



## Exelixis Announces Third Quarter 2012 Financial Results

November 7, 2012

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 7, 2012-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the quarter ended September 30, 2012.

During the quarter, Exelixis continued to advance the COMET-1 and COMET-2 phase 3 pivotal trials of cabozantinib in patients with metastatic castration-resistant prostate cancer (mCRPC). In August 2012, the company completed concurrent public offerings of common stock and 4.25% convertible senior subordinated notes due 2019, generating net proceeds of \$416.1 million.

**Revenues** for the quarter ended September 30, 2012 were \$13.3 million, compared to \$128.3 million for the comparable period in 2011. This decrease is primarily due to the acceleration of license revenue as a result of the termination of the company's agreement with Bristol Myers-Squibb Company for XL281 in October 2011, the transfer in April 2011 of substantially all development activities pertaining to XL147 and XL765 to Sanofi and the termination in December 2011 of the company's PI3K discovery collaboration with Sanofi. The decreases in revenue were partially offset by a milestone payment of \$5.5 million received in August 2012 under the company's collaboration with Daiichi Sankyo for XL550.

**Research and development expenses** for the quarter ended September 30, 2012 were \$30.7 million, compared to \$37.5 million for the comparable period in 2011. The decrease of approximately 18% is primarily due to the completion of various clinical pharmacology studies that occurred in 2011 in support of the company's new drug application (NDA) filing for unresectable, locally advanced, or metastatic medullary thyroid cancer (MTC), the wind down of the company's randomized discontinuation trial for cabozantinib as well as the gradual wind down of EXAM, the company's phase 3 pivotal trial for cabozantinib in progressive MTC. These decreases in clinical trial expenses were partially offset by an increase in costs primarily related to clinical trial activities for the COMET-1 and COMET-2 phase 3 pivotal trials in mCRPC. Personnel costs, stock-based compensation, and general corporate costs were lower for the quarter ended September 30, 2012 compared to the same period in 2011 as a result of the company's 2010, 2011 and 2012 restructurings.

**General and administrative expenses** for the quarter ended September 30, 2012 were \$7.3 million, compared to \$8.2 million for the comparable period in 2011. The decrease of approximately 10% is primarily due to a decrease in facility and personnel costs, depreciation and amortization and stock-based compensation relating to the company's 2010, 2011 and 2012 restructurings. These decreases were offset by an increase in costs associated with pre-commercialization activities.

**Restructuring charge** for the quarter ended September 30, 2012 was \$0.7 million, compared to \$2.9 million for the comparable period in 2011. The restructuring charge for the quarter ended September 30, 2012 was primarily related to termination benefits in connection with a workforce reduction of approximately 20 employees implemented in May 2012 as a result of the company's continued focus on the late-stage development and commercialization of cabozantinib.

**Other income (expense), net** for the quarter ended September 30, 2012 was a net expense of (\$7.4) million compared to (\$1.8) million in the quarter ended September 30, 2011. The increase in expense in 2012 compared to 2011 was primarily due to interest expense in connection with the \$287.5 million aggregate principal amount of 4.25% convertible senior subordinated notes due 2019 issued in August 2012. Included in interest expense for the quarter ended September 30, 2012 was (\$4.1) million of non-cash expense related to the accretion of the discount on both the 4.25% convertible senior subordinated notes due 2019 and the Deerfield financing.

**Net (loss) income** for the quarter ended September 30, 2012 was (\$32.8) million, or (\$0.20) per share, compared to \$77.9 million, or \$0.60 per share, basic, for the comparable period in 2011. The net loss was primarily due to decreases in revenues, as described above, partially offset by reductions in research and development and general and administrative expenses.

**Cash** and cash equivalents, marketable securities, short- and long-term restricted cash and investments and long-term investments totaled \$674.7 million at September 30, 2012, compared to \$283.7 million at December 31, 2011.

### Q3 2012 Highlights and Recent Events

- Presented additional cabozantinib data at the European Society for Medical Oncology (ESMO) 2012 Congress.
- Continued to advance both COMET-1 and COMET-2 trials, with continued clinical trial site activation and patient enrollment in both studies.
- Presentation of preliminary results from BRIM7, an ongoing phase 1b trial conducted by Roche and Genentech, Exelixis' collaborator and a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY), of the BRAF inhibitor (BRAFi) vemurafenib in combination with the MEK inhibitor GDC-0973 (XL518) in patients with locally advanced/unresectable or metastatic melanoma carrying a BRAF<sup>V600</sup> mutation.
- Raised net proceeds of \$416.1 million through concurrent offerings of common stock and 4.25% convertible senior subordinated notes due 2019.

"We believe that the data presented at ESMO and the advancement of the COMET programs continued the momentum and the enthusiasm around cabozantinib in the oncology community as we move toward our Prescription Drug User Fee Act (PDUFA) date," said Michael M. Morrissey, Ph.D.,

president and chief executive officer of Exelixis. "We are also pleased with the continued progress of GDC-0973 (XL518). Given our profit share arrangement and option to co-promote under our collaboration agreement with Genentech, GDC-0973 represents a significant opportunity for Exelixis in addition to our cabozantinib franchise."

### Update to Financial Outlook

Exelixis is updating its financial guidance for the full year 2012 by decreasing its operating expense guidance to a range of \$160.0 million to \$180.0 million from a range of \$190.0 million to \$220.0 million. The decrease is related to lower than expected expenses for the COMET trials, lower than expected expenses for the EXAM phase 3 pivotal trial and the phase 2 randomized discontinuation trial as these trials wind-down and greater than expected savings across various other expense items, including personnel, rent, utilities, and legal fees. Exelixis is also increasing its expected year-end cash and cash equivalents, marketable securities, short- and long-term restricted cash and investments and long-term investments balance to at least \$600.0 million from at least \$200.0 million principally to account for the proceeds of the company's financing activities during the third quarter 2012. Exelixis continues to expect year-end revenues in the range of \$40.0 million to \$60.0 million.

### Conference Call and Webcast

Exelixis' management will discuss the company's financial results for the quarter ended September 30, 2012, financial outlook and development program and plans for cabozantinib, and also provide a general business update, during a conference call beginning at 5:00 p.m. EST/2:00 p.m. PST today, Wednesday, November 7, 2012. To listen to a live webcast of the discussion, visit the Event Calendar page under Investors at [www.exelixis.com](http://www.exelixis.com).

An archived replay of the webcast will be available on the Event Calendar page under Investors at [www.exelixis.com](http://www.exelixis.com) and via phone until 11:59 p.m. PST on December 7, 2012. Access numbers for the phone replay are: 888-286-8010 (domestic) and 617-801-6888 (international); the passcode is 43220636.

### About Exelixis

Exelixis, Inc. is a biotechnology company committed to developing small molecule therapies for the treatment of cancer. Exelixis is focusing its proprietary resources and development efforts exclusively on cabozantinib (formerly known as XL184), its most advanced product candidate, in order to maximize the therapeutic and commercial potential of this compound. Exelixis has also established a portfolio of other novel compounds that it believes have the potential to address serious unmet medical needs, many of which are being advanced by partners as part of collaborations. For more information, please visit the company's web site at [www.exelixis.com](http://www.exelixis.com).

### Basis of Presentation

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

### Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to: the continued development and clinical, therapeutic and commercial potential of cabozantinib and GDC-0973 (XL518); potential future regulatory approval of cabozantinib and the timing thereof; the plan of Genentech and Exelixis to share U.S. profits and losses for GDC-0973 (XL518); Exelixis' option to co-promote GDC-0973 (XL518); other expected benefits to Exelixis under its collaboration agreement with Genentech for GDC-0973 (XL518); and Exelixis' updated financial outlook for 2012, including expected revenues and operating expenses and 2012 year-end cash and cash equivalents, marketable securities, short- and long-term restricted cash and investments and long-term investments balance. Words such as "believe," "continued," "move toward," "opportunity," "outlook," "guidance," "expect," "potential," and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Exelixis' current plans, assumptions, beliefs and expectations. Forward-looking statements involve risks and uncertainties. Exelixis' actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation: risks related to the potential failure of cabozantinib and GDC-0973 (XL518) to demonstrate safety and efficacy in clinical testing; Exelixis' ability to conduct clinical trials of cabozantinib sufficient to achieve a positive completion; Exelixis' dependence on its relationship with Genentech/Roche with respect to GDC-0973 (XL518) and Exelixis' ability to maintain its rights under the collaboration; the sufficiency of Exelixis' capital and other resources; the uncertain timing and level of expenses associated with the development of cabozantinib; the uncertainty of the FDA approval process; market competition; and changes in economic and business conditions. These and other risk factors are discussed under "Risk Factors" and elsewhere in Exelixis' quarterly report on Form 10-Q for the quarter ended September 28, 2012, filed with the Securities and Exchange Commission (SEC) on November 7, 2012, and Exelixis' other filings with the SEC. Exelixis expressly disclaims any duty, obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Exelixis' expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

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

<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
<b>September 30,</b>		<b>September 30,</b>	
<b>2012</b>	<b>2011</b>	<b>2012</b>	<b>2011</b>

Revenues:

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

**EXELIXIS, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEET DATA**  
(in thousands)

	<b>September 30, 2012</b>	<b>December 31, 2011 (1)</b>
	(unaudited)	
Cash and cash equivalents, marketable securities, short- and long-term restricted cash and investments and long-term investments (2)	\$ 674,708	\$ 283,721
Working capital	\$ 407,980	\$ 136,499
Total assets	\$ 762,613	\$ 393,262
Total stockholders' equity	\$ 340,845	\$ 90,632

(1) Derived from the audited consolidated financial statements.

(2) Short- and long-term restricted cash and investments consist of \$40.2 million and \$4.2 million as of September 30, 2012 and December 31, 2011, respectively.



Source: Exelixis, Inc.

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