EXELIXIS INC Form 10-Q October 27, 2011 Table of Contents

# **UNITED STATES**

# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-Q**

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

For the quarterly period ended September 30, 2011

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**)

04-3257395 (I.R.S. Employer

Identification No.)

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)

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 x 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 x No  $\ddot{}$ 

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
 x

 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 x
 "

As of October 21, 2011, there were 129,685,614 shares of the registrant s common stock outstanding.

#### EXELIXIS, INC.

## **QUARTERLY REPORT ON FORM 10-Q**

# FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2011

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# PART I. FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

# EXELIXIS, INC.

# CONDENSED CONSOLIDATED BALANCE SHEETS

### (in thousands)

	Septeml 201 (unaud	1	December 31, 2010 (1)
ASSETS	(		
Current assets:			
Cash and cash equivalents	\$ 6	6,211 5	\$ 97,440
Marketable securities	15	6,947	65,224
Other receivables		4,654	5,896
Prepaid expenses and other current assets	1	7,062	14,926
Total current assets	24	4,874	183,486
Restricted cash and investments		4,199	6,399
Long-term investments	8	5,787	87,314
Property and equipment, net	1	0,196	15,811
Goodwill		3,684	63,684
Other assets		2,896	4,096
Total assets	\$ 41	1,636 5	\$ 360,790
LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT) Current liabilities:	¢	2 200	
Accounts payable		3,390 5	
Accrued compensation and benefits		8,835	6,555
Accrued clinical trial liabilities		4,957	30,975
Other accrued liabilities		5,195	15,026
Current portion of notes payable and bank obligations		5,974	8,848 28,900
Current portion of convertible loans		28,900	28,900
Current portion of restructuring Deferred revenue		2,725 6,639	100,297
Deterred revenue	/	0,039	100,297
Total current liabilities	16	6,615	199,941
Long-term portion of notes payable and bank obligations	8	5,787	87,314
Long-term portion of convertible loans	8	9,295	83,396
Long-term portion of restructuring		7,670	6,987
Other long-term liabilities		8,247	9,005
Deferred revenue	5	0,968	202,472
Total liabilities	40	08,582	589,115
Commitments			
Stockholders equity (deficit):			
Common stock		129	109

Additional paid-in-capital	1,155,827	953,608
Accumulated other comprehensive income	(249)	12
Accumulated deficit	(1,152,653)	(1,182,054)
Total stockholders equity (deficit)	3,054	(228,325)
Total liabilities and stockholders equity (deficit)	\$ 411,636	\$ 360,790

(1) The condensed consolidated balance sheet at December 31, 2010 has been derived from the audited consolidated 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.

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

# EXELIXIS, INC.

# CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

## (in thousands, except per share data)

## (unaudited)

	Septen	nths Ended 1ber 30,	Septem		
Revenues:	2011	2010	2011	2010	
Contract	\$ 5.024	\$ 11,865	\$ 25,761	\$ 43,915	
License	122,703	24.542	\$ 23,701 167,984	73,648	
Collaboration reimbursements	545	18,067	2,583	26,706	
Total revenues	128,272	54,474	196,328	144,269	
Operating expenses:					
Research and development	37,465	49,388	126,058	168,375	
General and administrative	8,171	8,952	26,119	27,358	
Restructuring charge	2,937	339	6,190	25,823	
Total operating expenses	48,573	58,679	158,367	221,556	
Gain (loss) from operations	79,699	(4,205)	37,961	(77,287)	
Other income (expense):	,	() )			
Interest income (loss) and other, net	98	(376)	1,479	331	
Interest expense	(4,142)	(4,094)	(12,249)	(5,378)	
Gain on sale of business	2,210		2,210	7,797	
Total other income (expense), net	(1,834)	(4,470)	(8,560)	2,750	
Consolidated income (loss) before taxes	77,865	(8,675)	29,401	(74,537)	
Income tax benefit (provision)		72		72	
Net income (loss)	\$ 77,865	\$ (8,603)	\$ 29,401	\$ (74,465)	
Net income (loss) per share, basic	\$ 0.60	\$ (0.08)	\$ 0.24	\$ (0.69)	
Net income (loss) per share, diluted	\$ 0.59	\$ (0.08)	\$ 0.23	\$ (0.69)	
Shares used in computing basic income (loss) per share amounts	129,145	108,667	123,426	108,373	
Shares used in computing diluted income (loss) per share amounts	131,344	108,667	129,430	108,373	

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

# EXELIXIS, INC.

# CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

## (in thousands)

## (unaudited)

	Nine Months En 2011	ded Sep	otember 30, 2010
Cash flows from operating activities:			
Consolidated net income (loss)	\$ 29,401	\$	(74,465)
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Depreciation and amortization	5,035		8,276
Stock-based compensation expense	9,409		16,744
Impairment of assets due to restructuring	379		2,481
Gain on sale of business	(2,210)		(7,797)
Accretion of debt discount	5,900		1,661
Other	3,637		2,415
Changes in assets and liabilities:			
Other receivables	1,242		4,558
Prepaid expenses and other current assets	(1,522)		(2,957)
Other assets	701		(1,720)
Accounts payable and other accrued expenses	(2,225)		(1,210)
Restructuring liability	(3,886)		9,169
Other long-term liabilities	(758)		(1,256)
Deferred revenue	(175,162)		(78,201)
Net cash used in operating activities	(130,059)		(122,302)
Cash flows from investing activities:			
Purchases of property and equipment	(712)		(1,481)
Proceeds from sale of property and equipment			179
Proceeds on sale of business	3,010		8,600
Decrease in restricted cash and investments	2,200		45
Proceeds from maturities of marketable securities	117,244		95,100
Proceeds from sale of marketable securities			12,780
Purchases of marketable securities	(210,580)		(141,186)
Net cash used in investing activities	(88,838)		(25,963)
Cash flows from financing activities:			
Proceeds from issuance of common stock	179,377		
Proceeds from exercise of stock options and warrants	11.705		1.054
Proceeds from employee stock purchase plan	987		2,122
Proceeds from note payable and bank obligations	2,589		162,508
Principal payments on notes payable and bank obligations	(6,990)		(8,873)
Net cash provided by financing activities	187,668		156,811
Net (decrease) increase in cash and cash equivalents	(31,229)		8,546
Cash and cash equivalents, at beginning of period	97,440		86,796
Cash and cash equivalents, at end of period	\$ 66,211	\$	95,342

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

#### EXELIXIS, INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2011

#### (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 (XL184), our most advanced compound, 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. Cabozantinib inhibits MET, VEGFR2 and RET, proteins that are key drivers of tumor growth, vascularization and/or metastasis. Cabozantinib is being evaluated in a broad development program encompassing multiple cancer indications. We have also developed 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 (GAAP) 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 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. Certain reclassifications of prior period amounts have been made to our condensed consolidated financial statements to conform to the current period presentation.

Exelixis has adopted a 52- or 53-week fiscal year that ends on the Friday closest to December 31<sup>st</sup> of each year. Fiscal year 2010, a 52-week year, ended on December 31, 2010, and fiscal year 2011, a 52-week year, will end on December 30, 2011. For convenience, references in these Condensed Consolidated Financial Statements and Notes as of and for the fiscal quarters ended October 1, 2010 and September 30, 2011 are indicated as ended September 30, 2010 and 2011, respectively.

Operating results for the three and nine months ended September 30, 2011 are not necessarily indicative of the results that may be expected for the fiscal year ending December 30, 2011 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, 2010 included in our Annual Report on Form 10-K filed with the SEC on February 22, 2011.

#### **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, long-lived assets, derivative instruments, accrued liabilities, and share-based compensation. 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.

All marketable securities are classified as available-for-sale and are carried at fair value. We view our available-for-sale portfolio as available for use in current operations. Accordingly, we have classified certain investments as short-term marketable securities, even though the stated maturity date may be one year or more beyond the current balance sheet date. Available-for-sale securities are stated at fair value based upon quoted market prices of the securities. We have classified certain investments as cash and

cash equivalents or marketable securities that collateralize loan balances; however, they are not restricted to withdrawal. Funds that are used to collateralize equipment lines of credit that extend for over 12 months have been classified as long-term investments, in accordance with the loan arrangement. Unrealized gains and losses on available-for-sale investments are reported as a separate component of stockholders deficit. Realized gains and losses, net, on available-for-sale securities are recorded in our Consolidated Statement of Operations as Interest income and other, net. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are recorded in our Consolidated Statements of Operations as Interest income and other, net.

All of 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 included in cash and cash equivalents and restricted cash and investments as of September 30, 2011 (in thousands):

	000000000		000000000 Gross			0000000 Gross	0	0000000				
	A	mortized Cost		alized ains	-	Unrealized Losses						air Value
Money market funds	\$	96,475	\$		\$		\$	96,475				
Commercial paper		23,873		1				23,874				
Corporate bonds		120,999		12		(257)		120,754				
U.S. Government sponsored enterprises		33,702		1		(3)		33,700				
Municipal bonds		38,344		2		(5)		38,341				
Total	\$	313,393	\$	16	\$	(265)	\$	313,144				
	000000000 Amortized		000000000 Gross Unrealized		000000000 Gross Unrealized		0	0000000				
	п	Cost		ains	-	Losses	F	air Value				
As reported:												
Cash and cash equivalents	\$	66,211	\$		\$		\$	66,211				
Marketable securities		157,196		16		(265)		156,947				
Restricted cash and investments		4,199						4,199				
Long-term investments		85,787						85,787				
Total	\$	313,393	\$	16	\$	(265)	\$	313,144				

As of September 30, 2011, all securities that were in an unrealized loss position have been so for less than one year and the unrealized losses 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.

The following summarizes available-for-sale securities included in cash and cash equivalents and restricted cash and investments as of December 31, 2010 (in thousands):

			Fair Value
000000000	000000000	000000000	000000000

	A	Amortized Cost	Unr	ross ealized ains	Uni	Gross realized Josses	
Money market funds	\$	171,048	\$		\$		\$ 171,048
Commercial paper		19,283					19,283
Corporate bonds		36,869		18		(10)	36,877
U.S. Government sponsored enterprises		18,811		5			18,816
Municipal bonds		10,913				(1)	10,912
Total	\$	256,924	\$	23	\$	(11)	\$ 256,936

	00	0000000		)00000 ross		000000 Gross	00	0000000
	A	mortized Cost	ed Unrealized Gains		Unrealized Losses		Fa	air Value
As reported:								
Cash and cash equivalents	\$	98,001	\$		\$	(2)	\$	97,999
Marketable securities		65,210		23		(9)		65,224
Restricted cash and investments		6,399						6,399
Long-term investments		87,314						87,314
Total	\$	256,924	\$	23	\$	(11)	\$	256,936

The following summarizes available-for-sale securities included in cash and cash equivalents and restricted cash and investments as of September 30, 2011 by contractual maturity (in thousands):

	Amortized Cost	Unre	oss alized ains	Uni	Fross realized Josses	Fair Value
Mature in less than one year	\$ 297,888	\$	16	\$	(222)	\$ 297,682
Mature in one to two years	15,505				(43)	15,462
Total	\$ 313,393	\$	16	\$	(265)	\$ 313,144

As of December 31, 2010, all of our available-for-sale-securities matured in less than one year.

#### **Foreign Currency Forward Contract**

We have entered into foreign currency forward contracts to reduce our net exposure to Eurodollar currency fluctuations. On March 30, 2011, we entered into a new foreign contract for a notional amount of \$7.0 million that will expire in December 2011. The fair value of the foreign currency contract is estimated based on pricing models using readily observable inputs from actively quoted markets. As of September 30, 2011 and December 31, 2010, the fair values of the foreign currency forward contracts held were at losses of approximately \$0.3 million and \$0.2 million, respectively. The net unrealized gain or loss on our foreign currency forward contracts, neither of which has been designated as a hedge, is recorded in our Consolidated Statements of Operations as Interest income and other, net.

#### **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 financial instruments are valued using quoted prices in active markets or based upon other observable inputs. The following table sets forth the fair value of our financial assets that were measured on a recurring basis as of September 30, 2011 and December 31, 2010, respectively (in thousands):

As of September 30, 2011:

	Level 1	Level 2	Level 3	Total
Money market funds	\$ 96,475	\$	\$	\$ 96,475
Commercial paper		23,874		23,874
Corporate bonds		120,754		120,754
U.S. Government sponsored agencies		33,700		33,700
Municipal bonds and variable rate demand notes		38,341		38,341
Foreign currency forward contract		514		514
Total	\$ 96,475	\$217,183	\$	\$ 313,658

# As of December 31, 2010:

	Level 1	Level 2	Level 3	Total
Money market funds	\$ 171,048	\$	\$	\$ 171,048
Commercial paper		19,283		19,283
Corporate bonds		36,877		36,877
U.S. Government sponsored enterprises		18,816		18,816
Municipal bonds and variable rate demand notes		10,912		10,912
Foreign currency forward contract		(156)		(156)
Total	\$ 171,048	\$ 85,732	\$	\$ 256,780

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 our current borrowing rate for similar long-term debt. However, due to the unique structure of our 2010 financing agreement 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. See Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations Certain Factors Important to Understanding Our 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. The estimated fair value of our outstanding debt, excluding our 2010 financing with Deerfield, was as follows (in thousands):

	September 30, 2011	December 31, 2010		
GlaxoSmithKline loan	\$ 28,672	\$ 26,693		
Equipment lines of credit	11,708	16,064		
Silicon Valley Bank loan	77,480	77,480		
Total	\$ 117,860	\$ 120,237		

At September 30, 2011 and December 31, 2010, the book value of our debt outstanding, including our 2010 financing with Deerfield, was \$210.0 million and \$208.5 million, respectively. Our payment commitments associated with these debt instruments are fixed during the corresponding terms and are comprised of interest payments, principal payments or a combination thereof. 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.

In accordance with the terms of our loan and security agreement with GlaxoSmithKline, we have elected to repay the third and final installment of the loan in stock. The repayment shares are priced at \$6.66 per share, resulting in the issuance of 5,537,906 shares of our common stock to GlaxoSmithKline on October 27, 2011, as satisfaction in full of our \$36.9 million repayment obligation, including \$8.0 million in accrued interest, under the loan and security agreement.

#### 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 is less than its carrying amount. Long-lived assets include property and equipment and identified intangible assets. In the nine months ended September 30, 2011 and September 30, 2010, we wrote down property and equipment in the amount of approximately \$0.3 million and \$2.5 million, respectively, in connection with our 2010 and 2011 restructuring plans. These amounts exclude the impact of any auction proceeds received relating to the sale of these impaired assets. See Note 5 for further information on the restructuring plans.

#### **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, U.S. government agency obligations and U.S. government sponsored enterprises. 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 Income (Loss) Per Share

Basic net income (loss) per share is computed by dividing net income (loss) for the period by the weighted average number of shares of common stock outstanding during the period. Diluted net income (loss) per share gives effect to potential incremental common shares issuable upon the exercise of stock options and warrants and shares issuable pursuant to restricted stock units (RSUs) (calculated based on the treasury stock method), and upon conversion of our convertible debt (calculated using an as-if-converted method).

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

	Three Months Ended September 30, 2011 2010			Nine Months Ended September 30, 2011 2010			
Numerator:							
Net income (loss)	\$77,	865 \$	(8,603)	\$ 2	29,401	\$ (	74,465)
Denominator:							
Shares used in computing basic income (loss) per share amounts	129,	145	108,667	12	23,426	10	08,373
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 income (loss) per common share	2,	199			6,004		
Shares used in computing diluted income (loss) per share amounts	131,	344	108,667	129,430 108		08,373	
Net income (loss) per share, basic	\$ (	).60 \$	(0.08)	\$	0.24	\$	(0.69)
Net income (loss) per share, diluted	\$ (	).59 \$	(0.08)	\$	0.23	\$	(0.69)

For the three and nine months ended September 30, 2011, the total number of antidilutive outstanding common stock equivalents excluded from the net income per share computation was 15.5 million and 7.4 million, respectively. As of September 30, 2010, 47.7 million common stock equivalents were excluded from the total number of dilutive shares because their effect is anti-dilutive.

#### **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. On December 11, 2008, we entered into a worldwide Collaboration Agreement with Bristol-Myers Squibb Company (Bristol-Myers Squibb) for the development of cabozantinib and XL281, which was amended and restated by the Amended and Restated Collaboration Agreement dated as of April 15, 2011 by and between us and Bristol-Myers Squibb (as amended and restated, the 2008 Agreement). However, on June 18, 2010, we regained full rights to develop and commercialize cabozantinib under the 2008 Agreement following receipt of notice from Bristol-Myers Squibb of its decision to terminate the 2008 Agreement, solely as to cabozantinib, on a worldwide basis. Prior to the termination of the 2008 Agreement as to cabozantinib, both parties were actively involved with compound development and certain research and development expenses were partially reimbursable to us on a net basis by compound. On an annual basis, amounts owed by Bristol-Myers Squibb to us, net of amounts reimbursable to Bristol-Myers Squibb by us for the development of cabozantinib and XL281, were recorded as collaboration reimbursement revenues. Conversely, research and development expenses would include the net settlement of amounts we owed Bristol-Myers Squibb for research and development expenses that Bristol-Myers Squibb incurred in connection with the development of cabozantinib, less amounts reimbursable to us by Bristol-Myers Squibb for the development of both cabozantinib and XL281. On July 8, 2011, we received written notification from Bristol-Myers Squibb of its decision to terminate the 2008 Agreement in its entirety. Due to this termination, which became effective on October 8, 2011, for the period ended September 30, 2011, reimbursement payments were presented as collaboration reimbursement revenues and will

continue to be presented as such through the period ending December 31, 2011, at which point we do not expect to record any further collaboration cost-sharing expense or collaboration reimbursement revenues under our current collaborations. See Note 4 for further information on our 2008 cancer collaboration with Bristol-Myers Squibb.

Revenues and expenses from collaborations that are not co-development agreements are recorded as contract revenues or research and development expenses in the period incurred.

#### **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.

#### **Recent Accounting Pronouncements**

In October 2009, the FASB issued ASU No. 2009-13, Revenue Recognition *Multiple Deliverable Revenue Arrangements* (ASU 2009-13). ASU 2009-13 provides application guidance on whether multiple deliverables exist, how the deliverables should be separated and how the consideration should be allocated to one or more units of accounting. This update establishes a selling price hierarchy for determining the selling price of a deliverable. The selling price used for each deliverable will be based on vendor-specific objective evidence, if available, third-party evidence if vendor-specific objective evidence is not available, or estimated selling price if neither vendor-specific or third-party evidence is available. Under ASU 2009-13, we may be required to exercise considerable judgment in determining the estimated selling price of delivered items under new agreements and our revenue under new agreements may be more accelerated as compared to the prior accounting standard. We adopted this guidance beginning January 1, 2011, and expect that this adoption could have a material impact on our financial statements going forward.

In June 2011, Accounting Standards Codification Topic 220, *Comprehensive Income* was amended to increase the prominence of items reported in other comprehensive income. Accordingly, a company can present all non-owner changes in stockholders equity either in a single continuous statement of comprehensive income or in two separate but consecutive statements. We plan to adopt this guidance as of January 1, 2012 on a retrospective basis and do not expect the adoption thereof to have a material effect on our consolidated financial statements.

#### NOTE 2. Comprehensive Income (Loss)

Comprehensive income (loss) represents consolidated net income (loss) plus any unrealized gains and losses on available-for-sale securities not reflected in our Consolidated Statements of Operations. Comprehensive income (loss) was as follows (in thousands):

	Three Months Ended September 30, Nine Months Ended Septeml								
	2011			2010		2011		2010	
Consolidated net income (loss)	\$	77,865	\$	(8,603)	\$	29,401	\$	(74,465)	
Unrealized losses on available-for-sale securities, net of taxes		(236)				(261)		(138)	
Comprehensive income (loss)	\$	77,629	\$	(8,603)	\$	29,140	\$	(74,603)	

#### **NOTE 3. Stock-Based Compensation**

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

	Months En 2011	tember 30, 2010	Months E 2011	otember 30, 2010
Research and development expense	\$ 1,378	\$ 2,477	\$ 4,557	\$ 9,148
General and administrative expense	1,401	2,956	4,102	6,546
Restructuring-related stock-based compensation expense	176		625	961
Total employee stock-based compensation expense	\$ 2,955	\$ 5,433	\$ 9,284	\$ 16,655

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:

	Stock Options Three Months Ended September 30,				*			mber 30,	
	201	1	20	10 (1)	ź	2011	2	2010	
Weighted average fair value of awards	\$	3.28	\$	N/A	\$	4.24	\$	2.08	
Risk-free interest rate		0.97%		N/A		0.10%		0.25%	
Dividend yield		0%		N/A		0%		0%	
Volatility		70%		N/A		70%		75%	
Expected life	5.4 y	ears		N/A	0.	5 years	0.:	5 years	

(1) There were no options granted during the three months ended September 30, 2010.

		Options led September 30,	ESI Nine Months Ende	-	
	2011	2010	2011	2010	
Weighted average fair value of awards	\$ 3.52	\$ 3.60	\$ 3.05	\$ 1.99	
Risk-free interest rate	1.05%	2.25%	0.13%	0.20%	
Dividend yield	0%	0%	0%	0%	
Volatility	70%	70%	68.%	66.%	
Expected life	5.5 years	5.2 years	0.5 years	0.5 years	

A summary of all stock option activity for the nine months ended September 30, 2011 is presented below:

	Shares	0	hted Average ercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Options outstanding at December 31, 2010	19,630,030	\$	7.52		
Granted	2,268,701		5.91		
Exercised	(2,028,647)		5.77		
Cancelled	(1,889,114)		8.71		
Options outstanding at September 30, 2011	17,980,970	\$	7.38	4.95 years	\$ 1,111,592

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Exercisable at September 30, 2011	13,660,215	\$	7.80	4.28 years	\$	795,535
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As of September 30, 2011, \$12.1 million of total unrecognized compensation expense related to employee stock options was expected to be recognized over a weighted-average period of 2.77 years.

A summary of all RSU activity for the nine months ended September 30, 2011 is presented below:

	Shares	0	ted Average ate Fair Value	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
RSUs outstanding at December 31, 2010	2,172,431	\$	7.31		
Awarded	354,270		6.17		
Released	(574,670)		7.44		
Forfeited	(462,007)		7.46		
RSUs outstanding at September 30, 2011	1,490,024	\$	6.95	1.59 years	\$ 8,135,531

As of September 30, 2011, \$7.2 million of total unrecognized compensation expense related to employee RSUs was expected to be recognized over a weighted-average period of 2.85 years.

#### **NOTE 4. Collaborations**

#### **Bristol-Myers Squibb**

#### 2008 Cancer Collaboration

In December 2008, we entered into a worldwide collaboration with Bristol-Myers Squibb for cabozantinib and XL281 (BMS-908662), a RAF inhibitor. Upon effectiveness of the 2008 Agreement in December 2008, Bristol-Myers Squibb made a nonrefundable upfront cash payment of \$195.0 million for the development and commercialization rights to both programs. The 2008 Agreement required Bristol-Myers Squibb to make additional license payments to us of \$45.0 million, which were received during 2009.

On July 8, 2011, we and one of our wholly-owned subsidiaries received written notification from Bristol-Myers Squibb of its decision to terminate the 2008 Agreement, on a worldwide basis as to XL281. The termination was made pursuant to the terms of the 2008 Agreement and became effective on October 8, 2011. Bristol-Myers Squibb informed us that the termination was based upon Bristol-Myers Squibb s review of XL281 in the context of Bristol-Myers Squibb s overall research and development priorities and pipeline products. Upon the effectiveness of the termination, Bristol-Myers Squibb s license relating to XL281 terminated, and rights to XL281 reverted to us. We also received, subject to certain terms and conditions, licenses from Bristol-Myers Squibb to research, develop and commercialize XL281. We plan to wind down ongoing activities related to XL281 and do not currently expect to further research, develop or commercialize XL281 following the wind-down.

Under the 2008 Agreement, we and Bristol-Myers Squibb originally agreed to co-develop cabozantinib and Bristol-Myers Squibb also received an exclusive worldwide license to develop and commercialize XL281. On June 18, 2010, we received a notice from Bristol-Myers Squibb of its decision to terminate the 2008 Agreement solely as to cabozantinib, on a worldwide basis, pursuant to the terms of the 2008 Agreement. We continued to carry out certain clinical trials of XL281 under the 2008 Agreement, and Bristol-Myers Squibb was responsible for funding all future development of XL281, including our activities. We were eligible for development and regulatory milestones of up to \$315.0 million on XL281, sales performance milestones of up to \$150.0 million and double-digit royalties on worldwide sales of XL281.

For purposes of recognizing upfront license fees received under the 2008 Agreement, prior to receiving the termination notification from Bristol-Myers Squibb in July 2011, we were recognizing revenue related to the upfront license fees through the estimated period of our involvement, or April 2014. As a result of the July 2011 termination, the estimated research term was revised to end on October 8, 2011. Accordingly, we accelerated the recognition of the remaining deferred revenue balance through the revised end of the research term and recognized \$109.9 million in revenue during the quarter ended September 30, 2011. We expect to recognize the remaining \$10.4 million in revenue in the fourth quarter of 2011. Amounts attributable to programs under the 2008 Agreement consisted of the following (in thousands):

	Three Months I	Ended September 30	, Nine Months En	ded September 30,	
	2011 2010		2011	2010	
Exelixis research and development expenses (1)	\$ 478	\$ 845	\$ 2,376	\$ 41,320	

Net amount due from collaboration partner	545	18,067	2,583	26,706

(1) Total research and development expenses attributable to us include direct third party expenditures plus estimated internal personnel costs and are calculated in accordance with the terms of the particular collaboration.

#### sanofi-aventis

In May 2009, we entered into a global license agreement with sanofi-aventis for XL147 and XL765 and a broad collaboration for the discovery of inhibitors of phosphoinositide-3 kinase (PI3K) for the treatment of cancer. The license agreement and collaboration agreement became effective on July 7, 2009. In connection with the effectiveness of the license and collaboration, on July 20, 2009, we received upfront payments of \$140.0 million (\$120.0 million for the license and \$20.0 million for the collaboration), less applicable withholding taxes of \$7.0 million, for a net receipt of \$133.0 million. We expect to receive a refund payment from the French government in early 2012 with respect to the withholding taxes previously withheld.

Under the license agreement, sanofi-aventis received a worldwide exclusive license to XL147 and XL765, which are in phase 1, phase 1b/2 and phase 2 clinical trials, and has sole responsibility for all subsequent clinical, regulatory, commercial and manufacturing activities. sanofi-aventis is responsible for funding all development activities with respect to XL147 and XL765, including our activities. Following the effectiveness of the license agreement, we had been conducting the majority of the clinical trials for XL147 and XL765 at the expense of sanofi-aventis. As provided for under the license agreement, however, the parties agreed to transition all future development activities for these compounds to sanofi-aventis. The transition was substantially completed by the end of June 2011. As a result of the transition of development activities to sanofi-aventis, we expect to no longer receive reimbursements from sanofi-aventis with respect to XL147 and XL765 and we have reduced our headcount commensurately such that no further material operating expenses will be incurred in connection with these programs going forward.

Under the collaboration agreement, the parties agreed to combine efforts in establishing several pre-clinical PI3K programs and jointly share responsibility for research and preclinical activities related to isoform-selective inhibitors of PI3K-a and -B. sanofi-aventis is required to provide us with guaranteed annual research and development funding during the research term and is responsible for funding all development activities for each product following approval of the investigational new drug application filed with the applicable regulatory authorities for such product. We are entitled to receive guaranteed research funding of \$21.0 million over three years to cover certain of our costs under the collaboration agreement. sanofi-aventis will have sole responsibility for all subsequent clinical, regulatory, commercial and manufacturing activities of any products arising from the collaboration; however, we may be requested to conduct certain clinical trials at sanofi-aventis expense. The research term under the collaboration is three years, although sanofi-aventis has the right to extend the term for an additional one-year period upon prior written notice.

Under the license agreement and the collaboration agreement combined, we are eligible to receive total development, regulatory and commercial milestones of over \$1.0 billion in the aggregate, as well as royalties on sales of any products commercialized under the license agreement or collaboration agreement.

sanofi-aventis may, upon certain prior notice to us, terminate the license as to products containing XL147 or XL765. In the event of such termination election, sanofi-aventis license relating to such product would terminate and revert to us, and we would receive, subject to certain terms, conditions and potential payment obligations, licenses from sanofi-aventis to research, develop and commercialize such product.

The collaboration will automatically terminate under certain circumstances upon the expiration of the research term, in which case all licenses granted by the parties to each other will terminate and revert to the respective party, subject to sanofi-aventis right to receive, under certain circumstances, the first opportunity to obtain a license from us to any isoform-selective PI3K inhibitor. In addition, sanofi-aventis may, upon certain prior written notice to us, terminate the collaboration in whole or as to certain products following expiration of the research term, in which case we would receive, subject to certain terms, conditions and potential payment obligations by us, licenses from sanofi-aventis to research, develop and commercialize such products.

#### **NOTE 5. Restructurings**

During 2010, we implemented two restructuring plans that resulted in an overall reduction in our workforce by 386 employees. In March 2011, we implemented an additional restructuring plan that resulted in further terminations in 2011. Taking into consideration certain employees who have since been recalled, there has been an aggregate reduction in headcount from the 2010 and 2011 restructuring plans of 402 employees. The restructuring plans are a consequence of our decision to focus our proprietary resources and development efforts on the late-stage development and commercialization of cabozantinib. Further personnel reductions are expected to be made through the end of 2012 as we complete our obligations under collaboration agreements and withdraw resources from completed projects.

In connection with the 2010 and 2011 restructuring plans, we have recorded aggregate restructuring charges of \$38.9 million, of which \$20.4 million related to termination benefits and \$18.5 million related to facility charges and the impairment of various assets. In connection with these restructurings, for the nine months ended September 30, 2011, we recorded \$6.2 million in total restructuring charges, of which \$4.3 million related to lease-exit and moving costs. Our facility-related charges take into consideration our entry into two sublease agreements for portions of

our building at 170 Harbor Way, South San Francisco, California ( $\$ Building 170 $\$ ) that we

entered into in July 2011. The balance of our restructuring charges primarily related to termination benefits for employees of \$2.7 million. Additionally, we received auction proceeds from the sale of excess equipment and other assets, partially offset by impairment charges for such assets.

With respect to our restructuring plans, we expect to incur an additional restructuring charge of \$3.7 million relating to the sublease of portions of Building 170 and a building we lease at 249 East Grand Avenue, South San Francisco, California that we exited and subleased in 2010 (Building 249), plus additional restructuring charges of up to \$15 million in connection with the anticipated exit of additional facilities in South San Francisco, California. We expect to record the remaining facility-related charges, as they are determined, through the end of 2017, or the end of the building lease terms.

As of September 30, 2011, the 2010 and 2011 restructuring plans resulted in aggregate cash expenditures of \$23.0 million, of which \$14.1 million was paid in 2010 and \$8.9 million has been paid in 2011. We expect to pay an additional \$8.0 million, net of cash received from our subtenant, for Building 249 and an additional \$6.1 million, net of cash received from our subtenants, for Building 170. In addition, we expect to make cash expenditures of \$0.7 million relating to termination benefits and up to \$18 million relating to facility costs in connection with the anticipated exit of additional facilities in South San Francisco, California. We expect the termination benefits to be paid during the fourth quarter of 2011 and the facility costs to be paid through 2017, or the end of our lease term for both Building 170 and Building 249.

The total outstanding restructuring liability is included in Current portion of restructuring and Long-term portion of restructuring on our Condensed Consolidated Balance Sheet and is based upon restructuring charges recognized as of September 30, 2011 in connection with the 2010 and 2011 restructuring plans. As of September 30, 2011, the components of these liabilities are summarized in the following table (in thousands):

	An	ee Severance d Other enefits	Facility Charges	Asset Impairment	0	al and er Fees	Total
Balance as of December 31, 2010	\$	5,523	\$ 8,688	\$	\$	70	\$ 14,281
Restructuring charge recorded in the nine months ended							
September 30, 2011		2,689	4,276	(773)		27	6,219
Cash payments		(6,809)	(2,938)	844		(16)	(8,919)
Adjustments or non-cash credits including stock compensation expense		(711)	(374)	(71)		(30)	(1,186)
Ending accrual balance as of September 30, 2011	\$	692	\$ 9,652	\$	\$	51	\$ 10,395

#### NOTE 6. Sale 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 \$179.4 million in net proceeds from the offering after deducting the underwriting discount and related offering expenses.

#### NOTE 7. Debt

#### Silicon Valley Bank Loan and Security Agreement

In December 2007, we entered into a third loan modification agreement to the loan and security agreement originally entered into in May 2002 with Silicon Valley Bank. The terms associated with the original line of credit under the May 2002 agreement and the subsequent loan modifications were not modified. The December 2007 loan modification agreement provided for an additional equipment line of credit in the amount of up to \$30.0 million with a draw down period of approximately 2 years (the 2007 Line of Credit ). Each advance must be repaid in 48 equal, monthly installments of principal, plus accrued interest, at an annual rate of 0.75% fixed. In December 2009, we amended the agreement and extended the draw down period on the 2007 Line of Credit for an additional 18 months through June 2011 and increased the principal amount of the line of credit from \$30.0 million to \$33.6 million. Pursuant to the terms of the amendment, we were required to make minimum draws of \$2.5 million every 6 months through June 2011, for total additional draws of \$7.5 million. The loan facility required security for the 2007 Line of Credit in the form of a non-interest bearing certificate of deposit account with the bank, in an amount equal to at least 100% of the outstanding obligations under the line of credit. In June 2008, we drew down \$13.6 million under the 2007 Line of Credit, in December 2009,

we drew down \$5.0 million, and we drew down an additional \$2.5 million in each of June 2010, December 2010 and June 2011 in accordance with the terms of the modified agreement. In accordance with the amended loan terms, the 2007 Line of Credit has expired and we have no further draw down obligations under the line of credit.

On June 2, 2010, we amended our loan and security agreement with Silicon Valley Bank to provide for a new seven-year term loan in the amount of \$80.0 million. 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 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 were required to maintain at all times on deposit in one or more non-interest bearing demand deposit accounts with Silicon Valley Bank or one of its affiliates a compensating balance, constituting support for the obligations under the term loan, with a principal balance in value equal to at least 100% of the outstanding principal balance of the term loan.

In August 2011, we amended our term loan agreement to allow for the compensating balance to be maintained on deposit in one or more investment accounts with Silicon Valley Bank or one of its affiliates and to earn interest which would be recognized as additional interest income in our consolidated income statement. This compensating balance is to have a value equal to at least 100%, but not to exceed 107%, of the outstanding principal balance of the term loan and all lines of credit associated with Silicon Valley Bank. 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.

The total outstanding obligation under the term loan and all other lines of credit with Silicon Valley Bank as of September 30, 2011 and December 31, 2010 was \$91.8 million and \$96.1 million, respectively. The total collateral balance as of September 30, 2011 and December 31, 2010 was \$93.6 million and \$96.9 million, respectively, and is reflected in our Condensed Consolidated Balance Sheet as Cash and cash equivalents and Marketable securities as the deposit account is not restricted as to withdrawal.

## NOTE 8. Artemis

On November 20, 2007, we entered into a share sale and transfer agreement with Taconic Farms, Inc. (Taconic), pursuant to which Taconic acquired from us, for \$19.8 million in cash, 80.1% of the outstanding share capital in our wholly-owned subsidiary, Artemis Pharmaceuticals GmbH (Artemis), located in Cologne, Germany. Subsequent to the transaction, Artemis was renamed TaconicArtemis GmbH. In connection with the sale and transfer agreement, we also entered into a shareholders agreement and approved amended articles of association of Artemis that govern the relationship between us and Taconic as shareholders of Artemis, particularly with respect to matters of corporate governance and the transfer of our respective ownership interests. The shareholders agreement provides that we may require Taconic to purchase our remaining 19.9% interest in Artemis between 2010 and 2015 or in the event of a change in control of Taconic, and that Taconic may require us to sell our 19.9% interest to Taconic between 2013 and 2015 or in the event of a change in control of Exelixis, in each case subject to certain conditions set forth in the shareholders agreement. On September 27, 2011, in accordance with the terms and conditions of the shareholders agreement, we exercised our right to sell our remaining 19.9% interest in Artemis to Taconic is obligated to remit payment for such interest within 90 days. Pursuant the terms of the shareholder s agreement, during the quarter ended September 30, 2011, we recognized a gain of \$2.2 million after writing off the carrying value of our investment in Artemis and we expect to receive approximately \$3.0 million within 90 days of exercising our right to sell our remaining 19.9% interest.

#### **NOTE 9. Provision for Income Taxes**

In 2009, we recorded an income tax credit as a result of the Housing and Economic Recovery Act of 2008, which credit was extended through 2009 in connection with the enactment of the American Recovery and Reinvestment Act of 2009. In the third quarter of 2010, after filing our 2009 tax return, we adjusted the credit associated with the 2009 refundable credit and recorded an increase to our tax benefit of \$0.1 million.

As a result of the termination of our 2008 Agreement with Bristol Myers-Squibb, which became effective on October 8, 2011, we accelerated the remaining deferred revenue balance under the 2008 Agreement and recognized \$109.9 million in revenue during the three months ended September 30, 2011. This acceleration of revenue under the 2008 Agreement caused us to have book income for the three and nine months ended September 30, 2011. However, since the income from our 2008 Agreement with Bristol Myers-Squibb was recorded in 2008 and 2009 for tax purposes, the acceleration of the recognition of license revenue under the 2008 Agreement did not impact our tax position and therefore no tax provision was required for the three and nine months ended September 30, 2011.

#### 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 to be materially different from any future results, levels of activity, performance or achievements by, the forward-looking statements. Words such as believe, anticipate, expect, intend, plan, focus, goal, objective, will, may, could, would, estimate, predict, potential, continue, encouraging, or the negative of such terms or other similar expressions identify 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, 2010, filed with the Securities and Exchange Commission, or SEC, on February 22, 2011. 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 (XL184), our most advanced compound, 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.

Cabozantinib inhibits MET, VEGFR2 and RET, proteins that are key drivers of tumor growth, vascularization and/or metastasis. 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 metastatic castration-resistant prostate cancer and medullary thyroid cancer and will be expanded to other solid tumor indications, based on encouraging interim data that has emerged from a randomized discontinuation trial, or RDT, investigating cabozantinib in nine distinct tumor types, and other clinical trials.

Our strategy is to aggressively advance cabozantinib through development toward commercialization. In doing so, we will pursue a pragmatic development plan focused on those cancer indications where we believe cabozantinib has the greatest therapeutic and commercial potential. We are aggressively managing our expenses to preserve our cash resources and ensure we are appropriately dedicating those resources towards successfully executing our strategy.

As part of our ongoing effort to manage costs and our strategy to focus our proprietary resources and development efforts on our most advanced compound, cabozantinib, we implemented two restructuring plans during 2010 and an additional restructuring plan in March 2011 that resulted in an overall reduction in our workforce by 402 employees. Personnel reductions were made across our entire organization, including discovery, development and general and administrative departments. We expect to make additional reductions through the end of 2012 as we complete our obligations under collaboration agreements and withdraw resources from completed projects. With the exception of activities related to cabozantinib, we are discontinuing efforts with respect to all of our compounds and programs that are not funded by partners pursuant to collaboration agreements and are actively pursuing collaborations or other external opportunities for the continued development of these compounds and programs. Discovery and clinical activities under various collaborations will continue to be funded by partners until we complete our contractual obligations.

#### Cabozantinib

Cabozantinib is a first-in-class inhibitor of tumor growth, metastasis and angiogenesis that simultaneously targets MET, VEGFR2 and RET, which are key kinases involved in the development and progression of many cancers. It has recently been shown in preclinical models that treatment with selective inhibitors of VEGF signaling can result in tumors that are more invasive and aggressive compared to control treatment. In preclinical studies, upregulation of MET has been shown to occur in concert with development of invasiveness after selective anti-VEGF therapy, and may constitute a mechanism of acquired or evasive resistance to agents that target VEGF signaling without inhibiting MET. Accordingly, treatment with cabozantinib in similar preclinical studies resulted in tumors that were less invasive and aggressive compared to control or selective anti-VEGF treatment. Therefore, we believe that cabozantinib has the potential for improving outcomes in a range of indications, including those where selective anti-VEGF therapy has shown minimal or no activity.

#### EXAM Phase 3 Clinical Trial in Medullary Thyroid Cancer

We continue to advance our efforts on our ongoing phase 3 clinical trial of cabozantinib as a potential treatment for medullary thyroid cancer, known as the EXAM trial. This registration trial was initiated in July 2008 following agreement between the United States Food and Drug Administration, or FDA, and us on the trial design through the FDA s Special Protocol Assessment, or SPA, process. The SPA documents the FDA s agreement that the design and planned analyses of the EXAM trial are appropriate to support a regulatory submission for product registration, assuming a positive trial outcome and subject to review of complete data from the trial.

EXAM is an international, randomized, placebo-controlled, double-blinded trial of cabozantinib in patients with progressive, unresectable, locally advanced, or metastatic medullary thyroid cancer. Patients were randomized in a 2:1 ratio to receive cabozantinib or placebo administered at a daily dose of 175 mg. The trial does not allow for cross-over from the placebo arm to cabozantinib. Progression-free survival, or PFS, is the primary endpoint in this trial. With an enrollment target of 315 patients and a planned event-driven analysis, the trial provides 90% power to detect a 75% increase in PFS. Additionally, the trial is designed to assess overall survival at a later time point once the survival events have been achieved, and is powered to detect a 50% improvement in survival compared with placebo.

On October 24, 2011, we announced the top-line results of the primary endpoint of the EXAM trial. The trial met its primary endpoint of improving PFS compared with placebo and substantially exceeded the threshold of a 75% increase in PFS originally assumed when the trial was designed. Cabozantinib significantly improved median PFS by 7.2 months compared with placebo. The median PFS on the cabozantinib arm was 11.2 months versus 4.0 months on the placebo arm; hazard ratio (HR) 0.28, (95% CI 0.19, 0.40), p < 0.0001. We intend to report data from the EXAM trial at an upcoming medical conference.

We are requesting permission from the FDA to initiate a rolling submission of a new drug application, or NDA, for cabozantinib in medullary thyroid cancer. If the FDA permits a rolling submission, we plan to initiate the submission in December 2011 or January 2012 by submitting to the FDA key parts of the NDA, including preclinical and chemistry, manufacturing and controls information, and we would expect to complete the NDA filing in the first half of 2012. Cabozantinib is eligible for a potential rolling submission as a result of the FDA s granting Fast Track designation for cabozantinib in medullary thyroid cancer, as described below. The timing of our NDA submission will depend upon the outcome of our pre-NDA meeting with the FDA, which is scheduled to occur in December 2011. Assuming a rolling submission and approval of our NDA by the FDA, we currently anticipate a potential commercial launch of cabozantinib for the treatment of medullary thyroid cancer in the second half of 2012.

In January 2011, we announced that the FDA granted orphan drug designation to cabozantinib for the treatment of follicular, medullary and anaplastic thyroid carcinoma, and metastatic or locally advanced papillary thyroid cancer. Orphan drug status is granted to treatments for diseases that affect fewer than 200,000 people in the U.S. and provides the benefits of potential market exclusivity for the orphan-designated product for the orphan designated indication for seven years, tax credits of up to 50% of the qualified clinical trial expenses and a waiver of FDA application user fees.

In April 2011, the FDA designated cabozantinib as a Fast Track development program for patients with unresectable, locally advanced or metastatic medullary thyroid carcinoma. The Fast Track process is designed to facilitate the development, and expedite the review of drugs to treat serious diseases and fill an unmet medical need. A drug that receives Fast Track designation is eligible for rolling submission, which means that a sponsor can submit completed modules of its NDA separately for review by the FDA. In addition, most drugs that receive Fast Track designation are likely to be considered appropriate to receive a priority review.

#### **Opportunity in Castration-Resistant Prostate Cancer and Other Solid Tumors**

The broader clinical program for cabozantinib beyond medullary thyroid cancer is focused on the treatment of metastatic castration-resistant prostate cancer and will be expanded to other solid tumor indications, based on encouraging interim data that has emerged from the RDT investigating cabozantinib in nine distinct tumor types, and other clinical trials. Data from the RDT were released at the American Society of Clinical Oncology, or ASCO, Annual Meeting in June 2010 and demonstrated broad activity for cabozantinib across multiple tumor types, in particular, metastatic castration-resistant prostate, ovarian, non-small cell lung and hepatocellular cancers. Updated interim data presented at the 22<sup>nd</sup> EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics in November 2010, at the ASCO 2011 Genitourinary Cancers Symposium in February 2011, and at the 2011 ASCO Annual Meeting in June 2011 suggest that cabozantinib has a novel and differentiated clinical profile in metastatic castration-resistant prostate cancer and other solid tumors. The data presented indicate that cabozantinib has shown novel activity against bone and soft tissue lesions in patients with metastatic castration-resistant prostate cancer. In addition, we have observed resolution of metastatic bone lesions on bone scan in patients with metastatic breast cancer, renal cell carcinoma, thyroid cancer and melanoma. It will be a priority for us to generate additional data in the various other cohorts of the RDT, including ovarian cancer, melanoma, breast cancer, non-small cell lung cancer and hepatocellular cancer, to support further prioritization of our clinical and commercial options. In addition, we are conducting ongoing exploratory clinical trials for cabozantinib in other tumor types, including renal cell

carcinoma and differentiated thyroid cancer. Objective tumor responses have been observed in patients with cabozantinib in 12 of 13 individual tumor types investigated to date, reflecting the broad potential clinical activity and commercial opportunity with this new agent.

#### Planned Phase 3 Clinical Trials in Castration - Resistant Prostate Cancer

In June 2011, we submitted to the FDA the protocol for a planned pivotal trial for cabozantinib in metastatic castration-resistant prostate cancer using an endpoint of pain reduction and bone scan response (XL184-306) for consideration of an SPA. Our goal is to initiate this trial by the end of 2011. We are also planning two additional pivotal trials in castration-resistant prostate cancer for overall survival and bone metastasis-free survival (XL184-307 and XL184-308, respectively), and expect to initiate both of these trials in 2012.

#### **Other Discovery and Development Programs**

Based on the strength of our expertise in biology, drug discovery and development, we have established collaborations with leading pharmaceutical and biotechnology companies, including Bristol-Myers Squibb Company, or Bristol-Myers Squibb, sanofi-aventis, Genentech, Inc. (a wholly owned member of the Roche Group), GlaxoSmithKline and Daiichi Sankyo Company Limited 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. With respect to our partnered compounds, we are eligible to receive potential milestone payments under our collaborations totaling approximately \$2.9 billion in the aggregate on a non-risk adjusted basis, of which 12.3% are related to clinical development milestones, 46.2% are related to regulatory milestones and 41.5% are related to commercial milestones.

## **Recent Development**

#### Planned Repayment of GlaxoSmithKline Loan Repayment Obligations

In October 2002, we entered into a collaboration with GlaxoSmithKline to discover and develop novel therapeutics in the areas of vascular biology, inflammatory disease and oncology. As part of the collaboration, we entered into a loan and security agreement with GlaxoSmithKline, pursuant to which we borrowed \$85.0 million for use in our efforts under the collaboration. The loan bears interest at a rate of 4.0% per annum and was secured by certain intellectual property, technology and equipment created or utilized pursuant to the collaboration. Repayment of all or any of the amounts advanced to us under the loan and security agreement may, at our election, be made in the form of our common stock at fair market value, subject to certain conditions, or cash. We have elected to repay the third and final installment of the loan in stock. The repayment shares are priced at \$6.66 per share, resulting in the issuance of 5,537,906 shares of our common stock to GlaxoSmithKline on October 27, 2011, as satisfaction in full of our \$36.9 million repayment obligation, including \$8.0 million in accrued interest, under the loan and security agreement.

#### 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.

#### Clinical Development of Cabozantinib and Other Product Candidates

On December 11, 2008, we entered into a worldwide Collaboration Agreement with Bristol-Myers Squibb for cabozantinib and XL281, which was amended and restated by the Amended and Restated Collaboration Agreement dated as of April 15, 2011 by and between us and Bristol-Myers Squibb, or as amended and restated, the 2008 Agreement. Upon effectiveness of the 2008 Agreement in December 2008, Bristol-Myers Squibb made a nonrefundable upfront cash payment of \$195.0 million for the development and commercialization rights to both programs. The 2008 Agreement required Bristol-Myers Squibb to make additional license payments to us of \$45.0 million, which were received during 2009.

On June 18, 2010, we regained full rights to develop and commercialize cabozantinib under the 2008 Agreement following receipt of notice from Bristol-Myers Squibb of its decision to terminate the 2008 Agreement, solely as to cabozantinib, on a worldwide basis. Bristol-Myers Squibb informed us that the termination was based upon its review of cabozantinib in the context of Bristol-Myers Squibb s overall research and development priorities and pipeline products. On June 28, 2010, in connection with the termination, we received a \$17.0 million transition payment from Bristol-Myers Squibb in satisfaction of its obligations under the 2008 Agreement to continue to fund its share of development costs for cabozantinib for a period of three months following the notice of termination. As a result of the termination, Bristol-Myers Squibb s license relating to cabozantinib terminated and its rights to cabozantinib reverted to us, and we received, subject to certain terms and conditions,

licenses from Bristol-Myers Squibb to research, develop and commercialize cabozantinib.

We are focusing our proprietary resources and development efforts on the development of cabozantinib. However, the product candidate may fail to show adequate safety or efficacy in clinical testing. Furthermore, predicting the timing of the initiation or

completion of clinical trials is difficult, and our trials may be delayed due to many factors, including factors outside of our control. The future development path of cabozantinib depends upon the results of each stage of clinical development. We expect to incur increased expenses for the development of cabozantinib as it advances in clinical development.

With the exception of activities related to cabozantinib, we are discontinuing efforts with respect to all of our compounds and programs that are not funded by partners pursuant to collaboration agreements and are actively pursuing collaborations or other external opportunities for the continued development of these compounds and programs. Discovery and clinical activities under various collaborations are expected to continue at funded levels 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 revenues from the sale of pharmaceutical products in the near term and expect that all of our 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 that have been licensed to our partners.

#### Liquidity

As of September 30, 2011, we had \$313.1 million in cash and cash equivalents, marketable securities and long-term investments, which included restricted cash and investments of \$4.2 million and approximately \$93.6 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 filing date of this report. However, our future capital requirements will be substantial and depend on many factors, including the following:

the progress and scope of the development activity with respect to cabozantinib;

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 a 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; and

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

Our minimum liquidity needs are also determined 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 any of our product candidates fails to show adequate safety or efficacy in clinical testing.

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 for an aggregate purchase price of \$80.0 million, less closing fees and expenses of approximately \$2.0 million. The outstanding principal amount of the 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 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 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 notes (other than prepayments upon the occurrence of specified transactions relating to a change of control or a substantial sale of assets), all accrued interest that would have accrued between the date of such prepayment and the next anniversary of the note purchase agreement. In lieu of making any optional or

mandatory prepayment in cash, at any time after July 1, 2011, 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 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) with shares of our common stock. Additionally, in lieu of making any payment of accrued and unpaid interest in respect of the notes in cash, at any time after July 1, 2011, subject to certain limitations, we may elect to satisfy any such payment with shares of our common stock. The number of shares of our common stock issuable upon conversion or in settlement of principal and interest obligations will be based upon the discounted trading price of our common stock over a specified trading period. Upon certain changes of control of our company, a sale or transfer of assets in one transaction or a series of related transactions for a purchase price of more than \$400 million or a sale or transfer of more than 50% of our assets, Deerfield may require us to prepay the notes at the optional prepayment price, plus accrued and unpaid interest and any other accrued and reimbursable expenses, or the Put Price. Upon an event of default, Deerfield may declare all or a portion of the Put Price to be immediately due and payable.

We also entered into a security agreement in favor of Deerfield which provides that our obligations under the notes will be secured by substantially all of our assets except intellectual property. 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.

#### sanofi-aventis

In May 2009, we entered into a global license agreement with sanofi-aventis for XL147 and XL765 and a broad collaboration for the discovery of inhibitors of phosphoinositide-3 kinase, or PI3K, for the treatment of cancer. The license agreement and collaboration agreement became effective on July 7, 2009. In connection with the effectiveness of the license and collaboration, on July 20, 2009, we received upfront payments of \$140.0 million (\$120.0 million for the license and \$20.0 million for the collaboration), less applicable withholding taxes of \$7.0 million, for a net receipt of \$133.0 million. We expect to receive a refund payment from the French government in early 2012 with respect to the withholding taxes previously withheld.

Under the license agreement, sanofi-aventis received a worldwide exclusive license to XL147 and XL765, which are in phase 1, phase 1b/2 and phase 2 clinical trials, and has sole responsibility for all subsequent clinical, regulatory, commercial and manufacturing activities. sanofi-aventis is responsible for funding all development activities with respect to XL147 and XL765, including our activities. Following the effectiveness of the license agreement, we had been conducting the majority of the clinical trials for XL147 and XL765 at the expense of sanofi-aventis. As provided for under the license agreement, however, the parties agreed to transition all future development activities for these compounds to sanofi-aventis. The transition was substantially completed by the end of June 2011. As a result of the transition of development activities to sanofi-aventis, we expect to no longer receive reimbursements from sanofi-aventis with respect to XL147 and XL765 and we have reduced our headcount commensurately such that no further material operating expenses will be incurred in connection with these programs going forward.

Under the collaboration agreement, the parties agreed to combine efforts in establishing several pre-clinical PI3K programs and jointly share responsibility for research and preclinical activities related to isoform-selective inhibitors of PI3K-a and -ß. sanofi-aventis is required to provide us with guaranteed annual research and development funding during the research term and is responsible for funding all development activities for each product following approval of the investigational new drug application filed with the applicable regulatory authorities for such product. We are entitled to receive guaranteed research funding of \$21.0 million over three years to cover certain of our costs under the collaboration agreement. sanofi-aventis will have sole responsibility for all subsequent clinical, regulatory, commercial and manufacturing activities of any products arising from the collaboration; however, we may be requested to conduct certain clinical trials at sanofi-aventis expense. The research term under the collaboration is three years, although sanofi-aventis has the right to extend the term for an additional one-year period upon prior written notice.

Under the license agreement and the collaboration agreement combined, we are eligible to receive total development, regulatory and commercial milestones of over \$1.0 billion in the aggregate, as well as royalties on sales of any products commercialized under the license agreement or collaboration agreement.

sanofi-aventis may, upon certain prior notice to us, terminate the license as to products containing XL147 or XL765. In the event of such termination election, sanofi-aventis license relating to such product would terminate and revert to us, and we would receive, subject to certain terms, conditions and potential payment obligations, licenses from sanofi-aventis to research, develop and commercialize such products.

The collaboration will automatically terminate under certain circumstances upon the expiration of the research term, in which case all licenses granted by the parties to each other would terminate and revert to the respective party, subject to sanofi-aventis right to receive, under certain circumstances, the first opportunity to obtain a license from us to any isoform-selective PI3K inhibitor. In addition, sanofi-aventis may, upon certain prior written notice to us, terminate the collaboration in whole or as to certain products following expiration of the research term, in which case we would receive, subject to certain terms, conditions and potential payment obligations by us, licenses from sanofi-aventis to

research, develop and commercialize such products.

#### **Restructuring Plans**

During 2010, we implemented two restructuring plans that resulted in an overall reduction in our workforce by 386 employees. In March 2011, we implemented an additional restructuring plan that resulted in further terminations in 2011. Taking into consideration certain employees who have since been recalled, there has been an aggregate reduction in headcount from the 2010 and 2011 restructuring plans of 402 employees. The restructuring plans are a consequence of our decision to focus our proprietary resources and development efforts on the late-stage development and commercialization of cabozantinib. Further personnel reductions are expected to be made through the end of 2012 as we complete our obligations under collaboration agreements and withdraw resources from completed projects.

In connection with the 2010 and 2011 restructuring plans, we have recorded aggregate restructuring charges of \$38.9 million, of which \$20.4 million related to termination benefits and \$18.5 million related to facility charges and the impairment of various assets. In connection with these restructuring plans, for the nine months ended September 30, 2011, we recorded \$6.2 million in total restructuring charges, of which \$4.3 million related to lease-exit and moving costs. Our facility-related charges take into consideration our entry into two sublease agreements for portions of our building at 170 Harbor Way, South San Francisco, California, or Building 170, that we entered into in July 2011. The balance of our restructuring charges primarily related to termination benefits for employees of \$2.7 million. Additionally, we received auction proceeds from the sale of excess equipment and other assets, partially offset by impairment charges for such assets.

With respect to our restructuring plans, we expect to incur an additional restructuring charge of \$3.7 million relating to the sublease of portions of Building 170 and a building we lease at 249 East Grand Avenue, South San Francisco, California that we exited and subleased in 2010, or Building 249, plus additional restructuring charges of up to \$15 million in connection with the anticipated exit of additional facilities in South San Francisco, California. We expect to record the remaining facility-related charges, as they are determined, through the end of 2017, or the end of the building lease terms.

As of September 30, 2011, the 2010 and 2011 restructuring plans had resulted in aggregate cash expenditures of \$23.0 million, of which \$14.1 million was paid in 2010 and \$8.9 million has been paid in 2011. We expect to pay an additional \$8.0 million, net of cash received from our subtenant, for Building 249 and an additional \$6.1 million, net of cash received from our subtenants, for Building 170. In addition, we expect to make cash expenditures of \$0.7 million relating to termination benefits and up to \$18 million relating to facility costs in connection with the anticipated exit of additional facilities in South San Francisco, California. We expect the termination benefits to be paid during the fourth quarter of 2011 and the facility costs to be paid through 2017, or the end of our lease term for both Building 170 and Building 249.

The restructuring charges that we expect to incur in connection with the restructuring plans are subject to a number of assumptions, and actual results may materially differ. We may also incur other material charges not currently contemplated due to events that may occur as a result of, or associated with, the restructuring plans. See Note 5 of the Notes to Consolidated Financial Statements for a further discussion on our restructuring charges.

#### **Critical Accounting Estimates**

Our consolidated financial statements and related notes are prepared in accordance with U.S. generally accepted accounting principles which require us to make judgments, estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. We have based our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our senior management has discussed the development, selection and disclosure of these estimates with the Audit Committee of our Board of Directors. Actual results may differ from these estimates under different assumptions or conditions.

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 the following critical accounting policies reflect the more significant estimates and assumptions used in the preparation of our consolidated financial statements.

#### **Revenue Recognition**

Our revenues are derived from three primary sources: license fees, milestone payments and collaborative agreement reimbursements.

Revenues from license fees and milestone payments primarily consist of upfront license fees and milestone payments received under various collaboration agreements. We initially recognize upfront fees received from third party collaborators as unearned revenues and then recognize these amounts on a ratable basis over the expected term of the research collaboration. Therefore, any changes in the expected term of the research collaboration will impact revenue recognition for the given period. For example, in the fourth quarter of 2010, in association with the new ROR agreement with Bristol-Myers Squibb, the estimated research term under our 2007 cancer collaboration with Bristol-Myers Squibb was extended from December 2011 until April 2014, resulting in an extension in the period over which we recognized milestone revenues and a decrease in the milestone revenues recognized each quarter. Often, the total research term is not contractually defined and an estimate of the term of our total obligation must be made. For example, under the 2008 Agreement with Bristol-Myers Squibb, we originally estimated our term to be through August 2013, which is the estimated term of our performance obligations for XL281. We estimated that this would be the period over which we would be obligated to perform services and therefore the appropriate term with which to ratably recognize any license fees. During the fourth quarter of 2010, this estimate was extended to April 2014 as a result of the decision with Bristol-Myers Squibb to complete additional phase 1 trial programs for XL281. On July 8, 2011, we received written notification from Bristol-Myers Squibb of its decision to terminate the 2008 Agreement in its entirety. As a result of the termination of the 2008 Agreement, the estimated research term was revised to end on October 8, 2011. Accordingly, we accelerated the remaining deferred revenue balance through the revised end of the research term and recognized \$109.9 million in revenue during the quarter ended September 30, 2011. We expect to recognize the remaining \$10.4 million in revenue in the fourth quarter of 2011. License fees are classified as license revenues in our consolidated statement of operations.

Although milestone payments are generally non-refundable once the milestone is achieved, we recognize milestone revenues on a straight-line basis over the expected research term of the arrangement. This typically results in a portion of a milestone being recognized on the date the milestone is achieved, with the balance being recognized over the remaining research term of the agreement. In certain situations, we may receive milestone payments after the end of our period of continued involvement. In such circumstances, we would recognize 100% of the milestone revenues when the milestone is achieved. Milestones are classified as contract revenues in our consolidated statement of operations.

Collaborative agreement reimbursement revenues consist of research and development support received from collaborators and are recorded as earned based on the performance requirements by both parties under the respective contracts. Under the 2008 Agreement with Bristol-Myers Squibb and prior to its termination by Bristol-Myers Squibb as to cabozantinib, both parties were actively involved with compound development and certain research and development expenses were partially reimbursable to us. On an annual basis, amounts owed by Bristol-Myers Squibb to us, net of amounts reimbursable to Bristol-Myers Squibb by us for the development of cabozantinib and XL281, were recorded as collaboration reimbursement revenues. Conversely, research and development expenses would include the net settlement of amounts we owed Bristol-Myers Squibb for research and development expenses that Bristol-Myers Squibb incurred in connection with the development of cabozantinib, less amounts reimbursable to us by Bristol-Myers Squibb for the development of both cabozantinib and XL281. In annual periods when net research and development funding payments were payable to Bristol-Myers Squibb, these payments were presented as collaboration cost-sharing expenses. Reimbursements under co-development agreements were classified as collaboration reimbursement revenues, while reimbursements under other arrangements were classified as contract revenues in our consolidated statement of operations.

As a result of the termination of the 2008 Agreement with Bristol-Myers Squibb, which became effective on October 8, 2011, for the period ended September 30, 2011, reimbursement payments were presented as collaboration reimbursement revenues and will continue to be presented as such through the period ending December 31, 2011 at which point we do not expect to record any further collaboration cost-sharing expense or collaboration reimbursement revenues under our current collaborations. See Note 4 of the Notes to the Consolidated Financial Statements for further information on our 2008 Agreement with Bristol-Myers Squibb.

Some of our research and licensing arrangements have multiple deliverables in order to meet our customer s needs. For example, the arrangements may include a combination of intellectual property rights and research and development services. Multiple element revenue agreements are evaluated to determine whether the delivered item has value to the customer on a stand-alone basis and whether objective and reliable evidence of the fair value of the undelivered item exists. Deliverables in an arrangement that do not meet the separation criteria are treated as one unit of accounting for purposes of revenue recognition. Generally, the revenue recognition guidance applicable to the final deliverable is followed for the combined unit of accounting. For certain arrangements, the period of time over which certain deliverables will be provided is not contractually defined. Accordingly, management is required to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. For example, in 2008, under our collaboration with GlaxoSmithKline, we accelerated \$18.5 million in previously deferred revenue as a result of the development term concluding on the earliest scheduled end date of October 27, 2008, instead of the previously estimated end date of October 27, 2010.

# **Clinical Trial Accruals**

All of our clinical trials have been performed by third-party contract research organizations, or CROs, and other vendors. We accrue costs for clinical trial activities performed by CROs based upon the estimated amount of work completed on each trial. For

clinical trial expenses, the significant factors used in estimating accruals include the number of patients enrolled, the number of active clinical sites, and the duration for which the patients will be enrolled in the trial. We monitor patient enrollment levels and related activities to the extent possible through internal reviews, correspondence with CROs and review of contractual terms. We base our estimates on the best information available at the time. However, additional information may become available to us which will allow us to make a more accurate estimate in future periods. In this event, we may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain. Such increases or decreases in cost are generally considered to be changes in estimates and will be reflected in research and development expenses in the period first known.

#### Stock Option Valuation

Our estimate of compensation expense requires us to determine the appropriate fair value model and a number of complex and subjective assumptions including our stock price volatility, employee exercise patterns, future forfeitures and related tax effects. The most significant assumptions are our estimates of the expected volatility and the expected term of the award. We have limited historical information available to support the underlying estimates of certain assumptions required to value stock options. The value of a stock option is derived from its potential for appreciation. The more volatile the stock, the more valuable the option becomes because of the greater possibility of significant changes in stock price. Because there is a market for options on our common stock, we have considered implied volatilities as well as our historical realized volatilities when developing an estimate of expected volatility. The expected option term also has a significant effect on the value of the option. The longer the term, the more time the option holder has to allow the stock price to increase without a cash investment and thus, the more valuable the option. Further, lengthier option terms provide more opportunity to exploit market highs. However, empirical data shows that employees, for a variety of reasons, typically do not wait until the end of the contractual term of a nontransferable option to exercise. Accordingly, companies are required to estimate the expected term of the option for input to an option-pricing model. As required under the accounting rules, we review our valuation assumptions at each grant date and, as a result, from time to time we will likely change the valuation assumptions we use to value stock based awards granted in future periods. The assumptions used in calculating the fair value of share-based payment awards represent management s best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our stock-based compensation expense could be materially different in the future. In addition, we are required to estimate the expected forfeiture rate and recognize expense only for those shares expected to vest. If our actual forfeiture rate is materially different from our estimate, the stock-based compensation expense could be significantly different from what we have recorded in the current period. As of September 30, 2011, \$12.1 million of total unrecognized compensation expense related to stock options was expected to be recognized over a weighted-average period of 2.77 years in addition to \$7.2 million of total unrecognized compensation expense relating to restricted stock units, which was expected to be recognized over 2.85 years. See Note 3 of the Notes to Consolidated Financial Statements for a further discussion on stock-based compensation.

#### **Restructuring Charges**

We record costs and liabilities associated with exit and disposal activities at fair value in the period in which the cost or liability is incurred. Restructuring charges consist of charges related to employee severance and benefits, lease termination costs, equipment write-downs and other restructuring related charges. Charges related to employee severance and benefits are determined based on the estimated severance and fringe benefit charge for identified employees. Our facility charges are based upon our ability to vacate certain of our facilities and the timing and nature of potential future sublease rates. Based on our future equipment needs, we have disposed of certain assets no longer in use and recorded a charge to impair the book value to an amount relative to our expected future use of the remaining assets.

If the actual amounts differ from our estimates, the amount of restructuring charges could be materially impacted. See Note 5 of the Notes to Consolidated Financial Statements for a further discussion on our restructuring plans.

#### **Fiscal Year Convention**

We have adopted a 52- or 53-week fiscal year that ends on the Friday closest to December 31<sup>st</sup> of each year. Fiscal year 2010, a 52-week year, ended on December 31, 2010, and fiscal year 2011, a 52-week year, will end on December 30, 2011. For convenience, references in this report as of and for the fiscal quarters ended October 1, 2010 and September 30, 2011 and as of the fiscal year ending December 30, 2011 are indicated as ended September 30, 2010 and 2011 and as ending December 31, 2011, respectively.

#### **Results of Operations**

#### Revenues

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

	e Months End 2011	-	mber 30, 2010	Months En 2011	ded Sep	tember 30, 2010
Contract revenue:						
Research and development funding	\$ 0.6	\$	10.5	\$ 14.0	\$	32.6
Milestones	4.5		1.4	11.7		11.4
License revenue and amortization of upfront payments	122.7		24.5	168.0		73.6
Collaboration reimbursements	0.5		18.1	2.6		26.7
Total revenues	\$ 128.3	\$	54.5	\$ 196.3	\$	144.3
Dollar increase	\$ 73.8			\$ 52.0		
Percentage increase	135%			36%		

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

	e Months En 2011	ded September 30, 2010	Nine Months Ender 2011	d September 30, 2010
Bristol-Myers Squibb	\$ 119.0	\$ 34.6	\$ 153.3	\$ 75.9
sanofi-aventis	9.3	19.2	40.3	58.6
Genentech			2.0	7.0
Boehringer Ingelheim		0.7	0.7	2.8
Total revenues	\$ 128.3	\$ 54.5	\$ 196.3	\$ 144.3
Dollar decrease	\$ 73.8		\$ 52.0	
Percentage increase	135%		36%	

The increase in revenues for the three and nine months ended September 30, 2011, as compared to the comparable periods for the prior year, was primarily due to the acceleration of license revenue as a result of the July 2011 termination of our 2008 Agreement with Bristol Myers-Squibb which became effective on October 8, 2011. This increase was partially offset by a decline in collaboration reimbursement revenue and research funding related to the termination of our 2008 Agreement with Bristol Myers-Squibb and the transfer of substantially all development activities pertaining to XL147 and XL765 under our 2009 collaboration agreement with sanofi-aventis. Furthermore, there was a decline in revenue relating to the one-time milestone payments made by Genentech of \$2.0 million in 2011 for the Notch agreement and \$7.0 million in 2010 for the MEK agreement.

Total collaboration reimbursement revenue consisted of research and development expenses and reimbursements related to our 2008 Agreement with Bristol Myers-Squibb for cabozantinib and XL281. To the extent that net annual research and development funding payments were expected to be received from Bristol-Myers Squibb, these payments would have been presented as collaboration reimbursement revenues. In years when net research and development funding payments were expected to be payable to Bristol-Myers Squibb, these payments would have been presented as collaboration cost-sharing expense. As a result of the complete termination of the 2008 Agreement with Bristol-Myers Squibb, which became effective on October 8, 2011, we do not expect any further collaboration reimbursement revenues or collaboration cost-sharing expenses to be recorded with respect to this agreement for either cabozantinib or XL281.

#### **Research and Development Expenses**

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

	Three Mont	hs Ended September 30	), Nine Months Ei	Nine Months Ended September 30,		
	2011	2010	2011	2010		
Research and development expenses	\$ 37.5	\$ 49.4	\$ 126.1	\$ 168.4		
Dollar decrease	\$ 11.9		\$ 42.3			
Percentage decrease	24	%	25%			

The decrease for the three and nine months ended September 30, 2011, as compared to the comparable periods in 2010, resulted primarily from the following:

Personnel Personnel expense, which includes salaries, bonuses, related fringe benefits, recruiting and relocation costs, decreased by \$4.5 million, or 39%, and \$17.3 million, or 41%, respectively, primarily due to the reduction in headcount resulting from our 2010 and 2011 restructuring plans.

General Corporate Costs There was a decrease of \$1.6 million, or 20%, and \$6.2 million, or 22%, respectively, in the allocation of general corporate costs (such as facility costs, property taxes and insurance) to research and development, primarily as a result of a decrease in personnel and the exit of certain facilities in San Diego and South San Francisco, as a result of our 2010 and 2011 restructuring plans, and the resulting decrease in costs to be allocated.

Laboratory Supplies Laboratory supplies decreased by \$1.2 million, or 73%, and \$5.7 million, or 79%, respectively, primarily due to the decrease in headcount and other cost cutting measures as a result of our 2010 and 2011 restructuring plans.

Stock-Based Compensation Stock-based compensation expense decreased by \$1.1 million, or 44%, and \$4.6 million, or 50%, respectively, as a result of our reduction in headcount from our 2010 and 2011 restructuring plans.

Clinical Trial Costs Clinical trial expenses, which include services performed by third-party contract research organizations and other vendors, decreased by \$2.2 million, or 11%, and \$4.1 million, or 6%, respec