



Exelixis Announces First Quarter 2012 Financial Results

May 3, 2012

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May. 3, 2012-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the quarter ended March 31, 2012.

The financial results for the quarter reflect Exelixis' successful transition to a company focused on the cabozantinib development program, which encompasses phase 3 pivotal trials in medullary thyroid cancer (MTC) and metastatic castration-resistant prostate cancer (CRPC), as well as other clinical trials evaluating cabozantinib's potential in other tumor indications.

Revenues for the quarter ended March 31, 2012 were \$18.5 million, compared to \$35.9 million for the comparable period in 2011. This decrease is primarily due to the transfer of substantially all development activities pertaining to XL147 and XL765 to Sanofi in April 2011, the termination of our PI3K discovery collaboration with Sanofi in December 2011 and the termination of our agreement with Bristol Myers-Squibb for XL281 in October 2011. The decrease in revenues was partially offset by \$10.7 million in revenue recognized under our license agreement with Merck for our PI3K program signed in December 2011.

Research and development expenses for the quarter ended March 31, 2012 were \$33.1 million, compared to \$45.7 million for the comparable period in 2011. The decrease of approximately 28% is primarily due to lower clinical trial expenses as a result of the transfer of XL147 and XL765 to Sanofi described above as well as the gradual wind down of EXAM, our phase 3 pivotal trial for cabozantinib in MTC, for which we expect to complete our new drug application (NDA) submission in the second quarter of 2012. These decreases in clinical trial expenses were partially offset by an increase in costs related to clinical trial activities for our COMET-2 phase 3 pivotal trial in metastatic CRPC and costs in preparation for the initiation of our COMET-1 phase 3 pivotal trial in metastatic CRPC. Personnel costs, stock-based compensation, and general corporate costs were lower for the quarter ended March 31, 2012 compared to the comparable period in 2011 as a result of our 2010 and 2011 restructurings.

General and administrative expenses for the quarter ended March 31, 2012 were \$7.9 million, compared to \$9.2 million for the comparable period in 2011. The decrease in general and administrative expenses was primarily due to a decrease in rent, utilities and equipment, personnel costs, and stock compensation resulting from our 2010 and 2011 restructurings. These decreases were partially offset by a decrease in allocation of general corporate costs to research and development as a result of the reduction in research and development headcount from our 2010 and 2011 restructurings.

Restructuring (credit) charge for the quarter ended March 31, 2012 was \$(0.2) million, compared to \$4.8 million for the comparable period in 2011. The restructuring credit for the quarter ended March 31, 2012 was primarily due to asset auctions and direct sales of previously impaired assets, partially offset by facility-related charges due to the exit of all or portions of three of our South San Francisco buildings. For the comparable period in 2011 the restructuring charge related primarily to facility charges associated with the exit and sublease of portions of one of our South San Francisco buildings.

Other income (expense), net for the quarter ended March 31, 2012 was \$(3.8) million, which was approximately the same as the amount for 2011, reflecting the absence of any significant changes in interest income, interest expense or other income (expense) between the periods.

Net loss for the quarter ended March 31, 2012 was \$(26.2) million, or \$(0.18) per share, compared to \$(27.5) million, or \$(0.24) per share, for the comparable period in 2011. The decrease in net loss was primarily due to the reductions in research and development, general and administrative, and restructuring expenses, partially offset by decreases in revenue, as described above.

Cash and cash equivalents, marketable securities, restricted cash and investments and long-term investments totaled \$332.1 million at March 31, 2012, compared to \$283.7 million at December 31, 2011.

Q1 2012 Highlights and Recent Developments

- Continued enrollment in COMET-2, a phase 3 pivotal trial in metastatic CRPC focused on pain palliation and narcotic reduction, and finalized plans to initiate COMET-1, a phase 3 pivotal trial in metastatic CRPC focused on overall survival, in the second quarter 2012.
- Reported positive preliminary data for cabozantinib from the cohort of patients with hepatocellular carcinoma (HCC) participating in our phase 2 randomized discontinuation trial. The Week 12 disease control rate (PR and SD at Week 12) was 68%, and objective tumor regression was observed in 78% of patients. Median progression-free survival (PFS) was 4.2 months, and was similar for sorafenib-pretreated and sorafenib-naïve patients.
- Reported preliminary data for cabozantinib from a heavily pretreated cohort of patients with metastatic refractory renal cell carcinoma (RCC) from a phase 1b clinical trial. Seven of 25 patients (28%) had a confirmed partial response (per RECIST criteria) as their best overall response, and tumor regression was observed in 19 of 21 patients (90%) with >1 post-baseline assessment. The rate of disease control at Week 16 for all 25 patients was 72%, and median progression-free survival was 14.7 months.
- Completed an underwritten public offering of 12,650,000 shares of common stock, raising net proceeds of approximately

\$65 million after deducting the underwriting discount and estimated offering expenses.

- Publication of peer-reviewed preclinical data demonstrating that simultaneous inhibition of MET and VEGF-pathway signaling by cabozantinib reduces tumor invasiveness and metastasis in preclinical models of cancer. The findings, which were made in the laboratory of Dr. Donald M. McDonald at the University of California, San Francisco Comprehensive Cancer Center, were published in the March 1, 2012 issue of *Cancer Discovery*, a journal of the American Association for Cancer Research.
- Announced the initiation of a phase 1 dose-finding trial of cabozantinib in combination with abiraterone in men with metastatic CRPC through our investigator-sponsored trial program.
- Announced that cabozantinib will be the subject of nine presentations at the upcoming Annual Meeting of the American Society of Clinical Oncology (ASCO) to be held June 1-5, 2012, in Chicago, Illinois. Investigators will present updated data from a variety of trials including EXAM, our phase 3 pivotal trial in MTC; the CRPC, hepatocellular cancer, melanoma, and non-small cell lung cancer cohorts of our phase 2 randomized discontinuation trial; and the RCC cohort from our phase 1b clinical trial.
- Announced the approval of an initial program of twelve proposed clinical trials under our Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute's Cancer Therapy Evaluation Program (NCI-CTEP). The proposed trials approved include multiple randomized and non-randomized phase 2 clinical trials, phase 2 signal search trials and earlier stage studies.

"The first quarter of 2012 was a productive one for Exelixis, with important progress on all components of the business, including advancing both the MTC NDA filing and the COMET pivotal trials for metastatic CRPC," said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. "Even as we advanced our MTC and CRPC programs internally, we continued to lay the groundwork for an emerging cabozantinib franchise through data presentations in HCC and RCC, as well as the announcement of the approved initial slate of NCI-sponsored trials in a variety of other indications. With nine data abstracts having been accepted for presentation, we expect that the upcoming ASCO Annual Meeting will be an important opportunity to further demonstrate cabozantinib's differentiated clinical profile and broad activity in diverse oncology indications."

Conference Call and Webcast

Exelixis' management will discuss the company's financial results for the quarter ended March 31, 2012, financial outlook 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, May 3, 2012. 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. EDT on June 3, 2012. Access numbers for the phone replay are: 888-286-8010 (domestic) and 617-801-6888 (international); the passcode is 33847783.

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 (XL184), its most advanced 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, broadly-active, 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, 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.

Basis of Presentation

Exelixis adopted a 52- or 53-week fiscal year that ends on the Friday closest to December 31st. 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 press release and the accompanying Condensed Consolidated Statements of Operations and Condensed Consolidated Balance Sheet Data as of and for the fiscal quarters ended April 1, 2011 and March 30, 2012, and as of the fiscal year ended December 30, 2011, are indicated as ended March 31, 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; the timing for completion of the NDA submission for cabozantinib in MTC; the expected initiation of the COMET-1 trial; updated data presentations at the 2012 ASCO Annual Meeting and the belief that the meeting will be an important opportunity to further demonstrate cabozantinib's differentiated clinical profile and broad activity; the expansion of the cabozantinib development program through the initial program of trials approved under our CRADA with NCI-CTEP; and the emerging cabozantinib franchise. Words such as "expect," "will," "further," "continued," "emerging," "opportunity," "demonstrate," "potential," "believes," 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; 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 March 30, 2012 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.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)
(unaudited)

	Three Months Ended March 31,	
	2012	2011
Revenues:		
Contract	\$ 3,831	\$ 12,410
License	14,679	22,789
Collaboration reimbursement	—	694
Total revenues	<u>18,510</u>	<u>35,893</u>
Operating expenses:		
Research and development	33,096	45,691
General and administrative	7,905	9,165
Restructuring (credit) charge	(195)	4,767
Total operating expenses	<u>40,806</u>	<u>59,623</u>
Loss from operations	(22,296)	(23,730)
Other income (expense), net:		
Interest income and other, net	160	183
Interest expense	(4,004)	(3,943)
Total other income (expense), net	<u>(3,844)</u>	<u>(3,760)</u>
Loss before income taxes	(26,140)	(27,490)
Income tax provision	(11)	—
Net loss	<u>\$ (26,151)</u>	<u>\$ (27,490)</u>
Net loss per share, basic and diluted	<u>\$ (0.18)</u>	<u>\$ (0.24)</u>
Shares used in computing basic and diluted net loss per share	<u>141,940</u>	<u>113,215</u>

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

	March 31,	December 31,
	2012	2011 (1)
	(unaudited)	
Cash and cash equivalents, marketable securities and long-term investments (2)	\$ 332,114	\$ 283,721
Working capital	\$ 162,557	\$ 136,499
Total assets	\$ 412,600	\$ 393,262
Total stockholders' equity	\$ 132,349	\$ 90,632

(1) Derived from the audited consolidated financial statements.

(2) These amounts include restricted cash and investments of \$4.2 million as of March 31, 2012 and December 31, 2011, respectively.



Source: Exelixis, Inc.

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