



## Exelixis Announces Second Quarter 2011 Financial Results

August 4, 2011

SOUTH SAN FRANCISCO, Calif., Aug 04, 2011 (BUSINESS WIRE) -- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the second quarter ended June 30, 2011. The company continued to make significant progress in advancing the development of cabozantinib during the quarter and the financial results continue to reflect the impact of the company's 2010 and 2011 restructurings with significant decreases in all major expense categories.

**Revenues** for the quarter ended June 30, 2011 were \$32.2 million, compared to \$47.6 million for the comparable period in 2010. The decrease was primarily due to lower collaboration reimbursement revenue as a result of having regained the rights to cabozantinib from Bristol-Myers Squibb Company (BMS) in 2010. In addition, the transfer of substantially all development activities relating to XL147 and XL765 to Sanofi during the second quarter of 2011 resulted in lower contract revenue during the quarter. These decreases were partially offset by increased revenues under our collaboration with BMS for TGR5, which became effective in November 2010, as well as a milestone payment of \$2.0 million related to our Notch collaboration with Genentech in 2011.

**Research and development expenses** for the quarter ended June 30, 2011 were \$42.9 million compared to \$54.2 million for the comparable period in 2010. The decrease from 2010 to 2011 primarily reflected the reduction in personnel costs, laboratory costs and general corporate costs as a result of the restructuring plans we implemented in 2010 and 2011. In addition, clinical trial expenses decreased as a result of the discontinuation of trials for compounds other than cabozantinib.

**General and administrative expenses** for the quarter ended June 30, 2011 were \$8.8 million compared to \$9.6 million for the comparable period in 2010. The decrease from 2010 to 2011 was primarily due to decreased personnel and facility costs relating to our 2010 and 2011 restructuring plans. This decrease was partially offset by an increase in the allocation of general corporate costs to general and administrative from research and development as a result of the reduction in headcount due to our 2010 and 2011 restructuring plans, as well as an increase in marketing and promotional expenses relating to cabozantinib.

**Restructuring expenses(credit)** for the quarter ended June 30, 2011 were (\$1.5) million compared to \$9.4 million for the comparable period in 2010. The restructuring charge in 2010 primarily related to termination benefits, while the reduction in restructuring expenses in 2011 primarily reflects better than anticipated sublease terms in connection with the exit of one of our buildings in South San Francisco, California. In July 2011, we entered into two sublease agreements for portions of this building and as a result updated our estimate for facility charges to reflect the actual sublease terms. 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 June 30, 2011 was (\$3.0) million compared to \$3.0 million for the comparable period in 2010. The change in total other income for the quarter ended June 30, 2011, as compared to the similar period in 2010, was primarily due to the recording of a \$3.3 million gain in the second quarter of 2010 relating to the sale of our plant trait and cell factory businesses, as well as increased interest expense in the second quarter of 2011 as a result of the financing arrangement we entered into with Deerfield Management Company, L.P. in 2010.

**Net loss** for the quarter ended June 30, 2011 was \$21.0 million, or \$0.16 per share, compared to \$22.6 million, or \$0.21 per share, for the comparable period in 2010. The decrease in net loss from 2010 to 2011 was primarily due to decreases in operating expenses relating to our 2010 and 2011 restructuring plans.

**Cash** and cash equivalents, marketable securities, restricted cash and investments and long-term investments totaled \$353.6 million at June 30, 2011, compared to \$256.4 million at December 31, 2010.

### Q2 2011 Highlights and Recent Events

- Reported updated data from the ongoing phase 2 randomized discontinuation trial (RDT) of cabozantinib in multiple tumor types, including the castration-resistant prostate cancer (CRPC) and ovarian cancer cohorts at the American Society of Clinical Oncology (ASCO) 2011 Annual Meeting in June.
- Filed a Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration (FDA) for the cabozantinib XL184-306 trial, a phase 3 pivotal trial that will employ a primary endpoint of bone scan response and improvement of bone pain in patients with CRPC. Our goal is to initiate this trial by the end of 2011.
- Updated the timing for the readout of the top-line data for EXAM, the ongoing phase 3 trial in medullary thyroid cancer (MTC) evaluating cabozantinib versus placebo in patients with rapidly progressing disease, to approximately the end of the third quarter. We now plan to initiate a rolling submission of a New Drug Application (NDA) for cabozantinib in MTC by submitting key parts of the NDA, including the preclinical and chemistry, manufacturing and controls information, in the fourth quarter of 2011, and expect to complete the filing in the first quarter of 2012.
- An investigator-sponsored trial was initiated to determine effective lower starting doses of cabozantinib in CRPC.
- An abstract on anti-tumor activity observed in a phase 1 study of cabozantinib in differentiated thyroid cancer was

accepted for oral presentation at the upcoming meeting of the American Thyroid Association taking place October 26 - 30, 2011.

- The collaboration with BMS for XL281 will terminate effective October 8, 2011, which will result in the recognition of approximately \$110 million and \$10 million in revenue in the third and fourth quarter of 2011, respectively, relating to deferred revenue in connection with the up-front license fees under the amended and restated collaboration agreement.

"Exelixis continued to make important strides to advance cabozantinib in the first half of 2011," said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. "We have several important milestones in the second half of 2011, including the potential initiation of the 306 phase 3 pivotal trial under an SPA, an interim report of data on lower starting doses of cabozantinib in CRPC, and the expected release of top-line data from the EXAM trial. We believe we will be well-positioned to bring cabozantinib to market in 2012, and be on a path to initiate additional phase 3 trials in CRPC in 2012, and potentially to expand the development plan into multiple additional indications."

#### **Update to Financial Outlook**

We are updating our financial guidance for the full year 2011 by increasing our expected revenues to a range of \$220 to \$250 million from a range of \$145 million to \$160 million resulting from the recognition of deferred revenue in association with the termination of the BMS collaboration for XL281. We continue to expect operating expenses for the full year 2011 in the range of \$190 to \$220 million and cash and cash equivalents, marketable securities, restricted cash and investments and long-term investments of approximately \$380 million as of the end of 2011.

#### **Conference Call and Webcast**

Exelixis' management will discuss the company's financial results for the quarter ended June 30, 2011, financial outlook for 2011, corporate strategy, recent clinical data and development plans and priorities for cabozantinib, and provide a general business update, during a conference call beginning at 2:00 p.m. PDT/ 5:00 p.m. EDT today, Thursday, August 4, 2011. To listen to a live webcast of the discussion, visit the Event Calendar page under Investors at <http://www.exelixis.com>.

An archived replay of the webcast will be available on the Event Calendar page under Investors at <http://www.exelixis.com> and via phone until 11:59 p.m. EDT on September 4, 2011. Access numbers for the phone replay are: 888-286-8010 (domestic) and 617-801-6888 (international); the passcode is 53497277.

#### **About Exelixis**

Exelixis, Inc. is a biotechnology company committed to developing small molecule therapeutics for the treatment of cancer. Exelixis is focusing its 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 <http://www.exelixis.com>.

#### **Basis of Presentation**

Exelixis has adopted a 52- or 53-week fiscal year that ends on the Friday closest to December 31<sup>st</sup>. 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 July 2, 2010 and July 1, 2011 are indicated as ended June 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; Exelixis' goal to initiate the first pivotal trial of cabozantinib in CRPC (XL184-306) by the end of 2011 and the potential to initiate additional phase 3 trials in CRPC in 2012; the timeline for the ongoing phase 3 pivotal trial of cabozantinib in MTC, including the timing for reporting top-line data and the timing for submitting an NDA; the expected revenue recognition associated with the termination of the XL281 collaboration with Bristol-Myers Squibb; important milestones in the second half of 2011; an interim report of data on lower starting doses of cabozantinib in CRPC; the potential to bring cabozantinib to market in 2012; the potential to expand the cabozantinib development plan into multiple additional indications; 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 expected additional restructuring charges in 2011. Words such as "expect," "will," "goal," "plan," "potential," "believe," "well-positioned," "outlook," "guidance," "continue," 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 July 1, 2011, and 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)

|  | <b>Three Months Ended<br/>June 30,</b> |              | <b>Six Months Ended<br/>June 30,</b> |              |
|--|--|--------------|--------------------------------------|--------------|
|  | <b>2011</b>                            | <b>2010</b>  | <b>2011</b>                          | <b>2010</b>  |
| Revenues:  |  |              |                                      |              |
| Contract   | \$ 8,327                               | \$ 12,308    | \$ 20,737                            | \$ 32,048    |
| License  | 22,492                                 | 24,542       | 45,281                               | 49,107       |
| Collaboration reimbursement  | 1,343                                  | 10,746       | 2,038                                | 8,640        |
| Total revenues   | 32,162                                 | 47,596       | 68,056                               | 89,795       |
| Operating expenses:  |  |              |                                      |              |
| Research and development   | 42,901                                 | 54,237       | 88,593                               | 118,988      |
| General and administrative   | 8,783                                  | 9,571        | 17,948                               | 18,406       |
| Restructuring charge   | (1,514 )                               | 9,419        | 3,253                                | 25,484       |
| Total operating expenses   | 50,170                                 | 73,227       | 109,794                              | 162,878      |
| Loss from operations   | (18,008 )                              | (25,631 )    | (41,738 )                            | (73,083 )    |
| Other income (expense):  |  |              |                                      |              |
| Interest income and other, net                                       | 1,197                                  | 393          | 1,381                                | 709          |
| Interest Expense   | (4,164 )                               | (673 )       | (8,107 )                             | (1,285 )     |
| Gain on sale of business   | --                                     | 3,297        | --                                   | 7,797        |
| Total other income   | (2,967 )                               | 3,017        | (6,726 )                             | 7,221        |
| Net loss   | \$ (20,975 )                           | \$ (22,614 ) | \$ (48,464 )                         | \$ (65,862 ) |
| Net loss per share, basic and diluted attributable to Exelixis, Inc. | \$ (0.16 )                             | \$ (0.21 )   | \$ (0.40 )                           | \$ (0.61 )   |
| Shares used in computing basic and diluted net loss per share        | 128,245                                | 108,476      | 120,768                              | 108,226      |

EXELIXIS, INC.

**CONSOLIDATED BALANCE SHEET DATA**

(in thousands)

|  | <b>June 30,</b> | <b>December 31,</b> |
|--|-----------------|---------------------|
|  | <b>2011</b>     | <b>2010(1)</b>      |
|  |                 | (unaudited)         |
| Cash and cash equivalents, marketable securities and long-term investments (2) | \$ 353,555      | \$ 256,377          |
| Working capital  | \$ 90,158       | \$ (16,455 )        |
| Total assets   | \$ 454,182      | \$ 360,790          |
| Total stockholders' deficit  | \$ (81,815 )    | \$ (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 June 30, 2011 and December 31, 2010, respectively.

SOURCE: Exelixis, Inc.

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