Exelixis Announces First Quarter 2014 Financial Results

May 1, 2014

- Conference Call and Webcast Today at 5:00 PM Eastern Time -

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 1, 2014-- Exelixis, Inc. (Nasdaq:EXEL) today reported financial results for the quarter ended March 31, 2014.

Q1 2014 Highlights and Recent Events

- The European Commission approved COMETRIQ® (cabozantinib) for the treatment of adult patients with progressive, unresectable locally advanced or metastatic medullary thyroid cancer in January 2014. Additionally, the Committee for Orphan Medicinal Products recommended maintenance of orphan drug designation at the time of marketing authorization.
- The Independent Data Monitoring Committee (IDMC) for COMET-1, the phase 3 pivotal trial of cabozantinib in advanced metastatic castration-resistant prostate cancer (mCRPC) with the primary endpoint of overall survival, completed its planned interim analysis and recommended the trial proceed to its final analysis. Exelixis anticipates top-line results from COMET-1 in 2014.
- Appointed Jeffrey J. Hessekiel, J.D. as executive vice president and general counsel. Mr. Hessekiel is a veteran legal professional with more than a decade of corporate and commercial experience specific to the biopharmaceutical industry, most of it gained in senior roles at Gilead Sciences.
- Net product revenue from COMETRIQ sales was $4.9 million for the first quarter of 2014.
- Entered into an amendment to the company's financing arrangement with Deerfield Private Design Fund, L.P. and Deerfield Private Design International, L.P. (collectively, Deerfield) in January 2014 to provide the company with an option to extend to July 1, 2018 from July 1, 2015, the maturity date of the indebtedness incurred by the company under the financing arrangement.
- Completed an underwritten public offering of 10,000,000 shares of common stock in January 2014, raising net proceeds of approximately $75.6 million after deducting the underwriting discount and estimated offering expenses.

“For Exelixis, 2014 is a year focused on anticipated top-line results from four pivotal trials of cabozantinib and cobimetinib. Positive data from COMET-1 and COMET-2 could support future regulatory filings and help position cabozantinib as a differentiated treatment option for patients with mCRPC,” said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. “Concurrently, our partners Roche and Genentech, a member of the Roche Group, are advancing cobimetinib, an Exelixis-discovered MEK inhibitor that is under evaluation in a phase 3 pivotal trial with top-line results expected in 2014. We believe that, together, cabozantinib and cobimetinib have the potential to benefit a significant number of patients, and we look forward to the continued maturing datasets from studies exploring the use of these compounds as we progress through the year.”

First Quarter 2014 Financial Results

Net revenues for the quarter ended March 31, 2014 were $4.9 million, consisting entirely of product revenue related to the sale of COMETRIQ, compared to $9.7 million for the comparable period in 2013, consisting of $1.9 million of product revenue related to the sale of COMETRIQ and $7.8 million of license and contract revenue. The increase in product revenue reflects the ramp up in sales of COMETRIQ following its commercial launch in the United States in January 2013. The decrease in contract and license revenue was the result of having fully recognized all revenues from the company’s collaboration agreements with Bristol-Myers Squibb Company in the prior period.

Research and development expenses for the quarter ended March 31, 2014 were $54.8 million, compared to $32.7 million for the comparable period in 2013. The increase was primarily due to higher clinical trial costs but also reflects higher personnel related expenses in support of the company's four phase 3 pivotal trials for cabozantinib. The increase in clinical trial costs related predominantly to clinical trial activities for METEOR, the company's phase 3 pivotal trial in metastatic renal cell cancer and to a lesser degree COMET-1, the company's phase 3 pivotal trial in mCRPC, as well as start-up costs incurred in connection with CELESTIAL, the company's phase 3 pivotal trial in advanced hepatocellular cancer. Clinical trial costs for METEOR included a $7.5 million comparator drug purchase during the quarter ended March 31, 2014. The increases in costs for those trials was partially offset by lower clinical trial expenses as a result of the continued wind down of various studies for cabozantinib, most notably the company's randomized discontinuation trial and EXAM, the company's phase 3 pivotal trial in medullary thyroid cancer.

Selling, general and administrative expenses for the quarter ended March 31, 2014 were $14.7 million, compared to $10.5 million for the comparable period in 2013. Approximately half of the increase was the result of increased personnel expenses, as compared to the comparable period in 2013, the majority of which reflects the expansion of the company's U.S. sales force. The remaining increases relate predominantly to marketing expenses, stock based compensation expenses as well as an increase in expenses for cobimetinib under the company's collaboration agreement with Roche and Genentech.

Other income (expense), net for the quarter ended March 31, 2014 was a net expense of ($9.6) million compared to ($10.7) million for the comparable period in 2013. Included in interest expense for the quarter ended March 31, 2014 was $7.0 million of non-cash expense related to the accretion of the discounts on both the 4.25% Convertible Senior Subordinated Notes due 2019 and the company's financing arrangement with Deerfield, as compared to $6.3 million for the comparable period in 2013. The overall decrease in other income (expense), net was due in part to a $1.7 million unrealized gain on warrants issued to Deerfield in connection with the January 2014 amendment to the company's financing arrangement.

Net loss for the quarter ended March 31, 2014 was ($74.6) million, or ($0.39) per share, basic, compared to ($44.7) million, or ($0.24) per share, basic, for the comparable period in 2013. The increased net loss was primarily due to a decrease in license and contract revenues, which was partially offset by an increase in product revenues, and increases in research and development expenses and selling, general and administrative expenses.

Cash and cash equivalents, short- and long-term investments and short- and long-term restricted cash and investments totaled $407.7 million at March 31, 2014, compared to $415.9 million at December 31, 2013.

Conference Call and Webcast

Exelixis management will discuss the company's financial results for the quarter ended March 31, 2014 and provide a general business update during a conference call beginning at 5:00 p.m. EDT/2:00 p.m. PDT today, Thursday, May 1, 2014. To join the call, participants may dial 866-202-3048 (domestic) or 617-213-8843 (international) and use passcode 28848437. To listen to a live webcast of the conference call, visit the Event Calendar page under Investors & Media at www.exelixis.com.

An archived replay of the conference call will be available on the Event Calendar page under Investors & Media at www.exelixis.com and via phone until 11:59 p.m. PDT on June 1, 2014. Access numbers for the phone replay are: 888-286-8010 (domestic) and 617-801-6888 (international); the passcode is 74388407.

About Exelixis

Exelixis, Inc. is a biopharmaceutical company committed to developing small molecule therapies for the treatment of cancer. Exelixis is focusing its development and commercialization efforts primarily on COMETRIQ® (cabozantinib), its wholly-owned inhibitor of multiple receptor tyrosine kinases. Another Exelixis-discovered compound, cobimetinib, a highly selective inhibitor of MEK, is being evaluated by Roche and Genentech, Inc. (a member of the Roche Group) in a broad development program under a collaboration with Exelixis. 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 quarters ended March 29, 2013 and March 28, 2014, and as of the fiscal year ended December 27, 2013, are indicated as ended March 31, 2013, March 31, 2014, and December 31, 2013, 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, and opportunities for, cabozantinib and cobimetinib; anticipated developments in, and the expected timing of, various trials, including expected top-line results from four pivotal trials in 2014; and future potential regulatory filings. Words such as “anticipates,” “focused,” “could,” “support,” “future,” “help,” “position,” “option,” “advancing,” “expected,” “believe,” “potential,” “look forward,” “continued,” “maturing,” “exploring,” “progress,” or other similar expressions, identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking.In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements are based upon Exelixis' current plans, assumptions, beliefs, expectations, estimates and projections. Forward-looking statements involve risks and uncertainties. Exelixis' actual results and the timing of events could differ materially from those anticipated in the forward-looking statements as a result of these risks and uncertainties, which include, without limitation: the availability of data at the expected times; risks related to the potential failure of cabozantinib or cobimetinib 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; Exelixis' dependence on its relationship with Genentech/Roche for the development of cobimetinib and Exelixis’ ability to maintain its rights; the uncertainty of regulatory approval processes; the risk that unanticipated developments could adversely affect the commercialization of COMETRIQ® (cabozantinib); the degree of market acceptance of COMETRIQ and the availability of coverage and reimbursement for COMETRIQ; 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; the sufficiency of Exelixis' capital and other resources; market competition; changes in economic and business conditions; and other factors discussed under the caption “Risk Factors” in Exelixis’ quarterly report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 1, 2014 and in Exelixis' other filings with the SEC. The forward-looking statements made in this press release speak only as of the date of this press release. 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, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)
(unaudited)

Three Months Ended March 31,

	2014	2013
Revenues:		
Net product revenues	$ 4,905	$ 1,856
License and contract revenues	—	7,813
Total revenues	4,905	9,669
Operating expenses:		
Cost of goods sold	309	280
Research and development	54,847	32,735
Selling, general and administrative	14,691	10,545
Restructuring charge	46	119
Total operating expenses	69,893	43,679
Loss from operations	(64,988)	(34,010)
Other income (expense), net:		
Interest income and other, net	2,131	338
Interest expense	(11,762)	(11,057)
Total other income (expense), net	(9,631)	(10,719)
Net loss	$ (74,619)	$ (44,729)
Net loss per share, basic and diluted	$ (0.39)	$ (0.24)
Shares used in computing basic and diluted net loss per share	191,699	183,742

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

	March 31, 2014 (unaudited)	December 31, 2013 (1)
Cash and investments (2)	$ 407,749	$ 415,862
Working capital	$ 227,253	$ 178,756
Total assets	$ 497,565	$ 503,287
Total stockholders' equity	$ 71,482	$ 66,238

(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 totaled $23.0 million and $29.1 million as of March 31, 2014 and December 31, 2013, respectively.

Source: Exelixis, Inc.

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