



Exelixis Announces Second Quarter 2012 Financial Results

August 2, 2012

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Aug. 2, 2012-- Exelixis, Inc. (NASDAQ:EXEL) today reported financial results for the quarter ended June 30, 2012.

During the quarter, Exelixis continued its progress in advancing cabozantinib towards commercialization and further expanding the cabozantinib development program in multiple indications. Most notably, the company completed the rolling submission of its New Drug Application (NDA) for cabozantinib as a treatment for progressive, unresectable, locally advanced, or metastatic medullary thyroid cancer (MTC) to the U.S. Food and Drug Administration (FDA). Exelixis also initiated COMET-1, a phase 3 pivotal trial of cabozantinib in men with metastatic castration-resistant prostate cancer (mCRPC). In addition, Exelixis expanded its investigator-sponsored trial (IST) program as well as its development program under the Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute's Cancer Therapy Evaluation Program (NCI-CTEP) to evaluate the potential of cabozantinib in renal cell carcinoma, hepatocellular carcinoma, non-small cell lung cancer, and other indications.

Revenues for the quarter ended June 30, 2012 were \$7.8 million, compared to \$32.2 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 the company's PI3K discovery collaboration with Sanofi in December 2011, and the termination of the company's agreement with Bristol Myers-Squibb for XL281 in October 2011.

Research and development expenses for the quarter ended June 30, 2012 were \$32.6 million, compared to \$42.9 million for the comparable period in 2011. The decrease of approximately 24% is primarily due to lower clinical trial expenses as a result of the gradual wind down of EXAM, the company's phase 3 pivotal trial for cabozantinib in MTC, for which the company completed its NDA submission in May 2012. These decreases in clinical trial expenses were partially offset by an increase in costs related to clinical trial activities for the company's COMET-2 phase 3 pivotal trial in mCRPC and costs pertaining to the preparation for the initiation of the company's COMET-1 phase 3 pivotal trial in mCRPC. Personnel costs, stock-based compensation, and general corporate costs were lower for the quarter ended June 30, 2012 compared to the same period in 2011 as a result of the company's 2010 and 2011 restructurings.

General and administrative expenses for the quarter ended June 30, 2012 were \$6.8 million, compared to \$8.8 million for the comparable period in 2011. The decrease of approximately 23% is primarily due to a decrease in facility and personnel costs, depreciation and amortization and stock-based compensation relating to the company's 2010 and 2011 restructurings, as well as a decrease in pre-commercial costs. These decreases were offset by a reduction in the allocation of general corporate costs to research and development as a result of the reduction in headcount from the company's 2010 and 2011 restructurings.

Restructuring charge (credit) for the quarter ended June 30, 2012 was \$1.2 million, compared to a credit of (\$1.5) million for the comparable period in 2011. The restructuring charge for the quarter ended June 30, 2012 was primarily related to termination benefits in connection with a workforce reduction of approximately 20 employees implemented in May as a result of the company's continued focus on the late-stage development and commercialization of cabozantinib. The credit in 2011 was primarily due to more favorable sublease terms than anticipated for one of the company's South San Francisco buildings.

Other (income) expense, net for the quarter ended June 30, 2012 was a net expense of \$3.8 million compared to \$3.0 million in the quarter ended June 30, 2011. The increase in 2012 compared to 2011 was primarily due to a one-time gain of \$1.0 million related to the sale of unused materials in the second quarter of 2011.

Net loss for the quarter ended June 30, 2012 was \$36.5 million, or \$0.25 per share, compared to \$21.0 million, or \$0.16 per share, for the comparable period in 2011. The increased 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, restricted cash and investments and long-term investments totaled \$294.8 million at June 30, 2012, compared to \$283.7 million at December 31, 2011.

Q2 2012 Highlights and Recent Developments

- Completed the rolling submission of the NDA for cabozantinib as a treatment for progressive, unresectable, locally advanced, or metastatic MTC to the FDA. The NDA was submitted under the FDA's Fast Track designation and was granted Priority Review designation with a stated action date of November 29, 2012.
- Initiated COMET-1, a phase 3 pivotal trial of cabozantinib in men with mCRPC who have failed docetaxel and abiraterone and/or enzalutamide. The primary endpoint for COMET-1 is overall survival. Data from this study are expected in the first half of 2014.
- Initiated two new trials through the company's investigator-sponsored trial program: a phase 2 clinical trial in non-small cell lung cancer patients who have tested positive for gene fusions that activate RET, and a phase 1 trial in multiple myeloma. The studies, which will be led by researchers at Memorial Sloan-Kettering Cancer Center and Massachusetts General Hospital, respectively, are designed to assess cabozantinib in specific tumor types in which the kinases inhibited by

cabozantinib are believed to play a key role.

- Significantly expanded the company's cabozantinib development program under the CRADA with the NCI-CTEP. The CRADA provides for funding for as many as 20 active clinical trials each year for a five-year period, which will allow for extensive assessment of cabozantinib in multiple tumor types in a cost-efficient manner. Thirteen initial clinical trials have been approved to date.
- Presented nine abstracts at the American Society of Clinical Oncology 2012 Annual Meeting demonstrating cabozantinib's clinical activity in multiple cancer indications, including the phase 3 EXAM trial and expanded phase 2 data in mCRPC demonstrating the unique activity profile of cabozantinib, including soft tissue and bone scan response, pain palliation and narcotic reduction. Expanded data sets in hepatocellular carcinoma, renal cell carcinoma, non-small cell lung cancer and melanoma showed encouraging progression-free survival and, where available, overall survival, including in heavily pretreated patients.

"We achieved a critical milestone for Exelixis in the second quarter with the completion of our first NDA submission for cabozantinib for progressive, unresectable, locally advanced, or metastatic MTC. The application was granted Priority Review with an action date of November 29, 2012," said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. "The submission is an important next step in our corporate evolution and a key advance in our development and regulatory strategy for cabozantinib. In addition, we advanced our development program for cabozantinib in CRPC through the initiation of the COMET-1 overall survival trial. The presentation of multiple data sets at ASCO highlighted cabozantinib's differentiated clinical profile in multiple tumor indications beyond MTC and CRPC. Finally, we believe the expansion of our CRADA with NCI-CTEP and our IST program will help in defining additional market opportunities for the compound beyond MTC and prostate cancer."

Conference Call and Webcast

Exelixis' management will discuss the company's financial results for the quarter ended June 30, 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, August 2, 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. PDT on September 2, 2012. Access numbers for the phone replay are: 888-286-8010 (domestic) and 617-801-6888 (international); the passcode is 13635336.

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 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 report as of and for the fiscal quarters ended July 1, 2011 and June 29, 2012, and as of the fiscal year ended December 30, 2011, are indicated as ended June 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; potential future regulatory approval of cabozantinib and the timing thereof; the anticipated timing for the availability of data from COMET-1; the expansion of the cabozantinib development program through Exelixis' IST program and CRADA with NCI-CTEP; the goals and expected benefits arising from the IST program and the CRADA; and the importance to Exelixis of the referenced NDA submission. Words such as "potential," "expected," "will," "designed," "believe," "action date," "next step," "evolution," "advance," "strategy," 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 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 June 29, 2012, filed with the Securities and Exchange Commission (SEC) on August 2, 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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CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(unaudited)

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|--------------------------------|--------------------|------------------------------|--------------------|
| | 2012 | 2011 | 2012 | 2011 |
| Revenues: | | | | |
| Contract | \$ 3,802 | \$ 8,327 | \$ 7,633 | \$ 20,737 |
| License | 4,011 | 22,492 | 18,690 | 45,281 |
| Collaboration reimbursement | — | 1,343 | — | 2,038 |
| Total revenues | <u>7,813</u> | <u>32,162</u> | <u>26,323</u> | <u>68,056</u> |
| Operating expenses: | | | | |
| Research and development | 32,610 | 42,901 | 65,706 | 88,593 |
| General and administrative | 6,760 | 8,783 | 14,665 | 17,948 |
| Restructuring charge (credit) | 1,166 | (1,514) | 971 | 3,253 |
| Total operating expenses | <u>40,536</u> | <u>50,170</u> | <u>81,342</u> | <u>109,794</u> |
| Loss from operations | (32,723) | (18,008) | (55,019) | (41,738) |
| Other income (expense), net: | | | | |
| Interest income and other, net | 340 | 1,197 | 500 | 1,381 |
| Interest expense | (4,092) | (4,164) | (8,096) | (8,107) |
| Total other income (expense), net | <u>(3,752)</u> | <u>(2,967)</u> | <u>(7,596)</u> | <u>(6,726)</u> |
| Loss before income taxes | (36,475) | (20,975) | (62,615) | (48,464) |
| Income tax provision | (12) | — | (23) | — |
| Net loss | <u>\$ (36,487)</u> | <u>\$ (20,975)</u> | <u>\$ (62,638)</u> | <u>\$ (48,464)</u> |
| Net loss per share, basic and diluted | <u>\$ (0.25)</u> | <u>\$ (0.16)</u> | <u>\$ (0.43)</u> | <u>\$ (0.40)</u> |
| Shares used in computing basic and diluted net loss per share | <u>148,654</u> | <u>128,245</u> | <u>145,297</u> | <u>120,768</u> |

EXELIXIS, INC.

CONDENSED CONSOLIDATED BALANCE SHEET DATA

(in thousands)

| | June 30, | December 31, |
|--|-------------|--------------|
| | 2012 | 2011 (1) |
| | (unaudited) | |
| Cash and cash equivalents, marketable securities and long-term investments (2) | \$ 294,786 | \$ 283,721 |
| Working capital | \$ 123,676 | \$ 136,499 |
| Total assets | \$ 374,488 | \$ 393,262 |
| Total stockholders' equity | \$ 99,049 | \$ 90,632 |

(1) Derived from the audited consolidated financial statements.

(2) These amounts include restricted cash and investments of \$4.1 million and \$4.2 million as of June 30, 2012 and December 31, 2011, respectively.



Source: Exelixis, Inc.

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