exception of activities related to cabozantinib and our obligations with respect to GDC-0973 (XL518), we have discontinued efforts with respect to all of our compounds and programs that are not funded by partners pursuant to collaboration agreements. We expect discovery and clinical activities under various collaborations to continue to be funded by partners until we complete our contractual obligations.

Limited Sources of Revenues

We have no pharmaceutical products that have received marketing approval, and we have generated no revenues to date from the sale of such products. We do not expect to generate meaningful revenues from the sale of pharmaceutical products in the near term and expect that all of our other near-term revenues, such as research and development funding, license fees and milestone payments and royalty revenues, will be generated from collaboration agreements with our current and potential future partners. Milestones under these agreements may be tied to factors that are outside of our control, such as significant clinical or regulatory events with respect to compounds or programs that have been out-licensed to our partners.

Liquidity

As of September 30, 2012, we had \$674.7 million in cash and cash equivalents, marketable securities, short- and long-term restricted cash and investments and long-term investments, which included short- and long-term restricted cash and investments of \$40.2 million and \$82.9 million of cash and cash equivalents and marketable securities that we are required to maintain on deposit with Silicon Valley Bank or one of its affiliates pursuant to covenants in our loan and security agreement with Silicon Valley Bank. We anticipate that our current cash and cash equivalents, marketable securities, long-term investments and funding that we expect to receive from existing collaborators will enable us to maintain our operations for a period of at least 12 months following the end of the third quarter of 2012. However, our future capital requirements will be substantial, and we will need to raise additional capital in the future. Our capital requirements will depend on many factors, and we may need to use available capital resources and raise additional capital significantly earlier than we currently anticipate. These factors include:

- the progress and scope of the development and commercialization activities with respect to cabozantinib;
- whether we elect to redeem for cash, all or a portion of the 4.25% convertible senior subordinated notes due 2019, or the 2019 Notes, issued and sold by us on August 14, 2012, prior to their maturity date;
- whether we elect to pay cash or to issue shares of our common stock in respect of any conversion of the 2019 Notes;
- whether we elect to pay cash or to issue shares of our common stock in respect of any conversion of our principal, prepayments or payments of interest in connection with the secured convertible notes we issued to entities affiliated with Deerfield Management Company, L.P., or Deerfield, under our note purchase agreement;
- whether we elect to prepay the amounts advanced under our loan from Silicon Valley Bank;
- 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 cabozantinib) that provide additional capital; and
- our obligation to share U.S. marketing and commercialization costs for GDC-0973 (XL518) under our collaboration with Genentech.



## Table of Contents

Our minimum liquidity needs are also affected by financial covenants in our loan and security agreement with Silicon Valley Bank and our note purchase agreement with Deerfield, 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 2019 Notes for net proceeds of \$277.7 million. The 2019 Notes were issued pursuant to an indenture, as supplemented by a supplemental indenture, collectively, the Indenture, with Wells Fargo Bank, National Association, as trustee, or the Trustee, and mature on August 15, 2019, unless earlier converted, redeemed or repurchased. The 2019 Notes bear interest at a rate of 4.25% per annum, payable semi-annually in arrears on February 15 and August 15 of each year, beginning February 15, 2013. Subject to certain terms and conditions, at any time on or after August 15, 2016, we may redeem for cash all or a portion of the 2019 Notes. The redemption price will equal 100% of the principal amount of the 2019 Notes to be redeemed, plus accrued and unpaid interest, if any, to, but excluding, the redemption date.

Upon the occurrence of certain circumstances, holders may convert their 2019 Notes prior to the close of business on the business day immediately preceding May 15, 2019. On or after May 15, 2019, until the close of business on the second trading day immediately preceding August 15, 2019, holders may surrender their 2019 Notes for conversion at any time. Upon conversion, we will pay or deliver, as the case may be, cash, shares of our common stock or a combination of cash and shares of our common stock, at our election. The initial conversion rate of 188.2353 shares of common stock per \$1,000 principal amount of the 2019 Notes is equivalent to a conversion price of approximately \$5.31 per share of common stock. The conversion rate is subject to adjustment upon the occurrence of certain events.

In connection with the issuance and sale 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. 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 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. The outstanding principal amount of the Deerfield Notes bears interest in the annual amount of \$6.0 million, payable quarterly in arrears. We will be required to make mandatory prepayments on the Deerfield Notes on an annual basis in 2013, 2014 and 2015 equal to 15% of certain payments from our collaborative arrangements received during the prior fiscal year, subject to a maximum annual prepayment amount of \$27.5 million and, for payments due in January 2013 and 2014, a minimum prepayment amount of \$10.0 million. 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. Pursuant to the amendment of the note purchase agreement, any optional prepayment of the Deerfield Notes made on or prior to July 2, 2013 will be determined as if such prepayment occurred as of July 3, 2013. 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 first \$10.0 million of mandatory prepayments required in 2013 and 2014 and any optional prepayments made prior to July 3, 2013) 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 Deerfield Notes at the optional prepayment price, plus accrued and unpaid interest and any other accrued and



## Table of Contents

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. In connection with the amendment of the note purchase agreement, the security agreement was also amended to exclude any escrowed proceeds from the issuance of 2019 Notes from the collateral pledged to Deerfield. 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. 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 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 at all times in one or more accounts with Silicon Valley Bank and certain other designated financial institutions as support for our obligations under the loan and security agreement. 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

During 2010, we implemented two restructurings that resulted in an overall reduction in our workforce of 386 employees. 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 additional restructurings in both March 2011 and May 2012, resulting in further reductions to our workforce. The aggregate reduction in headcount from the 2010, 2011, and 2012 restructurings, or collectively, the Restructurings, is 422 employees.

We have recorded aggregate restructuring charges of \$44.6 million in connection with the Restructurings, of which \$21.3 million related to termination benefits and \$23.3 million related to facility charges and the impairment of various assets. For the nine months ended September 30, 2012 and 2011, we recorded restructuring charges of approximately \$1.7 million and \$6.2 million, respectively. The charge for the nine months ended September 30, 2012, was primarily related to termination benefits and facility-related charges in connection with the exit of all or portions of three of our South San Francisco buildings. The total outstanding restructuring liability related to the Restructurings is included in current and long-term portion of restructuring on our Condensed Consolidated Balance Sheet.

We expect to incur additional restructuring charges of approximately \$1.3 million, primarily related to the exit of all or portions of three of our South San Francisco buildings and will be recorded through the end of the building lease terms, the last of which ends in 2017.

The remaining charges that we expect to incur in connection with our restructuring efforts 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, our restructuring efforts.

Critical Accounting Estimates

The preparation of the consolidated financial statements is in conformity with accounting principles generally accepted in

Table of Contents

the United States which require 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 revenue recognition, clinical trial accruals, restructuring liability and stock option valuation. 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 revenue recognition, clinical trial accruals, restructuring liability, stock option valuation and convertible debt valuation reflect the more significant estimates and assumptions used in the preparation of our consolidated financial statements.

Table of Contents

2019 Notes

The 2019 Notes are accounted for in accordance with ASC Subtopic 470-20, Debt with Conversion and Other Options. Under ASC Subtopic 470-20, issuers of certain convertible debt instruments that have a net settlement feature and may be settled in cash upon conversion, including partial cash settlement, are required to separately account for the liability (debt) and equity (conversion option) components of the instrument. The carrying amount of the liability component of any outstanding debt instrument is computed by estimating the fair value of a similar liability without the conversion option. The amount of the equity component is then calculated by deducting the fair value of the liability component from the principal amount of the convertible debt instrument. The effective interest rate used in determining the liability component of the 2019 Notes was approximately 10%. See Note 6 to the Condensed Consolidated Financial Statements for further information regarding the 2019 Notes.

Other than the 2019 Notes, there have been no other significant changes in our critical accounting policies and estimates during the nine months ended September 30, 2012, 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, 2011.

Fiscal Year Convention

Exelixis adopted a 52- or 53-week fiscal year that ends on the Friday closest to December 31<sup>st</sup>. Fiscal year 2011, a 52-week year, ended on December 30, 2011, and fiscal year 2012, a 52-week year, will end on December 28, 2012. For convenience, references in this report as of and for the fiscal quarters ended September 30, 2011 and September 28, 2012, and as of the fiscal year ended December 30, 2011, are indicated as ended September 30, 2011 and 2012, and as ended December 31, 2011, respectively.

Table of Contents

## Results of Operations

## Revenues

Total revenues by category, as compared to the prior year periods, were as follows (dollar amounts are presented in millions):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2012	2011	2012	2011
Contract				
Research and development funding	\$—	\$0.6	\$—	\$14.0
Milestones	9.3	4.5	16.9	11.7
License (1)	4.0	122.7	22.7	168.0
Collaboration reimbursement	—	0.5	—	2.6
Total revenues	\$13.3	\$128.3	\$39.6	\$196.3
Dollar change	\$(115.0	)	\$(156.7	)
Percentage change	(89.6	)%	(79.8	)%

(1) Includes amortization of up-front payments.

Total revenues by customer, as compared to the prior year periods, were as follows (dollar amounts are presented in millions):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2012	2011	2012	2011
Sanofi	\$—	\$9.3	\$—	\$40.3
Bristol-Myers Squibb	7.8	119.0	23.4	153.3
Daiichi Sankyo	5.5	—	5.5	—
Boehringer Ingelheim	—	—	—	0.7
Merck	—	—	10.7	—
Genentech	—	—	—	2.0
Total revenues	\$13.3	\$128.3	\$39.6	\$196.3
Dollar change	\$(115.0	)	\$(156.7	)
Percentage change	(89.6	)%	(79.8	)%

The decrease in revenues for the three and nine months ended September 30, 2012, as compared to the prior year periods, is primarily due to the acceleration of license revenue as a result of the termination of our 2008 agreement with Bristol Myers-Squibb for XL281 in October 2011, the transfer in April 2011 of substantially all development activities pertaining to XL147 and XL765 to Sanofi under our 2009 license agreement for these compounds and the termination in December 2011 of our 2009 collaboration with Sanofi for the discovery of inhibitors of phosphoinositide-3 kinase, or PI3K. This decrease in revenues was partially offset by a milestone payment of \$5.5 million received from Daiichi Sankyo in August 2012 related to our collaboration agreement for XL550. For the nine months ended September 30, 2012, the decrease in revenues was further offset by \$10.7 million in revenue recognized under our agreement with Merck for our PI3K-delta program signed in December 2011.

## Research and Development Expenses

Total research and development expenses, as compared to the prior year periods, were as follows (dollar amounts are presented in millions):



Table of Contents

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2012	2011	2012	2011
Research and development expenses	\$30.7	\$37.5	\$96.4	\$126.1
Dollar change	\$(6.8	)	\$(29.7	)
Percentage change	(18.1	)%	(23.5	)%

The decrease for the three and nine months ended September 30, 2012, as compared to the prior year periods, resulted primarily from the following:

**Clinical Trial Costs** — Clinical trial expenses, which include services performed by third-party contract research organizations and other vendors, decreased by \$4.5 million, or 25%, and \$18.7 million, or 31%, respectively, primarily due to various cabozantinib clinical pharmacology studies that occurred in 2011 in support of our NDA filing for MTC, the gradual wind down of our randomized discontinuation trial for cabozantinib as well as the gradual wind down of EXAM, and the transfer of XL147 and XL765 to Sanofi. These decreases were partially offset by an increase in clinical trial activities for our COMET-1 and COMET-2 trials, as well as an increase in chemistry, manufacturing and control, or CMC, expenses associated with launch preparation and increases for various IST trials, resulting in a net decrease for the three and nine months ended September 30, 2012. We expect our clinical trial expenses to increase in the fourth quarter of 2012 due to continued increases in COMET-1 and COMET-2 clinical trial activities.

**General Corporate Costs** — There was a decrease of \$1.1 million, or 16%, and \$4.5 million, or 21%, respectively, in the allocation of general corporate costs (such as facility costs, property taxes and insurance) to research and development, due to the decrease in research personnel related to the Restructurings, and the resulting decrease in allocated costs.

**Personnel** — Personnel expense, which includes salaries, bonuses, related fringe benefits, recruiting, relocation costs and temporary employees, decreased by \$1.4 million, or 16.4%, and \$4.5 million, or 15.6%, respectively, primarily due to the reduction in headcount related to the Restructurings.

**Stock-Based Compensation** — Stock-based compensation expense decreased by \$0.4 million, or 30%, and \$1.4 million, or 30%, respectively, primarily as a result of our reduction in headcount related to the Restructurings and lower fair value of options granted.

**Lab Supplies** — Expenses related to lab supplies decreased \$0.4 million, or 82%, and \$0.8 million, or 52%, respectively, as a result of the Restructurings.

We do not track total research and development expenses separately for each of our research and development programs. We group 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. 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. Our strategy is to aggressively advance cabozantinib through development toward commercialization, and as a result, we expect nearly all of our future research and development expenses to relate to the clinical development of cabozantinib. Historically, drug discovery was a significant aspect of our business and 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. As a consequence of our focus on cabozantinib, since 2010 we have gradually discontinued all of our drug discovery efforts except for those funded under our ROR collaboration agreement with Bristol-Myers Squibb, and intend to terminate such remaining drug discovery efforts when we complete our obligations under the ROR collaboration agreement. Drug discovery expenses relate primarily to personnel expense, lab supplies and general corporate costs. The other category primarily includes stock-based compensation expense.

We principally consider qualitative factors in making decisions regarding our research and development programs. These factors include enrollment in clinical trials for our drug candidates, the results of and data from clinical trials, the potential indications for our drug candidates, the therapeutic and commercial potential for our drug candidates and

competitive dynamics. We also make our research and development decisions in the context of our overall business strategy, which historically included the pursuit of commercial collaborations with major pharmaceutical and biotechnology companies for the development of our drug candidates.

The expenditures summarized in the following table reflect total research and development expenses by category, including allocations for general and administrative expense (in millions):

28

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Table of Contents

	Three Months Ended		Nine Months Ended		Inception to date (1)
	September 30,		September 30,		
	2012	2011	2012	2011	
Development	\$27.9	\$32.0	\$84.3	\$106.3	\$797.6
Drug discovery	1.8	4.0	8.8	14.3	465.3
Other	1.0	1.5	3.3	5.5	104.1
Total	\$30.7	\$37.5	\$96.4	\$126.1	\$1,367.0

(1) Inception is as of January 1, 2006, the date on which we began tracking research and development expenses by category.

While we do not track total research and development expenses separately for each program, beginning in fiscal 2006, we began tracking third party expenditures directly relating to each program as a way of monitoring external costs. Our third party research and development expenditures relate principally to our clinical trial and related development activities, such as preclinical and clinical studies and contract manufacturing, and represent only a portion of the costs related to each program. Third party expenditures for programs initiated prior to the beginning of fiscal 2006 have not been tracked from project inception, and therefore these expenditures from the actual inception for most of our programs are not available. We do not accumulate on a program-specific basis internal research and development expenses, such as salaries and personnel expenses, facilities overhead expenses and external costs not directly attributable to a specific project. Nevertheless, we believe that third party expenditures by program provide a reasonable estimate of the percentage of our total research and development expenses that are attributable to each such program. Under our current strategy, we are focusing our proprietary resources and development efforts exclusively on the development and commercialization of cabozantinib. As a result, as of September 30, 2012, substantially all of our external third party research and development expenditures were spent on this program. The expenses for the cabozantinib program were primarily included in the development category of our research and development expenses and exclude the impact of any amounts reimbursed by our partners.

We do not have reliable estimates regarding the timing of our clinical trials. We estimate that typical phase 1 clinical trials last approximately one year, phase 2 clinical trials last approximately one to two years and phase 3 clinical trials last approximately two to four years. However, the length of time may vary substantially according to factors relating to the particular clinical trial, such as the type and intended use of the drug candidate, the clinical trial design and the ability to enroll suitable patients. In general, we will incur increased research and development expenses for compounds that advance in clinical development, whereas expenses will end for compounds that do not warrant further clinical development.

Table of Contents

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

**General and Administrative Expenses**

Total general and administrative expenses, as compared to the prior year periods, were as follows (dollar amounts are presented in millions):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2012	2011	2012	2011
General and administrative expenses	\$7.3	\$8.2	\$22.0	\$26.1
Dollar change	\$(0.8	)	\$(4.1	)
Percentage change	(10.1	)%	(15.7	)%

The decrease in general and administrative expenses for the three and nine months ended September 30, 2012, as compared to the prior year periods in 2011, was primarily due to a decrease in facility costs and stock-based compensation related to the Restructurings, as well as lower legal and accounting fees and, solely with respect to the three months ended September 30, 2012, personnel costs. These decreases were partially offset by a reduction in the allocation of general corporate costs to research and development as a result of the reduction in headcount from the Restructurings and, solely with respect to the three months ended September 30, 2012, an increase in costs associated with pre-commercialization activities.

We expect an increase in general and administrative expenses in the fourth quarter of 2012 due to continued increases in preparatory activities in connection with a potential approval of our NDA for cabozantinib as a treatment for MTC.

**Restructuring Charges**

The restructuring charges, as compared to the prior year periods, were as follows (dollar amounts are presented in millions):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2012	2011	2012	2011
Restructuring charges	\$0.7	\$2.9	\$1.7	\$6.2
Dollar change	\$(2.2	)	\$(4.5	)
Percentage change	(75.0	)%	(72.5	)%

We incurred restructuring charges of \$0.7 million and \$1.7 million for the three and nine months ended September 30, 2012, respectively. These charges were largely due to termination benefits related to the 2012 restructuring and facility charges related to the exit of all or portions of three of our South San Francisco buildings. The decrease for the three and nine months ended September 30, 2012, as compared to the same prior year periods, was primarily related to lower termination benefits and facility-related charges in 2012.

The remaining charges that we expect to incur in connection with our restructuring efforts 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, our restructuring efforts.

**Total Other Income (Expense), Net**

Total other income (expense), net as compared to the prior year periods, was as follows (dollar amounts are presented in millions):



Table of Contents

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2012	2011	2012	2011
Total other income (expense), net	\$(7.4 )	\$(1.8 )	\$(15.0 )	\$(8.6 )
Dollar change	\$(5.5 )		\$(6.4 )	
Percentage change	(301.4 )%		(74.7 )%	

Total other income (expense), net consists primarily of interest income earned on our marketable securities, offset by interest expense incurred on our loan with Silicon Valley Bank, our convertible loan with GlaxoSmithKline, which was repaid in October 2011, the Deerfield Notes and the 2019 Notes which include both a cash coupon component and non-cash accretion of interest. The decrease in total other income (expense), net for the three and nine months ended September 30, 2012, as compared to the prior year periods, was primarily due to interest expense related to the 2019 Notes as well as a gain of \$2.2 million recognized in 2011 relating to the September 2011 sale of our remaining 19.9% equity interest in TaconicArtermis GmbH (formerly known as Artemis Pharmaceuticals GmbH), or Artemis, and a one-time gain of \$1.0 million related to the sale of excess materials during the nine months ended September 30, 2011.

## Liquidity and Capital Resources

## Sources and Uses of Cash

The following table summarizes our cash flow activities for the nine months ended September 30, 2012 and 2011 (in thousands):

	Nine Months Ended September 30,	
	2012	2011
Net (loss) income	\$(95,452 )	\$29,401
Adjustments to reconcile net (loss) income to net cash used in operating activities	22,226	22,150
Changes in operating assets and liabilities	(11,184 )	(181,610 )
Net cash used in operating activities	(84,410 )	(130,059 )
Net cash used in investing activities	(159,841 )	(88,838 )
Net cash provided by financing activities	478,799	187,668
Net increase (decrease) in cash and cash equivalents	234,548	(31,229 )
Cash and cash equivalents, at beginning of period	74,257	97,440
Cash and cash equivalents, at end of period	\$308,805	\$66,211

To date, we have financed our operations primarily through the sale of equity, receipts 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, 2012, we had \$674.7 million in cash and cash equivalents, marketable securities, short- and long-term restricted cash and investments and long-term investments, which included short- and long-term restricted cash and investments of \$40.2 million and \$82.9 million of cash and cash equivalents and marketable securities that we are required to maintain on deposit with Silicon Valley Bank or one of its affiliates pursuant to covenants in our loan and security agreement with Silicon Valley Bank.

## Operating Activities

Our operating activities used cash of \$84.4 million for the nine months ended September 30, 2012, compared to cash used of \$130.1 million for the prior year 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 the timing of revenue recognition of an up-front payment under our P13K-delta license agreement with Merck entered into in December 2011 and non-cash revenue recognized related to our 2007 and 2010 collaboration agreements with Bristol-Myers Squibb. In addition, we paid \$3.5 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.

Cash used by operating activities for the 2011 period related primarily to a reduction in our deferred revenue balance of \$175.2 million as a result of the termination of our 2008 agreement with Bristol Myers-Squibb. In addition, there was a decrease in our restructuring liability as we made severance payments relating to our 2010 and 2011 restructuring plans, and a

Table of Contents

reduction in our other accrual balances due to the timing of payments made to vendors. These increases in cash used were partially offset by non-cash charges relating to stock-based compensation, depreciation and amortization, accretion of implied interest under our 2010 note purchase agreement with Deerfield, impairment of assets due to our 2010 and 2011 restructuring plans, and other non-cash changes.

**Investing Activities**

Our investing activities used cash of \$159.8 million for the nine months ended September 30, 2012, compared to cash used of \$88.8 million for the comparable period in 2011. Cash used by investing activities for the 2012 period was primarily due to the purchase of \$359.5 million of marketable securities and a net increase in restricted cash of \$36.0 million, primarily in connection with the 2019 Notes. These uses were partially offset by proceeds from the maturity of marketable securities of \$236.3 million. Cash used by investing activities for the 2011 period was primarily driven by the purchase of \$210.6 million in marketable securities offset by proceeds received from the maturity of marketable securities of \$117.2 million and a decrease in our restricted cash balance of \$2.2 million.

**Financing Activities**

Our financing activities provided cash of \$478.8 million for the nine months ended September 30, 2012, compared to cash provided of \$187.7 million for the comparable period in 2011. Cash provided by our financing activities for the 2012 period was 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.

Cash provided by our financing activities for the 2011 period consisted of net proceeds of \$179.4 million from the issuance of 17.3 million shares of common stock, proceeds from the exercise of stock options of \$11.7 million and \$2.6 million from our Silicon Valley Bank loan agreement. These increases were partially offset by cash used for principal payments on notes payable and bank obligations of \$7.0 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, as discussed under "Cash Requirements".

**Cash Requirements**

We have incurred net losses since inception through the nine months ended September 30, 2012, with the exception of the fiscal year ended 2011. We had net income for the fiscal year 2011, 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 three and nine months ended September 30, 2012, we incurred net losses of \$32.8 million and \$95.5 million, respectively. As of September 30, 2012, we had \$674.7 million in cash and cash equivalents, marketable securities, short- and long-term restricted cash and investments and long-term investments, which included short- and long-term restricted cash and investments of \$40.2 million and \$82.9 million of cash and cash equivalents and marketable securities that we are required to maintain on deposit with Silicon Valley Bank or one of its affiliates pursuant to covenants in our loan and security agreement with Silicon Valley Bank. We anticipate that our current cash and cash equivalents, marketable securities, long-term investments and funding that we expect to receive from existing collaborators will enable us to maintain our operations for a period of at least 12 months following the end of the third quarter of 2012. However, our future capital requirements will be substantial, and we may need to raise additional capital in the future. Our capital requirements will depend on many factors, and we may need to use available capital resources and raise additional capital significantly earlier than we currently anticipate. These factors include:

the progress and scope of the development and commercialization activities with respect to cabozantinib -- We are focusing our proprietary resources and development efforts on cabozantinib, our most advanced product candidate, which is being studied in a variety of tumor types, with the goal of rapidly commercializing the compound.

Cabozantinib is being evaluated in a broad development program encompassing multiple cancer indications. Our development and commercialization plans for cabozantinib are dependent on the extent of our available financial resources. There can be no assurance that we will have sufficient financial resources independently or through other

arrangements to fund the trials that are currently planned or in process, to fund other clinical trials that we may desire to initiate in the future or to fund commercialization efforts. If adequate funds are not available, we may be required to delay, discontinue or elect not to pursue one or more trials or commercialization efforts for cabozantinib;

Table of Contents

repayment of the 2019 Notes -- 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. There can be no assurance that we will have sufficient funds to repay the 2019 Notes when due or satisfy our payment obligations under the Indenture;

repayment of the Deerfield Notes -- The outstanding principal amount of the Deerfield Notes bears interest in the annual amount of \$6.0 million, payable quarterly in arrears. We are required to make certain mandatory prepayments on the Deerfield Notes on an annual basis in 2013, 2014 and 2015 and may also prepay all or a portion (not less than \$5.0 million) of the principal amount of the Deerfield Notes during their term. There can be no assurance that we will have sufficient funds to repay the Deerfield Notes or satisfy our payment obligations under the note purchase agreement when due or that we will comply with the conditions to our ability to convert the principal amount of the Deerfield Notes into or satisfy our payment obligations with shares of our common stock;

repayment of our loan from Silicon Valley Bank -- Our loan and security agreement with Silicon Valley Bank provides for both equipment lines of credit and a seven-year term loan. The principal amount of \$80.0 million outstanding under our 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. 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 also 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 at all times in one or more accounts with Silicon Valley Bank and certain other designated financial institutions as support for our obligations under the loan and security agreement. As a result, the proceeds of the term loan cannot be used to satisfy our other obligations without causing a default under our loan and security agreement with Silicon Valley Bank;

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 cabozantinib) that provide additional capital;

our ability to control costs;

our ability to remain in compliance with, or amend or cause to be waived, financial covenants contained in agreements with third parties;

the amount of our cash and cash equivalents and marketable securities 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 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

33

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Table of Contents

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 agreements with third parties. As described below, the terms of our debt owed to Deerfield and Silicon Valley Bank each contain covenants requiring us to maintain specified cash balances or levels of working capital:

Deerfield - Our note purchase agreement with Deerfield contains an event of default that would be triggered if our "cash and cash equivalents" fall below \$20.0 million as of December 28, 2012, subject to a cure period. Upon such an event of default, Deerfield may declare all or a portion of the Put Price to be immediately due and payable. "Cash and cash equivalents" for purposes of our note purchase agreement includes our total cash, cash equivalents and short-term and long-term marketable securities. As of September 30, 2012, our "cash and cash equivalents" were \$674.7 million.

Silicon Valley Bank - Our loan and security agreement with Silicon Valley Bank 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 cannot raise additional capital in order to remain in compliance with our financial covenants or if we are unable to renegotiate such covenants and the lender exercises its remedies under the agreement, we would not be able to operate under our current operating plan.

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our market risks at September 30, 2012 have not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2011, filed with the Securities and Exchange Commission on February 22, 2012. Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio and our long-term debt. We have estimated the effects on our interest rate sensitive assets and liabilities based on a one percentage point hypothetical adverse change in interest rates as of September 30, 2012 and December 31, 2011. As of September 30, 2012 and December 31, 2011, 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 \$18.4 million and \$7.2 million, respectively.

In addition, we have exposure to fluctuations in certain foreign currencies in countries in which we conduct clinical trials. Most of our foreign expenses incurred are associated with establishing and conducting clinical trials for cabozantinib and various other compounds in our pipeline at sites outside of the United States. Our agreements with the foreign sites that conduct these 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. As of September 30, 2012 and December 31, 2011, approximately \$1.5 million and \$2.8 million, respectively, of our clinical accrual balance related to foreign currencies. As of September 30, 2012 and December 31, 2011, an adverse change of one percentage point in the foreign currency exchange rates would have resulted in a net loss of \$0.02 million and \$0.03 million, respectively.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures. Based on the evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) of the Securities Exchange Act of 1934, as amended, or the Exchange Act) required by

34

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## Table of Contents

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.

## PART II. OTHER INFORMATION

### 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, 2011 filed with the Securities and Exchange Commission on February 22, 2012.

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

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

We will 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, 2012, we had \$674.7 million in cash and cash equivalents, marketable securities, short- and long-term restricted cash and investments and long-term investments, which included short- and long-term restricted cash and investments of \$40.2 million and \$82.9 million of cash and cash equivalents and marketable securities that we are required to maintain on deposit with Silicon Valley Bank or one of its affiliates pursuant to covenants in our loan and security agreement with Silicon Valley Bank. We anticipate that our current cash and cash equivalents, marketable securities, long-term investments and funding that we expect to receive from existing collaborators will enable us to maintain our operations for a period of at least 12 months following the end of the third quarter of 2012. However, our future capital requirements will be substantial, and we will need to raise additional capital in the future. Our capital requirements will depend on many factors, and we may need to use available capital resources and raise additional capital significantly earlier than we currently anticipate. These factors include:

• the progress and scope of the development and commercialization activities with respect to cabozantinib -- We are focusing our proprietary resources and development efforts on cabozantinib, our most advanced product candidate, which is being studied in a variety of tumor types, with the goal of rapidly commercializing the compound.

Cabozantinib is being evaluated in a broad development program encompassing multiple cancer indications. The current clinical program for cabozantinib is focused on the treatment of CRPC and MTC and will be expanded to

other solid tumor indications, based on encouraging interim data that have emerged from the RDT investigating cabozantinib in nine distinct tumor types and other clinical trials. In October 2011, we announced that our EXAM phase 3 clinical trial of cabozantinib in MTC met its primary endpoint and on July 30, 2012, we announced that the

Table of Contents

FDA accepted our NDA, based on data from our EXAM trial, for filing and granted a Priority Review designation with a stated action date of November 29, 2012. Assuming approval of our NDA by the FDA, we currently anticipate a potential commercial launch of cabozantinib for the treatment of MTC in late 2012 or early 2013. As part of our comprehensive development plan for cabozantinib in CRPC, in December 2011, we initiated our first phase 3 pivotal trial of cabozantinib in patients with CRPC using an endpoint of pain reduction (COMET-2) and in May 2012 we initiated a second phase 3 pivotal trial in patients with CRPC with an overall survival endpoint (COMET-1). We are also evaluating the initiation of additional phase 3 pivotal trials. Our development and commercialization plans for cabozantinib are dependent on the extent of our available financial resources. There can be no assurance that we will have sufficient financial resources independently or through other arrangements to fund the trials that are currently planned or in process, to fund other clinical trials that we may desire to initiate in the future or to fund commercialization efforts. If adequate funds are not available, we may be required to delay, discontinue or elect not to pursue one or more trials or commercialization efforts for cabozantinib;

repayment of the 2019 Notes -- On August 14, 2012, we issued and sold \$287.5 million aggregate principal amount of the 2019 Notes for net proceeds of \$277.7 million. The 2019 Notes mature on August 15, 2019, unless earlier converted, redeemed or repurchased and bear interest at a rate of 4.25% per annum, payable semi-annually in arrears on February 15 and August 15 of each year, beginning February 15, 2013. Subject to certain terms and conditions, at any time on or after August 15, 2016, we may redeem for cash all or a portion of the 2019 Notes. The redemption price will equal 100% of the principal amount of the 2019 Notes to be redeemed plus accrued and unpaid interest, if any, to, but excluding, the redemption date. Upon the occurrence of certain circumstances, holders may convert their 2019 Notes prior to the close of business on the business day immediately preceding May 15, 2019. On or after May 15, 2019, until the close of business on the second trading day immediately preceding August 15, 2019, holders may surrender their 2019 Notes for conversion at any time. Upon conversion, we will pay or deliver, as the case may be, cash, shares of our common stock or a combination of cash and shares of our common stock, at our election. The initial conversion rate of 188.2353 shares of common stock per \$1,000 principal amount of the 2019 Notes is equivalent to a conversion price of approximately \$5.31 per share of common stock and is subject to adjustment in connection with certain events. If a "Fundamental Change" (as defined in the Indenture) 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. There can be no assurance that we will have sufficient funds to repay the 2019 Notes when due or satisfy our payment obligations under the Indenture;

repayment of the Deerfield Notes -- On June 2, 2010, we entered into a note purchase agreement with 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, for an aggregate purchase price of \$80.0 million, less closing fees and expenses of \$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. The outstanding principal amount of the Deerfield Notes bears interest in the annual amount of \$6.0 million, payable quarterly in arrears. We will be required to make mandatory prepayments on the Deerfield Notes on an annual basis in 2013, 2014 and 2015 equal to 15% of specified payments from our collaborative arrangements received during the prior fiscal year, subject to a maximum annual prepayment amount of \$27.5 million and, for payments due in January 2013 and 2014, a minimum prepayment amount of \$10.0 million. 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. Pursuant to the amendment of the note purchase agreement, any optional prepayment of the Deerfield Notes made on or prior to July 2, 2013 will be determined as if such prepayment occurred as of July 3, 2013. In lieu of making any optional or mandatory prepayment in cash, subject to specified 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

Table of Contents

(other than the first \$10.0 million of mandatory prepayments required in 2013 and 2014 and any optional prepayments made prior to July 3, 2013) 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 specified 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. In the event the market price for our common stock is depressed or we do not have a sufficient number of authorized but unissued shares, we may not be able to convert the principal amount of the Deerfield Notes or satisfy our payment obligations in full using shares of our common stock due to restrictions in the agreement on the number of shares we may issue. In addition, the issuance of shares of our common stock to convert the Deerfield Notes or satisfy our payment obligations may result in significant dilution to our stockholders. As a result, we may need to obtain additional funding to satisfy our repayment obligations. There can be no assurance that we will have sufficient funds to repay the Deerfield Notes or satisfy our payment obligations under the note purchase agreement when due or that we will comply with the conditions to our ability to convert the principal amount of the Deerfield Notes into or satisfy our payment obligations with shares of our common stock;

repayment of our loan from 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 an amount of \$80.0 million. 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 also 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 at all times in one or more accounts with Silicon Valley Bank and certain other designated financial institutions as support for our obligations under the loan and security agreement. As a result, the proceeds of the term loan cannot be used to satisfy our other obligations without causing a default under our loan and security agreement with Silicon Valley Bank;

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 cabozantinib) that provide additional capital;

our ability to control costs;

our ability to remain in compliance with, or amend or cause to be waived, financial covenants contained in agreements with third parties;

the amount of our cash and cash equivalents and marketable securities 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 GDC-0973 (XL518) under our collaboration with Genentech;



our ability to share the costs of our clinical development efforts with third parties;

37

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Table of Contents

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 agreements with third parties. The terms of our debt owed to Deerfield and Silicon Valley Bank each contain covenants or events of default requiring us to maintain specified cash balances. The failure to comply with these covenants could result in an acceleration of the underlying debt obligations. If we cannot raise additional capital in order 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 nine months ended September 30, 2012, with the exception of the fiscal year ended 2011. We had net income for the fiscal year ended 2011, 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, 2012, we had a net loss of \$95.5 million; as of September 30, 2012, we had an accumulated deficit of \$1.2 billion. We have not yet completed the development, including obtaining regulatory approval, of cabozantinib or any other product candidates and, consequently, have not generated revenues from the sale of pharmaceutical products. We have derived substantially all of our revenues to date from collaborative research and development agreements. Revenues from research and development collaborations depend upon continuation of the collaborations, 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 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 through 2010 and for the nine months ended September 30, 2012, and we expect to spend significant additional amounts to fund the 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.

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, 2012, our total consolidated indebtedness through maturity was \$497.5 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;

Table of Contents

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 following a Fundamental Change or 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. These agreements may also make our repurchase of 2019 Notes an event of default under the 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, during 2010, we implemented two restructurings that resulted in an overall reduction in our workforce by 386 employees. 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 additional restructurings in both March 2011 and May 2012, resulting in further reductions to our workforce. The aggregate reduction in headcount from the Restructurings is 422 employees. We have recorded aggregate restructuring charges of \$44.6 million in connection with the Restructurings and anticipate that we will incur additional restructuring charges related to the exit of all or portions of three 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.

As part of the Restructurings, in 2011 we entered into two sublease agreements for portions of one of our buildings in South San Francisco, California. 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,

Table of Contents

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, 2012, 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 Development of Cabozantinib**

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

The success of our business is dependent upon the successful development and commercialization of cabozantinib. As part of our strategy, we intend to dedicate all of our proprietary resources to advance cabozantinib as aggressively as feasible. Our ability to realize the value of our investment is contingent on, among other things, successful clinical development, regulatory approval and market acceptance of cabozantinib. If we encounter difficulties in the development of cabozantinib due to any of the factors discussed in this “Risk Factors” section or otherwise, or we do not receive regulatory approval and are unable to commercialize cabozantinib, we will not have the resources necessary to continue our business in its current form.

Clinical testing of cabozantinib and other product candidates is a lengthy, costly, complex and uncertain process and may fail to demonstrate safety and efficacy.

Clinical trials are inherently risky and may reveal that our product candidates are ineffective or have unacceptable toxicity or other side effects that may significantly decrease the likelihood of regulatory approval.

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, 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
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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.

## Table of Contents

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 from cabozantinib 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, including those identified based on our discussions with the FDA. 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. For example, as discussed in “—Risks Related to Regulatory Approval of Cabozantinib-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 this product candidate,” we were not able to reach a timely agreement with the FDA under a Special Protocol Assessment, or SPA, on the proposed design and analyses of the COMET-2 trial.

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 as a product candidate. 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 that ultimately participate in the clinical trial;
- the duration of patient follow-up that is appropriate in view of the results;
- 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 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.

We do not have the ability to independently conduct clinical trials for cabozantinib, and we rely on third parties we do not control such as 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 successfully commercialize cabozantinib. We lack the capability to manufacture compounds for clinical trials and rely on third parties to manufacture cabozantinib, and we may be unable to obtain required material in a timely manner, at an acceptable cost or at a quality level required to receive regulatory approval.

We do not have the manufacturing capabilities or experience necessary to enable us to produce materials for our clinical trials. We rely on collaborators and third-party contractors to produce cabozantinib for clinical testing. These suppliers 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-party manufacturers may adversely affect our future profit margins and our ability to develop and commercialize cabozantinib on a timely and competitive basis. These manufacturers 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 timelines and applicable regulatory requirements. We may not be able to maintain or renew our existing third-party manufacturing arrangements, or enter into new arrangements, on acceptable terms, or at all. Our third-party manufacturers could terminate or decline to renew our manufacturing 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 may be delayed. Delays in preclinical or clinical testing could delay the initiation of clinical



trials.

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 supply arrangements, we may not be able to obtain approval from the FDA of any alternate supplier in a timely manner, or at

41

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Table of Contents

all, which could delay or prevent the clinical development and commercialization of cabozantinib. Failure of our third-party manufacturers or us to obtain approval from the FDA or to comply with applicable regulations could result in sanctions being imposed on us, including fines, civil penalties, delays in or failure to grant marketing approval of cabozantinib, injunctions, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products and compounds, operating restrictions and criminal prosecutions, any of which could have a significant adverse affect on our business.

Materials necessary to manufacture cabozantinib may not be available on commercially reasonable terms, or at all, which may delay its development and commercialization.

Some of the materials necessary for the manufacture of cabozantinib may, from time to time, be available either in limited quantities, or from a limited number of manufacturers, or both. Our contract manufacturers need to obtain these materials for our clinical trials and, potentially, for commercial distribution when and if we obtain marketing approval for cabozantinib. Suppliers may not sell us these materials at the time we need them or on commercially reasonable terms. If we are unable to obtain the materials needed to conduct our clinical trials, product testing and potential regulatory approval could be delayed, adversely affecting our ability to develop cabozantinib. Similarly, if we are unable to obtain critical manufacturing materials after regulatory approval has been obtained, the commercial launch of cabozantinib could be delayed or there could be a shortage in supply, which could materially affect our ability to generate revenues from sales of cabozantinib. If suppliers increase the price of manufacturing materials, the price for cabozantinib may increase, which may make it less competitive in the marketplace. If it becomes necessary to change suppliers for any of these materials or if any of our suppliers experience a shutdown or disruption at the facilities used to produce these materials, due to technical, regulatory or other reasons, it could harm the manufacture of cabozantinib.

**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, Inc. (a wholly- owned member of the Roche Group), GlaxoSmithKline, Merck (known as MSD outside of the United States and Canada) and Daiichi Sankyo Company Limited, or Daiichi Sankyo, for the development and ultimate commercialization of a significant number of compounds generated from our research and development efforts. We continue to 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 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 will devote to the development or commercialization of drug candidates or to their marketing and distribution;
- we may not be able to control the amount and timing of resources that our potential future collaborators may 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;
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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

## Table of Contents

of exclusivity;

future collaborators may require us to relinquish some important rights, such as marketing and distribution rights; and 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 upon continuation of the collaborations, 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 Regulatory Approval of Cabozantinib

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 this product candidate.\*

Cabozantinib, as well as the activities associated with the research, development and commercialization of the product candidate, 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 commercializing this product candidate. We have not received regulatory approval to market cabozantinib in any jurisdiction and have only limited experience in preparing and filing the applications necessary to gain regulatory approvals. The process of obtaining regulatory approvals 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. Before an NDA can be submitted to the FDA, the product candidate must undergo extensive clinical trials, which can take many years and require substantial expenditures.

Our EXAM phase 3 trial of cabozantinib as a potential treatment for MTC has been conducted under a SPA with the FDA. A SPA is designed to facilitate the FDA's review and provide feedback on the proposed design and size of clinical trials that are intended to form the primary basis for determining a product candidate's efficacy. If agreement is reached with the FDA, a SPA agreement documents the terms and conditions under which the design of the subject trial will be adequate for

43

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Table of Contents

submission of the efficacy and human safety portion of an NDA. However, there are circumstances under which we may not receive the benefits of a SPA, notably if the FDA subsequently identifies a substantial scientific issue essential to determining the product candidate's safety or efficacy, and we may be required to conduct significant additional development in order to obtain regulatory approval notwithstanding the SPA. We completed the submission of our rolling NDA in May 2012 based on the data from our EXAM trial. On July 30, 2012, we announced that the FDA accepted our NDA for filing and granted a Priority Review designation with a stated action date of November 29, 2012. However, our NDA may be subject to delay or lack of approval.

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 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 a new drug application, 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. For example, the FDA could determine that the design of a clinical trial is inadequate to produce reliable results. The regulatory process also requires preclinical testing, and data obtained from preclinical and clinical activities are susceptible to varying interpretations. The FDA has substantial discretion in the approval process and may refuse to approve any NDA (regardless of prior receipt of a SPA) or decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. For example, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of cabozantinib.

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

Even if the FDA or a comparable authority in another country 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. These agencies also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval.

We are subject to certain healthcare laws, regulation and enforcement, and will become subject to additional such laws, regulations and enforcement should cabozantinib receive marketing approval; our failure to comply with those laws could have a material adverse effect on our results of operations and financial condition.\*

We are also subject to several healthcare regulation 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:

## Table of Contents

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; 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;

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; and

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.

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, 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 operate our business and our financial results. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws.

### Risks Related to Commercialization of Cabozantinib

The commercial success of cabozantinib will depend upon the degree of market acceptance of the product candidate among physicians, patients, health care payors, and the medical community.\*

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

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

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell cabozantinib, we may be unable to generate product revenues.

We have no experience as a company in the sales and distribution of pharmaceutical products and do not have a sales organization. Developing a sales force could be expensive and time-consuming, could delay any product launch, including our potential launch of cabozantinib for the treatment of MTC, and we may never be able to develop this capacity. To the extent that we enter into arrangements with third parties to provide sales, marketing and distribution services, our product revenues may be lower than if we market and sell cabozantinib ourselves. If we are unable to



establish adequate sales, marketing and distribution capabilities, independently or with others, we may not be able to generate product revenues.

45

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Table of Contents

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

Our ability to commercialize cabozantinib will be highly dependent on the extent to which coverage and reimbursement for the product candidate 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 themselves for cabozantinib and will rely on third-party payors to pay for, or subsidize, their medical needs. If third-party payors do not provide coverage or reimbursement for cabozantinib, our revenues and prospects for profitability will suffer. In addition, even if third-party payors provide some coverage or reimbursement for cabozantinib, the availability of such coverage or reimbursement for prescription drugs under private health insurance and managed care plans often varies based on the type of contract or plan purchased.

Another factor that may affect the pricing of drugs is proposed congressional action regarding drug reimportation into the United States. For example, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 gives discretion to the Secretary of Health and Human Services to allow drug reimportation into the United States under some circumstances from foreign countries, including countries where the drugs are sold at a lower price than in the United States. Proponents of drug reimportation may attempt to pass legislation, which would allow direct reimportation under certain circumstances. If legislation or regulations were passed allowing the reimportation of drugs, it could decrease the price we receive for cabozantinib, thereby negatively affecting our revenues and prospects for profitability.

In addition, in some foreign countries, particularly the countries in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, price negotiations with governmental authorities can take six to twelve months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement and/or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of cabozantinib to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in the commercialization of cabozantinib. Third-party payors are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly approved health care products. In particular, third-party payors may limit the indications for which they will reimburse patients who use cabozantinib. Cost-control initiatives could decrease the price we might establish for cabozantinib, which would result in lower product revenues to us.

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

The U.S. 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 our products profitably. Among policy makers and payors in the U.S. 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 U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, PPACA, became law in the U.S. PPACA substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. The United States Supreme Court heard a constitutional challenge to the PPACA and in June 2012 held that the PPACA is constitutional. However, states are allowed to opt out of the expansion of eligibility criteria for Medicaid under the PPACA. 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 any approved product, and could seriously harm our business. 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 cabozantinib will successfully be placed on the list of drugs covered by particular health plan formularies, nor can we predict the negotiated price for cabozantinib, which will be determined by market factors. Many states have also created preferred drug lists and include drugs on those lists only when the manufacturers agree to pay a supplemental rebate. If cabozantinib 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 cabozantinib.

As a result of the PPACA and the 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

## Table of Contents

how much third-party payors will reimburse for newly-approved drugs, which in turn will put pressure on the pricing of drugs. Further, we do not have experience in ensuring approval by applicable third-party payors outside of the United States for coverage and reimbursement of cabozantinib. We also anticipate pricing pressures in connection with the sale of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative 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 could allow our competitors to bring products to market before us, which would impair our ability to commercialize cabozantinib. Our future success will depend upon our ability to maintain a competitive position with respect to technological advances. Any products that are developed through our technologies will compete in highly competitive markets. 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 marketing 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, if cabozantinib is commercialized, it may compete with existing therapies that have long histories of use, such as chemotherapy and radiation treatments in cancer indications. Examples of potential competition for cabozantinib include AstraZeneca's RET, VEGFR and EGFR inhibitor vandetanib, Algeta's development-stage alpha-pharmaceutical Alpharadin (Radium-223), other VEGF pathway inhibitors, including Genentech's bevacizumab, and other MET inhibitors, including Pfizer's crizotinib, ArQule's tivantinib (ARQ197), GlaxoSmithKline's foretinib (XL880), and Genentech's onartuzumab.

We may not be able to manufacture cabozantinib in commercial quantities, which would prevent us from commercializing the product candidate.

To date, cabozantinib has been manufactured in small quantities for preclinical and clinical trials. If cabozantinib is approved by the FDA or other regulatory agencies for commercial sale, we will need to manufacture it in larger quantities. We may not be able to successfully increase the manufacturing capacity, whether in collaboration with third-party manufacturers or on our own, for cabozantinib in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If we are unable to successfully increase the manufacturing capacity for cabozantinib, the regulatory approval or commercial launch of the product candidate may be delayed or there may be a shortage in supply. Cabozantinib requires precise, high-quality manufacturing. The failure to achieve and maintain these high manufacturing standards, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously hurt our business.

### 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.

## Table of Contents

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, the patent owner has failed to “work” the invention in that country or the third party has patented improvements). In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. Compulsory licensing of life-saving drugs is also becoming increasingly popular in developing countries either through direct legislation or international initiatives. Such compulsory licenses could be extended to include 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, 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

## Table of Contents

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 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 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 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. 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 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

Table of Contents

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. If we obtain marketing approval for cabozantinib, we intend to expand our insurance coverage to include the sale of commercial products, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. 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 research and development activities;
- recognition of up-front licensing or other fees or revenues;
- payments of non-refundable up-front 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 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 restructurings; and
- general and industry-specific economic conditions that may affect our collaborators' research and development expenditures.

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

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

Our stock price may be extremely volatile.\*

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

- adverse results or delays in our or our collaborators' clinical trials;
- announcement of FDA approval or non-approval, or delays in the FDA review process, of cabozantinib or our collaborators' product candidates or those of our competitors or actions taken by regulatory agencies with respect to our, our collaborators' or our competitors' clinical trials;
- the timing of achievement of our clinical, regulatory, partnering and other milestones, such as the commencement



Table of Contents

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.

Concurrent or future sales of our common stock and our issuance of convertible notes, which may result in future issuances of our common stock, or the perception that such sales 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 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 \$138.3 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



Table of Contents

convertible, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the 2019 Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital. Finally, we 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**

The table below provides information on our repurchases of our common stock, all of which were to satisfy tax obligations upon the vesting of restricted stock units under our 2000 Equity Incentive Plan, 2010 Inducement Award Plan and 2011 Equity Incentive Plan. We expect to make similar repurchases in the future to satisfy employee tax obligations upon the vesting of restricted stock units.

**ISSUER PURCHASES OF EQUITY SECURITIES**

Table of Contents

Period	(a) Total Number of Shares (or Units) Purchased	(b) Average Price Paid per Share (or Unit)	(c) Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
Month #1 (June 30, 2012 – July 27, 2012)	—	—	—	—
Month #2 (July 28, 2012 – August 24, 2012)	29,845	\$4.44	—	—
Month #3 (August 25, 2012 – September 28, 2012)	—	—	—	—
Total	29,845	\$4.44	—	—

## ITEM 6. EXHIBITS

## (a) Exhibits

The exhibits listed on the accompanying exhibit index are filed or incorporated by reference (as stated therein) as part of this Quarterly Report on Form 10-Q.

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: November 7, 2012

EXELIXIS, INC.

/s/ Frank Karbe

Frank Karbe

Executive Vice President and Chief Financial Officer

(Duly Authorized Officer and Principal Financial and Accounting Officer)



Table of Contents

## EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporation by Reference			Filing Date	Filed Herewith
		Form	File Number	Exhibit/ Appendix Reference		
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	2/7/2000	
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	10.8	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, National Association	8-K	000-30235	4.2	8/14/2012	
4.9		8-K	000-30235	4.2	8/14/2012	

Form of 4.25% Convertible Senior  
Subordinated Note due 2019

(Exhibit A)

10.1	Consent and Amendment dated August 6, 2012 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.	8-K	000-30235	10.1	8/6/2012
10.2	Pledge and Escrow Agreement dated August 14, 2012 by and among Exelixis, Inc., Wells Fargo Bank, National Association and Wells Fargo Bank, National Association.	8-K	000-30235	10.1	8/14/2012

Table of Contents

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

‡ Pursuant to applicable securities laws and regulations, we are deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and are not subject to liability under any anti-fraud provisions of the federal securities laws as long as we have made a good faith attempt to comply with the submission requirements and promptly amend the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. In accordance with Rule 406T of Regulation S-T, the information in these exhibits is furnished and deemed not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.