Exelixis Announces Second Quarter 2014 Financial Results

July 31, 2014

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

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jul. 31, 2014-- Exelixis, Inc. (Nasdaq:EXEL) today reported financial results for the quarter ended June 30, 2014.

Q2 2014 Highlights and Recent Events

- Reported positive top-line results from coBRIM, the phase 3 pivotal trial evaluating cobimetinib, a specific MEK inhibitor discovered by Exelixis, in combination with vemurafenib in previously untreated patients with unresectable locally advanced or metastatic melanoma harboring a $BRAF^{V600}$ mutation. On July 11, 2014, Exelixis' collaborator Genentech, a member of the Roche Group, informed the company that coBRIM met its primary endpoint, delivering a statistically significant increase in progression-free survival for the combination of cobimetinib plus vemurafenib versus vemurafenib alone. Adverse events were consistent with those observed in a previous study of the combination. Roche announced last week on their second quarter 2014 earnings conference call that the coBRIM data are planned for presentation at the European Society for Medical Oncology 2014 Congress taking place in Madrid, Spain, September 26 - 30, 2014. They have also stated that they plan to initiate regulatory filings before year end.
- Cabozantinib and cobimetinib were the subject of a total of ten presentations at the 2014 Annual Meeting of the American Society of Clinical Oncology, which was held May 30 to June 3, 2014 in Chicago, Illinois. Cabozantinib presentations included data from trials sponsored by Exelixis, independent investigators, and the National Cancer Institute's Cancer Therapy Evaluation Program. Cobimetinib was the subject of one oral presentation highlighting positive data from BRIM7, the phase 1b clinical trial conducted by Roche and Genentech which evaluated the combination of cobimetinib and vemurafenib in patients with locally advanced/unresectable or metastatic melanoma carrying a $BRAF^{V600}$ mutation.
- Announced final positive results from BRIM7 at the European Association of Dermato-Oncology Congress, which was held May 7-10, 2014 in Vilnius, Lithuania.
- Net product revenue from COMETRIQ® (cabozantinib) sales was $6.6 million for the second quarter of 2014.

"The Exelixis team made substantial clinical and commercial progress during the second quarter of 2014, driving the company forward for an impactful year," said Michael M. Morrissey, Ph.D., president and chief executive officer of the company. "The positive top-line results from the coBRIM pivotal trial, which we and our partner Genentech reported shortly after the quarter ended, are an important advance for the melanoma community, and they serve as further validation of Exelixis' ability to discover and develop therapies with the potential to improve the treatment of cancer patients."

Dr. Morrissey continued, "As we enter the second half of 2014, Exelixis is focused on delivering top-line results for three additional pivotal trials of cabozantinib: COMET-1 and COMET-2 in patients with metastatic castration-resistant prostate cancer and the overall survival results from EXAM in patients with progressive, metastatic medullary thyroid cancer. We also anticipate completing enrollment in a fourth pivotal trial of cabozantinib, METEOR, in metastatic renal cell cancer, which has seen strong support from the oncology community in advance of an anticipated read-out in 2015."

Second Quarter 2014 Financial Results

Net revenues for the quarter ended June 30, 2014 were $6.6 million, consisting entirely of product revenue related to the sale of COMETRIQ, compared to $11.9 million for the comparable period in 2013, which consisted of $4.0 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 continued ramp up in sales of COMETRIQ following its commercial launch in the United States in January 2013. The decrease in contract and license revenue reflects the company having fully recognized all revenues from its collaboration agreements with Bristol-Myers Squibb Company in 2013.

Research and development expenses for the quarter ended June 30, 2014 were $51.0 million, compared to $49.1 million for the comparable period in 2013. The increase was primarily due to higher personnel related expenses and consulting costs in support of the company's five phase 3 pivotal trials for cabozantinib. Clinical trial costs decreased by $1.6 million predominantly due to a $6.5 million comparator drug purchase for METEOR during the second quarter of 2013 which was offset in part by increases in other clinical trial costs for METEOR and COMET-2.

Selling, general and administrative expenses for the quarter ended June 30, 2014 were $16.5 million, compared to $13.2 million for the comparable period in 2013. Approximately two-thirds of the increase reflects increased personnel expenses, as compared to the comparable period in 2013, the majority of which is connected with the expansion of the company's U.S. sales force. The remaining increases related predominantly to stock-based compensation expenses and marketing expenses, including an increase in expenses for cobimetinib under the company's collaboration agreement with Roche and Genentech.

Other income (expense), net for the quarter ended June 30, 2014 was a net expense of ($11.7) million compared to ($10.9) million for the comparable period in 2013. Included in interest expense for the quarter ended June 30, 2014 was $7.3 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 $6.5 million for the comparable period in 2013.

Net loss for the quarter ended June 30, 2014 was ($73.4) million, or ($0.38) per share, basic, compared to ($62.2) million, or ($0.34) 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 $352.0 million at June 30, 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 June 30, 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, July 31, 2014. To join the call, participants may dial 800-706-7745 (domestic) or 617-614-3472 (international) and use passcode 46301934. 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. EDT on August 31, 2014. Access numbers for the phone replay are: 888-286-8010 (domestic) and 617-801-6888 (international); the passcode is 25592695.

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 (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 periods ended June 27, 2014 and June 28, 2013, and as of the fiscal year ended December 27, 2013, are indicated as ended June 30, 2014, June 30, 2013, 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; future coBRIM data presentations and regulatory filings; Exelixis' belief that 2014 will be an impactful year for the company; and anticipated developments and timing with respect to the company's ongoing phase 3 pivotal trials of cabozantinib. Words such as "plan," "initiate," "progress," "driving," "forward," "impactful," "advance," "validation," "potential," "focused," "delivering," "anticipate," 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 clinical, therapeutic and commercial value of cobimetinib and cabozantinib; Exelixis' dependence on its relationship with Genentech/Roche with respect to cobimetinib and Exelixis' ability to maintain its rights under the collaboration; the uncertainty of regulatory approval processes; the sufficiency of Exelixis' capital and other resources; 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 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; 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 July 31, 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 June 30,		Six Months Ended June 30,	
	2014	**2013**	**2014**	**2013**
Revenues:				
Net product revenues	$ 6,562	$ 4,043	$ 11,467	$ 5,899
License and contract revenues	—	7,813	—	15,626
Total revenues	6,562	11,856	11,467	21,525
Operating expenses:				
Cost of goods sold	477	285	786	565
Research and development	50,976	49,077	105,823	81,812
Selling, general and administrative	16,466	13,180	31,157	23,725
Restructuring charge	331	609	377	728
Total operating expenses	68,250	63,151	138,143	106,830
Loss from operations	(61,688)	(51,295)	(126,676)	(85,305)
Other income (expense), net:				
Interest income and other, net	359	373	2,490	711
Interest expense	(12,081)	(11,239)	(23,843)	(22,296)
Total other income (expense), net	(11,722)	(10,866)	(21,353)	(21,585)
Net loss	$ (73,410)	$ (62,161)	$ (148,029)	$ (106,890)
Net loss per share, basic and diluted	$ (0.38)	$ (0.34)	$ (0.77)	$ (0.58)
Shares used in computing basic and diluted net loss per share	194,929	183,981	193,323	183,861

EXELIXIS, INC.

CONDENSED CONSOLIDATED BALANCE SHEET DATA

(in thousands)

	June 30, 2014	**December 31, 2013** (1)
	(unaudited)	
Cash and investments (2)	$ 352,025	$ 415,862
Working capital	$ 86,726	$ 178,756
Total assets	$ 440,635	$ 503,287
Total stockholders' equity	$ 3,243	$ 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 June 30, 2014 and December 31, 2013, respectively.

Source: Exelixis, Inc.

Exelixis, Inc.
Deborah Burke, 650-837-7835
Interim Chief Financial Officer
dburke@exelixis.com
or
Exelixis, Inc.
Susan Hubbard, 650-837-8194
Investor Relations
& Corporate Communications

shubbard@exelixis.com