Exelixis Announces Fourth Quarter and Full Year 2012 Financial Results

February 21, 2013

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Feb. 21, 2013-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the fourth quarter and year ended December 31, 2012.

Q4 2012 Highlights and Recent Events

- The FDA approved COMETRIQ™ (cabozantinib) for the treatment of progressive, metastatic medullary thyroid cancer (MTC) on November 29, 2012. Approval was based on the results of EXAM, a randomized phase 3 clinical trial conducted under a Special Protocol Assessment in 330 patients with progressive, metastatic MTC, which met its primary efficacy endpoint progression-free survival (PFS). The median PFS on the cabozantinib arm was 11.2 months versus 4.0 months on the placebo arm, an improvement by 7.2 months. The hazard ratio was 0.28, (95% CI 0.19, 0.40), $p < 0.0001$.
- Announced in November 2012 that the European Medicines Agency (EMA) completed validation and accepted for review Exelixis' marketing authorization application (MAA) for COMETRIQ for the proposed indication of treatment of progressive, unresectable, locally advanced or metastatic MTC. Completion of the MAA validation process confirms the submission is sufficient to permit a substantive review for marketing authorization in the European Union.
- Announced in early January 2013 that Exelixis plans to initiate phase 3 pivotal trials of cabozantinib in advanced hepatocellular cancer (HCC) and metastatic renal cell cancer (RCC).
- Announced the commercial availability of COMETRIQ for the treatment of patients with progressive, metastatic MTC on January 24, 2013.

“Exelixis achieved an important milestone in the fourth quarter of 2012 with the approval of our first product, COMETRIQ, for the treatment of progressive, metastatic MTC,” said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. “We are proud of this important clinical and regulatory achievement and pleased to have launched COMETRIQ in the progressive, metastatic MTC indication. Our focus moving forward remains on expanding the commercial franchise for cabozantinib. Our primary objective in 2013 is to execute on the broad cabozantinib clinical development program, including our COMET pivotal trial program in metastatic, castration-resistant prostate cancer (CRPC), planned pivotal trials in HCC and RCC, and additional randomized phase 2 trials to generate data that continue to differentiate the compound and allow us to maximize its clinical and commercial potential.”

Revenues for the quarter ended December 31, 2012 were $7.8 million, compared to $93.3 million for the comparable period in 2011; and for the year ended December 31, 2012 were $47.5 million compared to $289.6 million for the year ended December 31, 2011. The decreases for both the quarter and year were primarily due to extraordinary one-time revenue events in 2011, namely: the acceleration of license revenue as a result of the termination of the company's agreement with Bristol Myers-Squibb Company for XL281 in October 2011, the termination in December 2011 of the company's PI3K discovery collaboration with Sanofi, and the transfer in April 2011 of substantially all development activities pertaining to XL147 and XL765 to Sanofi.

Research and development expenses for the quarter ended December 31, 2012 were $32.5 million, compared to $30.8 million for the comparable period in 2011; and for the year ended December 31, 2012 were $128.9 million compared to $156.8 million for the year ended December 31, 2011. The increase of approximately 6% for the quarter was primarily due to an increase in costs related to clinical trial activities for the COMET-1 and COMET-2 phase 3 pivotal trials in metastatic CRPC as well as an increase in wages and benefits related to employee bonuses. The decrease of approximately 18% for the full year was primarily due to the gradual wind down of EXAM, the company's phase 3 pivotal trial for cabozantinib in progressive, metastatic MTC, the completion of various clinical pharmacology studies that occurred in 2011 in support of the company's new drug application (NDA) filing for cabozantinib for the treatment of progressive, metastatic MTC and the wind down of the company's phase 2 randomized discontinuation trial for cabozantinib.

General and administrative expenses for the quarter ended December 31, 2012 were $9.8 million, compared to $7.0 million for the comparable period in 2011; and for the year ended December 31, 2012 were $31.8 million compared to $33.1 million for the year ended December 31, 2011. The increase of approximately 40% for the quarter was primarily due to increased marketing and commercialization activities in preparation for the launch of COMETRIQ, as well as wages and benefits related to employee bonuses in 2012. The decrease of approximately 4% for the full year was primarily related to lower rent and utilities, decreased legal and accounting fees and decreased depreciation and amortization. These decreases were partially offset by increases in consulting fees and reduced allocations to research and development as a result of lower headcount.

Restructuring charge for the quarter ended December 31, 2012 was $7.5 million, compared to $3.9 million for the comparable period in 2011; and for the year ended December 31, 2012 was $9.2 million compared to $10.1 million for December 31, 2011. The increase in the restructuring charges for the fourth quarter 2012 was primarily due to Exelixis' exit of the remaining portions of office and lab space in one of its buildings in South San Francisco, California for the remainder of the lease term. For the full year 2012, the restructuring charge included the facility charges described above, offset by a decrease in termination benefits compared to the full year 2011.

Other income (expense), net for the quarter ended December 31, 2012 was ($10.1) million compared to ($4.0) million in the quarter ended December 31, 2011; and for the year ended December 31, 2012 was ($25.1) million compared to ($12.5) million for the year ended December 31,

2011. The increase in expense for both the quarter and year was primarily due to interest expense in connection with the $287.5 million aggregate principal amount of 4.25% convertible senior subordinated notes due 2019 issued in August 2012. Included in interest expense for the quarter and year ended December 31, 2012 was ($6.5) million and ($15.6) million of non-cash interest expense related to the 4.25% convertible senior subordinated notes due 2019 and the company's financing arrangement with entities affiliated with Deerfield Management Company, L.P., respectively.

Net (loss) income for the quarter ended December 31, 2012 was ($52.2) million, or ($0.28) per share, compared to $46.3 million, or $0.35 per share, basic, for the comparable period in 2011; and for the year ended December 31, 2012 was ($147.6) million, or ($0.92) per share, compared to $75.7 million, or $0.60 per share, basic, for the year ended December 31, 2011. The increased net loss for the quarter was primarily due to decreases in revenues as well as increased restructuring and interest expense, as described above. The increased net loss for the full year was primarily due to decreases in revenues and increases in interest expense, partially offset by decreased research and development costs, as described above.

Cash and cash equivalents, short- and long-term investments and short- and long-term restricted cash and investments totaled $634.0 million at December 31, 2012, compared to $283.7 million at December 31, 2011.

Financial Outlook

For the full year 2013, Exelixis expects contract and license revenue of approximately $16 million. The company is not providing guidance on expected revenue from COMETRIQ product sales at this time. The company expects total costs and expenses in the range of $200 million to $230 million, including non-cash expenses of approximately $16 to $18 million related primarily to stock-based compensation expense. Exelixis further expects interest expense of approximately $45 million, which includes non-cash charges of $26 million. Exelixis expects its cash and cash equivalents, short- and long-term investments and short- and long-term restricted cash and investments to be approximately $400 million at the end of 2013.

Conference Call and Webcast

Exelixis' management will discuss the company's financial results for the quarter and year ended December 31, 2012, financial outlook, and development program and plans for COMETRIQ, and will also provide a general business update, during a conference call beginning at 5:00 p.m. EST/2:00 p.m. PST today, Thursday, February 21, 2013. To listen to a live webcast of the discussion, visit the Event Calendar page under Investors & Media at www.exelixis.com.

An archived replay of the webcast will be available on the Event Calendar page under Investors & Media at www.exelixis.com and via phone until 11:59 p.m. PST on March 21, 2013. Access numbers for the phone replay are: 888-286-8010 (domestic) and 617-801-6888 (international); the passcode is 32648982.

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 its lead product, COMETRIQ. 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 generally ends on the Friday closest to December 31st. For convenience, references in this press release as of and for the fiscal year ended December 28, 2012 are indicated on a calendar year basis, ended December 31, 2012, and references as of and for the fiscal quarters ended December 30, 2011 and December 28, 2012 are indicated as ended December 31, 2011 and 2012, respectively. Fiscal year 2013, a 52-week year, will end on December 27, 2013.

Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to: the referenced review for marketing authorization for COMETRIQ in the European Union; Exelixis' plans to initiate phase 3 pivotal trials of cabozantinib in advanced HCC and metastatic RCC; Exelixis' focus on expanding the commercial franchise for cabozantinib; Exelixis' primary objective to execute on the broad cabozantinib clinical development program, including Exelixis' COMET pivotal trial program in metastatic CRPC, planned pivotal trials in HCC and RCC, and additional randomized phase 2 trials; the continued development, clinical, therapeutic and commercial potential of COMETRIQ; and Exelixis' financial outlook for 2013, including expected contract and license revenue, total costs and expenses, including non-cash expenses, interest expense, including non-cash charges and 2013 year-end cash and cash equivalents, short- and long-term investments and short- and long-term restricted cash and investments balance. Words such as “confirms,” “permit,” “review,” “plans,” “initiate,” “focus,” “primary objective,” “continue,” “allow,” “potential,” “outlook,” “expects,” “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; the uncertain timing and level of expenses associated with the development of cabozantinib; Exelixis' ability to conduct clinical trials of cabozantinib sufficient to achieve a positive completion; the availability of data at the expected times; the risk that unanticipated developments could adversely affect the launch, commercialization, manufacturing, distribution and availability of COMETRIQ; the degree of market acceptance of COMETRIQ; the extent to which coverage and reimbursement for COMETRIQ will be available from third-party payors; risks and uncertainties related to Exelixis' compliance with applicable regulatory requirements, including healthcare fraud and abuse laws and post-marketing requirements; Exelixis' dependence on third-party vendors; timely receipt of potential reimbursements, milestones, royalties and profits under Exelixis' collaborative agreements; the sufficiency of Exelixis' capital and other resources; the uncertainty of the regulatory approval processes; market competition; and changes in economic and business conditions. These and other risk factors are discussed under “Risk Factors” and elsewhere in Exelixis' annual report on Form 10-K for the year ended December 28, 2012, filed with the Securities and Exchange Commission (SEC) on February 21, 2013, 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.

Exelixis and the Exelixis logo are registered U.S. trademarks.

EXELIXIS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2012	2011	2012	2011
	(unaudited)			
Revenues:				
Contract	$ 3,802	$ 15,549	$ 20,736	$41,309
License	4,012	77,565	26,714	245,549
Collaboration reimbursement	—	195	—	2,778
Total revenues	7,814	93,309	47,450	289,636
Operating expenses:				
Research and development	32,492	30,778	128,878	156,836
General and administrative	9,829	7,009	31,837	33,129
Restructuring charge	7,467	3,948	9,171	10,136
Total operating expenses	49,788	41,735	169,886	200,101
(Loss) income from operations	(41,974)	51,574	(122,436)	89,535
Other income (expense), net:				
Interest income and other, net	1,168	(16)	1,986	1,462
Interest expense	(11,313)	(4,010)	(27,088)	(16,259)
Gain on sale of business	—	44	—	2,254
Total other income (expense), net	(10,145)	(3,982)	(25,102)	(12,543)
(Loss) income before income taxes	(52,119)	47,592	(147,538)	76,992
Income tax provision	74	1,295	107	1,295
Net (loss) income	$ (52,193)	$ 46,297	$(147,645)	$75,697
Net (loss) income per share, basic	$ (0.28)	$ 0.35	$ (0.92)	$ 0.60
Net (loss) income per share, diluted	$ (0.28)	$ 0.35	$ (0.92)	$ 0.58
Shares used in computing basic net (loss) income per share	183,605	133,795	160,138	126,018
Shares used in computing diluted net (loss) income per share	183,605	133,936	160,138	130,479

EXELIXIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEET DATA (1)
(in thousands)

	December 31, 2012	December 31, 2011
Cash and investments (2)	$ 633,961	$ 283,721
Working capital	$ 350,837	$ 136,499
Total assets	$ 721,097	$ 393,262
Total stockholders' equity	$ 296,434	$ 90,632

(1) Derived from the audited consolidated financial statements.

(2) Cash and investments include cash and cash equivalents, short- and long-term investments and short- and long-term restricted cash and investments. Short- and long-term restricted cash and investments consist of $40.2 million and $4.2 million as of December 31, 2012 and December 31, 2011, respectively.

Source: Exelixis, Inc.

Exelixis, Inc.
Frank Karbe, 650-837-7565
Chief Financial Officer
fkarbe@exelixis.com
Charles Butler, 650-837-7277

Vice President
Investor Relations & Corporate Communications
cbutler@exelixis.com