



Exelixis Announces Fourth Quarter and Full Year 2011 Financial Results

February 8, 2012

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Feb. 8, 2012-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the fourth quarter and year ended December 31, 2011.

Revenues for the fourth quarter ended December 31, 2011 were \$93.3 million, compared to \$40.8 million for the comparable period in 2010. The increase was primarily due to the recognition of revenue as a result of the acceleration of deferred license revenue and the receipt of a one-time termination fee in connection with the wind-down in December 2011 of our 2009 collaboration with Sanofi for the discovery of inhibitors of Phosphoinositide-3 Kinase (PI3K). This increase was partially offset by lower reimbursement revenues as a result of the transfer in 2011 of substantially all development activities pertaining to XL147 and XL765 to Sanofi under our 2009 license agreement for these compounds as well as the recognition of lower milestone revenue in 2011 compared to 2010.

Revenues for the year ended December 31, 2011 were \$289.6 million compared to \$185.0 million in 2010. The increase was primarily due to the revenue recognized as a result of the acceleration of deferred license revenue related to the early termination of our 2008 Agreement with Bristol Myers-Squibb for XL281 in October 2011 and the wind-down in December 2011 of our Sanofi collaboration agreement mentioned above. These increases were partially offset by lower collaboration reimbursement revenue and research funding as a result of the collaboration with Bristol Myers-Squibb coming to an end and the transfer of substantially all development activities for XL147 and XL765 to Sanofi as well as lower milestone revenue recognized in 2011 compared to the prior year.

Research and development expenses for the fourth quarter ended December 31, 2011 were \$30.8 million compared to \$42.3 million for the comparable period in 2010; and for the year ended December 31, 2011 were \$156.8 million compared to \$210.7 million for 2010. The decrease from 2011 to 2010 in both the quarter and year primarily reflected the reduction in personnel costs, laboratory costs, stock-based compensation and general corporate costs as a result of our 2010 and 2011 restructurings. 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 fourth quarter ended December 31, 2011 were \$7.0 million compared to \$5.7 million for the comparable period in 2010; and for the year ended December 31, 2011 were \$33.1 million compared to \$33.0 million for 2010. The increase in 2011 from 2010 for both the quarter and the year were primarily due to an increase in the allocation of general corporate costs to general and administrative expenses as a result of the reduction in employee headcount in research and development related to our 2010 and 2011 restructurings as well as an increase in marketing expenses relating to cabozantinib. These increases were partially offset by a decrease in facility, personnel and stock-based compensation expense as a result of the restructurings mentioned above.

Restructuring expenses for the fourth quarter ended December 31, 2011 were \$3.9 million compared to \$6.9 million for the comparable period in 2010; and for the year ended December 31, 2011 were \$10.1 million compared to \$32.7 million for 2010. The restructuring charge for the quarter and year ended December 31, 2011 primarily related to our exit of additional surplus office and lab space in South San Francisco, California partially offset by rental income from subleases entered into during 2011. The 2010 restructuring charges for the fourth quarter related primarily to employee termination benefits and for the year related to both employee termination benefits as well as the exit of surplus office and lab space in South San Francisco, California.

Other income (expense) for the fourth quarter ended December 31, 2011 was (\$4.0) million compared to (\$3.8) million for the comparable period in 2010; and for the year ended December 31, 2011 were (\$12.5) million compared to (\$1.0) million for 2010. The difference in expense for the quarter primarily related to the gain recognized in 2010 on the sale of our cell factory business. Other income (expense) for the year ended December 31, 2011 includes interest expense of approximately (\$16.2) million primarily related to the note purchase agreement we entered into with Deerfield Management Company L.P. in June 2010 offset by the gain of approximately \$2.3 million related to the sale of our remaining 19.9% interest in our former German subsidiary TaconicArtemis GmbH (formerly known as Artemis Pharmaceuticals GmbH). Other income (expense) for the year ended December 31, 2010 includes interest expense of approximately (\$9.3) million primarily related to our 2008 Deerfield credit facility and GlaxoSmithKline loan, offset by approximately \$8.2 million in gains from the sale of our plant trait and cell factory businesses.

Tax (provision) benefit for the fourth quarter ended December 31, 2011 was (\$1.3) million compared to zero for the comparable period in 2010; and for the year ended December 31, 2011 was (\$1.3) million compared to \$0.1 million for 2010. In 2009 and 2010, we recorded an income tax benefit as a result of the enactment of the Housing and Economic Recovery Act of 2008. Approximately \$0.6 million of the 2011 provision relates to a downward adjustment of the tax benefit received in 2009 and 2010 after a reevaluation of the qualified expenses in 2011. The balance of \$0.7 million relates to a deferred tax revenue adjustment that resulted in a state tax liability.

Net income (loss) for the fourth quarter ended December 31, 2011 was net income of \$46.3 million, or \$0.35 earnings per share, basic and diluted, compared to a net loss of (\$17.9) million, or a net loss per share of (\$0.16), basic and diluted, for the comparable period in 2010. For the year ended December 31, 2011, net income was \$75.7 million, or \$0.60 earnings per share, basic and \$0.58 earnings per share, diluted compared to a net loss of (\$92.3) million, or a loss of (\$0.85) per share, basic and diluted for 2010. The change from a loss to income in 2011 primarily related to the acceleration of deferred revenue recognized in connection with the 2011 unwinding of our 2008 collaboration agreement with Bristol Myers-Squibb and the 2011 termination of our collaboration agreement with Sanofi as described above, in addition to lower operating expenses recorded as a result of our 2010

and 2011 restructurings.

Cash and cash equivalents, marketable securities, long-term investments and restricted cash and investments totaled \$283.7 million at December 31, 2011, compared to \$256.4 million at December 31, 2010. The 2011 year-end cash balance excludes \$27.3 million which we received in January 2012 in connection with the PI3K license agreement with Merck and the agreement to wind-down our discovery collaboration with Sanofi, both of which were signed in December 2011.

Q4 2011 Highlights and Recent Developments

- Reported top-line data for EXAM, a phase 3 pivotal trial in medullary thyroid cancer, which met its primary endpoint of progression-free survival demonstrating a 2.8-fold increase or 11.2 months vs. 4 months in progression-free survival for cabozantinib over placebo with a hazard ratio of 0.28, $p < 0.0001$.
- Reported preliminary data for cabozantinib in patients with metastatic castration-resistant prostate cancer (CRPC) with a daily starting dose of 40 mg. Eleven patients were evaluable at Week 6, of which 10 had bone scan responses. Eight of the 10 responding patients had a confirmation of the bone scan response at week 12 and continue on treatment with a median duration of treatment of 19 weeks. There were no dose reductions or interruptions during the first 12 weeks.
- Reported preliminary data from the non-randomized extension cohort in CRPC. Median best pain reduction from baseline was 46%, and 59% of patients had at least a 30% decrease in average worst pain. Of the 27 patients with average worst pain ≥ 4 and taking narcotics at baseline, 56% decreased their dose by at least 30%, including 26% who discontinued narcotic drugs completely, 15% had a stable dose and only 30% increased narcotic drug usage.
- Reported preliminary data for cabozantinib in women with metastatic breast cancer. In 44 evaluable patients with measurable disease and at least 12 weeks of follow up, of which 14% had a confirmed partial response (PR), 59% had stable disease (SD), and 20% had progressive disease (PD). The Week 12 disease control rate (week 12 SD or PR) was 48%. Ten patients had available bone scans at baseline and at least one post-baseline bone scan and of these, 40% achieved partial resolution of their metastatic bone lesions on bone scan by week 12.
- Initiated a phase 2 investigator-sponsored trial of cabozantinib in women with hormone receptor-positive metastatic breast cancer.
- Signed a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute's Cancer Therapy Evaluation Program (CTEP).
- Signed an exclusive worldwide license agreement for our PI3K-delta research and development program with Merck and received a \$12.0 million payment.
- Initiated the COMET-2 (previously known as the 306 trial) trial, a pivotal trial of cabozantinib vs. mitoxantrone with a pain palliation endpoint.
- Unwound the PI3K discovery collaboration with Sanofi and received a \$15.25 million payment.
- Appointed J. Scott Garland as executive vice president and chief commercial officer.
- Held the annual Exelixis R&D day in New York, NY.
- Reported preliminary data for cabozantinib in 25 patients with advanced renal cell carcinoma. Seven of 25 patients (28%) showed a confirmed partial response (PR). Importantly, PRs were observed in heavily pretreated patients. The rate of disease control (PR + SD) at week 16 for all 25 patients is 72%. The Kaplan Meier estimate of median progression-free survival is 14.7 months (95% CI, lower limit 7.3 months – upper limit not reached).

"The data for cabozantinib continues to mature and highlight the broad potential in prostate cancer as well as other significant indications. Prostate cancer, in particular, provides an ideal opportunity to convert the unique clinical profile of cabozantinib into a commercially differentiated product addressing length and quality of patients' lives," said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. "Over the last few months we have reported data in four non-CRPC tumor types. Most recently, we reported data in patients with renal cell carcinoma showing a 14.7 month median PFS and a 28 percent response rate in a heavily pre-treated population. We plan to expand the development program for cabozantinib to pursue RCC and other indications in a cost-efficient manner by leveraging our development agreement with the National Cancer Institute and a robust investigator-sponsored trial program."

Financial Outlook

For the full year 2012, we expect revenues in the range of \$40 million to \$60 million and operating expenses in the range of \$190 million to \$220 million. Our cash and cash equivalents, marketable securities, restricted cash and investments and long-term investment balance at the end of 2012 is expected to be at least \$200 million which is based on certain assumptions about cash inflows from new business development activities, milestone payments from existing collaborations, and/or potential financing activities, including accessing the capital markets.

Conference Call and Webcast

Exelixis' management will discuss the company's financial results for the quarter and year ended December 31, 2011, financial guidance for 2012, and development program and plans for cabozantinib, and also provide a general business update, during a conference call beginning at 2:00 p.m. PST/ 5:00 p.m. EST today, Wednesday, February 8, 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 <http://www.exelixis.com> and via phone until 11:59 p.m. EST on March 8, 2012. Access numbers for the phone replay are: (888) 286-8010 (domestic) and (617) 801-6888 (international); the passcode is 46993799.

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 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 30, 2011 are indicated on a calendar year basis, ended December 31, 2011 and references as of and for the fiscal quarters ended December 31, 2010 and December 30, 2011 are indicated as ended December 31, 2010 and 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; Exelixis' financial outlook for 2012, including expected revenues and operating expenses and 2012 year-end cash and cash equivalents, marketable securities, restricted cash and investments and long-term investments balance; and upcoming data presentations. Words such as "expect," "plan," "will," "believe," "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; 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 December 31,		Year Ended December 31,	
	2011	2010	2011	2010
Revenues:				
Contract	\$ 15,549	\$ 17,358	\$ 41,309	\$ 61,271
License	77,565	22,715	245,549	96,363
Collaboration reimbursement	195	704	2,778	27,411
Total revenues	93,309	40,777	289,636	185,045
Operating expenses:				
Research and development	30,778	42,304	156,836	210,678
General and administrative	7,009	5,662	33,129	33,020
Restructuring charge	3,948	6,920	10,136	32,744
Total operating expenses	41,735	54,886	200,101	276,442
Income (loss) from operations	51,574	(14,109)	89,535	(91,397)
Other income (expense):				
Interest income and other, net	(16)	(195)	1,462	138
Interest expense	(4,010)	(3,961)	(16,259)	(9,340)
Gain on sale of businesses	44	400	2,254	8,197
Total other income (expense)	(3,982)	(3,756)	(12,543)	(1,005)

Consolidated income (loss) before taxes	47,592	(17,865)	76,992	(92,402)
Income tax benefit (provision)	(1,295)	—	(1,295)	72
Net income (loss)	\$ 46,297	\$ (17,865)	\$ 75,697	\$ (92,330)
Shares used in computing basic income (loss) per share amounts	133,795	108,962	126,018	108,522
Shares used in computing diluted income (loss) per share amounts	133,936	108,962	130,479	108,522
Net income (loss) per share, basic	\$ 0.35	\$ (0.16)	\$ 0.60	\$ (0.85)
Net income (loss) per share, diluted	\$ 0.35	\$ (0.16)	\$ 0.58	\$ (0.85)

EXELIXIS, INC.

CONSOLIDATED BALANCE SHEET DATA

(in thousands)

	December 31, December 31,	
	2011	2010 (1)
	(unaudited)	
Cash and cash equivalents, marketable securities and long-term investments (2)	\$ 283,720	\$ 256,377
Working capital	\$ 136,499	\$ (16,455)
Total assets	\$ 393,262	\$ 360,790
Total stockholders' equity (deficit)	\$ 90,632	\$ (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 December 31, 2011 and 2010, respectively.

Source: Exelixis, Inc.

Exelixis, Inc.
Frank Karbe
Chief Financial Officer
650-837-7565
fkarbe@exelixis.com
Charles Butler
Vice President
Corporate Communications
& Investor Relations
650-837-7277
cbutler@exelixis.com