



Exelixis Announces Third Quarter 2011 Financial Results

October 27, 2011

SOUTH SAN FRANCISCO, Calif., Oct 27, 2011 (BUSINESS WIRE) --

Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the third quarter ended September 30, 2011.

Revenues for the quarter ended September 30, 2011 were \$128.3 million, compared to \$54.5 million for the comparable period in 2010. The increase was primarily due to the acceleration of deferred license revenue as a result of the notice of early termination received in July 2011 of our 2008 collaboration agreement for the development of XL281 with Bristol Myers-Squibb Company on a worldwide basis. This increase was partially offset by a decline in reimbursement revenues associated with the transfer in 2011 of substantially all development activities pertaining to XL147 and XL765 under our 2009 collaboration agreement with sanofi-aventis.

Research and development expenses for the quarter ended September 30, 2011 were \$37.5 million compared to \$49.4 million for the comparable period in 2010. The decrease primarily reflected the reduction in personnel costs, laboratory costs and general corporate costs as a result of restructuring plans we implemented in 2010 and 2011. In addition, clinical trial expenses continued to decrease as a result of the discontinuation of trials for compounds other than cabozantinib.

General and administrative expenses for the quarter ended September 30, 2011 were \$8.2 million compared to \$9.0 million for the comparable period in 2010. The decrease was primarily due to a decrease in facility and personnel costs as a result of the restructuring plans we implemented in 2010 and 2011. This decrease was partially offset primarily by a decrease in allocation of general corporate costs to research and development as a result of our 2010 and 2011 restructuring plans.

Restructuring expenses for the quarter ended September 30, 2011 were \$2.9 million compared to \$0.3 million for the comparable period in 2010. The restructuring charge in 2011 primarily relates to the exiting of additional office and lab space in South San Francisco, offset by income from subleases entered into during 2011. The restructuring charges in 2010 relate primarily to termination benefits. We expect to incur additional restructuring charges in 2011, mainly driven by the ongoing consolidation of our real estate footprint.

Other income (expense) for the quarter ended September 30, 2011 was (\$1.8) million compared to (\$4.5) million for the comparable period in 2010. The change in total other income for the quarter ended September 30, 2011, as compared to the comparable period in 2010, was primarily due to the recognition of a gain of \$2.2 million relating to the sale of our remaining 19.9% equity interest in our former German subsidiary TaconicArtemis GmbH (formerly known as Artemis Pharmaceuticals GmbH).

Net income (loss) for the quarter ended September 30, 2011 was income of \$77.9 million, or \$0.60 earnings per share, basic, compared to a loss of (\$8.6) million, or a loss of (\$0.08) per share, basic, for the comparable period in 2010. The change from a loss to income in 2011 is primarily related to the acceleration of deferred revenue recognized in connection with the 2011 termination of our collaboration agreement with Bristol Myers-Squibb for XL281 in addition to lower operating expenses in connection with our 2010 and 2011 restructuring plans.

Cash and cash equivalents, marketable securities, long-term investments and restricted cash and investments totaled \$313.1 million at September 30, 2011, compared to \$256.4 million at December 31, 2010.

Q3 2011 Highlights and Recent Events

- Reported top-line results for the pivotal EXAM trial in medullary thyroid cancer. Top-line results show that cabozantinib significantly improved median PFS by 7.2 months compared with placebo (a 2.8-fold increase). The median PFS on the cabozantinib arm was 11.2 months versus 4.0 months on the placebo arm; hazard ratio 0.28, (95% CI 0.19, 0.40), $p < 0.0001$. Safety was consistent with other cabozantinib trials reported to date.
- Submitted and had five abstracts accepted for presentation at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, which will be held in San Francisco, November 12-16, 2011.
- Elected to repay the third and final installment of our loan from GlaxoSmithKline 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.
- Hired J. Scott Garland as executive vice president and chief commercial officer to oversee all commercialization, sales and marketing efforts for cabozantinib. Garland comes to Exelixis from Genentech, where, since 2009, he served as vice president of the Avastin franchise.
- Exercised our contractual right to sell our remaining 19.9% stake in our former German subsidiary TaconicArtemis GmbH.

We expect to receive feedback from the United States Food and Drug Administration (FDA) shortly with respect to our special protocol assessment (SPA) submission for our planned XL184-306 pivotal trial in metastatic castration-resistant prostate cancer (CRPC) and its acceptability to support a

regulatory filing if the trial is successful and the resultant data are positive. We are actively planning to initiate the '306 pivotal trial this year and have selected clinical trial sites and vendors to enable the trial to start before the end of 2011.

"We have made significant progress this quarter in transforming our organization into a late-stage development and commercial company," said Michael M. Morrissey, Ph.D., president and chief executive officer. "For Exelixis, the importance of the positive top-line EXAM data is clear: cabozantinib is the first compound, solely discovered and developed at Exelixis, to progress through early development and show success in a randomized phase 3 pivotal trial. We look forward to receiving FDA feedback on the SPA and to initiating our first phase 3 pivotal trial in CRPC."

Update to Financial Outlook

Our full year financial guidance for revenues and operating expenses remains unchanged in the range of \$220.0 to \$250.0 million and \$190.0 to \$220.0 million, respectively. However, we are updating our financial guidance for the full year 2011 by decreasing our expected year-end cash and cash equivalents, marketable securities, restricted cash and investments and long-term investments to approximately \$300.0 million. The decrease is primarily related to our decision to extend the timeline for the evaluation of a potential transaction for Asian rights to cabozantinib, which we believe will allow us to best realize cabozantinib's commercial potential and create value for shareholders by leveraging the recent and upcoming cabozantinib clinical and regulatory milestones.

Conference Call and Webcast

Exelixis' management will discuss the company's financial results for the quarter ended September 30, 2011, financial guidance for 2011, and development program and plans for cabozantinib, and also provide a general business update, during a conference call beginning at 2:00 p.m. PDT/ 5:00 p.m. EDT today, Thursday, October 27, 2011. To listen to a live webcast of the discussion, visit the Event Calendar page under Investors at www.exelixis.com.

An archived replay of the webcast will be available on the Event Calendar page under Investors at www.exelixis.com and via phone until 11:59 p.m. EST on November 27, 2011. Access numbers for the phone replay are: 888-286-8010 (domestic) and 617-801-6888 (international); the passcode is 64691635.

About Exelixis

Exelixis, Inc. is a biotechnology company committed to developing small molecule therapeutics for the treatment of cancer. Exelixis is focusing its proprietary resources and development efforts exclusively on cabozantinib, its most advanced solely-owned product candidate, in order to maximize the therapeutic and commercial potential of this compound. Exelixis believes cabozantinib has the potential to be a high-quality, differentiated pharmaceutical product that can make a meaningful difference in the lives of patients. Exelixis has also established a portfolio of other novel compounds that it believes have the potential to address serious unmet medical needs. For more information, please visit the company's web site at www.exelixis.com.

Basis of Presentation

Exelixis has adopted a 52- or 53-week fiscal year that ends on the Friday closest to December 31st. For convenience, references in this press release as of and for the fiscal year ended December 31, 2010 are indicated on a calendar year basis, ended December 31, 2010 and 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. Certain reclassifications of prior period amounts have been made to our consolidated financial statements to conform to the current period presentation.

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; expected additional restructuring charges in 2011; upcoming data presentations; the timing for receiving feedback from the FDA regarding Exelixis' SPA submission for its planned XL184-306 trial and its acceptability to support a regulatory filing if the trial is successful and the resultant data are positive; the expected timing for the initiation of the XL184-306 trial; the transformation of Exelixis into a late-stage development and commercial stage company; Exelixis' updated financial outlook for 2011, including expected revenues and operating expenses and 2011 year-end cash and cash equivalents, marketable securities, restricted cash and investments and long-term investments balance; and the decision to extend the timeline for the evaluation of a potential transaction for Asian rights to cabozantinib and the belief that doing so will allow Exelixis to best realize cabozantinib's commercial potential and create value for shareholders by leveraging the recent and upcoming cabozantinib clinical and regulatory milestones. Words such as "expect," "will," "planned," "transformation," "look forward," "outlook," "guidance," "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 to demonstrate safety and efficacy in clinical testing; Exelixis' ability to conduct clinical trials of cabozantinib sufficient to achieve a positive completion; the availability of data at the referenced times; the sufficiency of Exelixis' capital and other resources; unanticipated restructuring charges not currently contemplated that may occur as a result of Exelixis' restructuring plans; the uncertain timing and level of expenses associated with the development of cabozantinib; the uncertainty of the FDA approval process; timely receipt of potential reimbursements, milestones, royalties and profits under Exelixis' collaborative agreements; Exelixis' ability to enter into new collaborations; 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 30, 2011 and Exelixis' other filings with the Securities and Exchange Commission. 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.

CONSOLIDATED STATEMENT OF OPERATIONS DATA

(in thousands, except per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Revenues:				
Contract	\$ 5,024	\$ 11,865	\$ 25,761	\$ 43,915
License	122,703	24,542	167,984	73,648
Collaboration reimbursement	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 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)	(1,834)	(4,470)	(8,560)	2,750
Consolidated income (loss) before taxes	77,865	(8,675)	29,401	(74,357)
Income tax benefit (provision)	--	72	--	72
Net income (loss)	\$ 77,865	\$ (8,603)	\$ 29,401	\$ (74,465)
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	131,296	108,667	129,149	108,373
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)

EXELIXIS, INC.

CONSOLIDATED BALANCE SHEET DATA

(in thousands)

	September 30, December 31, 2011 2010 (1)	
	(unaudited)	
Cash and cash equivalents, marketable securities and long-term investments (2)	\$ 313,144	\$ 256,377
Working capital	\$ 78,259	\$ (16,455)
Total assets	\$ 411,636	\$ 360,790
Total stockholders' equity (deficit)	\$ 3,054	\$ (228,325)

(1) Derived from the audited consolidated financial statements.

(2) These amounts include restricted cash and investments of \$4.2 million and \$6.4 million as of September 30, 2011 and December 31, 2010, respectively.

SOURCE: Exelixis, Inc.

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