Exelixis Announces Second Quarter 2013 Financial Results

August 6, 2013

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Aug. 6, 2013-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the quarter ended June 30, 2013.

Q2 2013 Highlights and Recent Events

- Reported net product revenue for COMETRIQ® (cabozantinib) of $4.0 million in the second quarter of 2013.
- Expanded the sales force to 14 representatives.
- Initiated METEOR, a phase 3 pivotal trial comparing cabozantinib to everolimus in patients with metastatic renal cell carcinoma (RCC) who have experienced disease progression following treatment with at least one prior VEGFR tyrosine kinase inhibitor (TKI). The trial is expected to enroll 650 patients, and the primary endpoint is progression-free survival (PFS). The secondary endpoint is overall survival (OS) and no cross-over will be allowed between the study arms.
- Cabozantinib was the subject of nine presentations at the American Society of Clinical Oncology (ASCO) 2013 Annual Meeting in June, including an oral presentation of data from the EXAM study, Exelixis' phase 3 pivotal trial in progressive, metastatic medullary thyroid cancer (MTC), as well as a poster discussion presentation of overall survival data from patients with metastatic castration-resistant prostate cancer (CRPC) in a non-randomized expansion (NRE) cohort of Exelixis' phase 2 randomized discontinuation trial. Additional presentations covered cabozantinib's potential activity in investigational studies of advanced urothelial carcinoma, metastatic uveal melanoma, and CRPC metastatic to the bone.

“We gained significant momentum in both commercial and development activities in the second quarter of 2013,” said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. “While continuing to focus on enrollment of the COMET phase 3 pivotal trials as our top priority, we initiated the METEOR phase 3 pivotal trial in metastatic RCC and finalized planning for our phase 3 pivotal trial in metastatic hepatocellular carcinoma (HCC). In addition, the overall survival and post-hoc analyses from the phase 2 NRE metastatic CRPC cohort were presented at the ASCO Annual Meeting and those data continue to support the rationale for the COMET pivotal trials in metastatic CRPC, for which we continue to expect top-line data in 2014."

Net revenues for the quarter ended June 30, 2013 were $11.9 million, compared to $7.8 million for the comparable period in 2012. The increase for the quarter was due to $4.0 million of net product revenue resulting from the sale of COMETRIQ, which became commercially available in the United States for the treatment of progressive, metastatic MTC in January 2013.

Research and development expenses for the quarter ended June 30, 2013 were $49.1 million, compared to $32.6 million for the comparable period in 2012. The increases were primarily due to increased clinical trial costs. The increase in clinical trial costs was primarily related to clinical trial activities for COMET-1, the phase 3 pivotal trial with the primary endpoint of overall survival in metastatic CRPC, as well as start-up costs incurred for the phase 3 pivotal trials for metastatic RCC and metastatic HCC.

Selling, general and administrative expenses for the quarter ended June 30, 2013 were $13.2 million, compared to $6.8 million for the comparable period in 2012. The increase was primarily due to an increase in expenses related to the sale of COMETRIQ, predominantly for consulting and outside services, as well as marketing expenses.

Other income (expense), net for the quarter ended June 30, 2013 was a net expense of ($10.9) million compared to ($3.8) million in the quarter ended June 30, 2012. The increase in expense in 2013 compared to 2012 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 ended June 30, 2013 was ($6.5) million of non-cash expense related to the accretion of the discount on both the 4.25% convertible senior subordinated notes due 2019 and the company's financing arrangement with Deerfield Management Company, L.P.

Net loss for the quarter ended June 30, 2013 was ($62.2) million, or ($0.34) per share, basic, compared to ($36.5) million, or ($0.25) per share, basic, for the comparable period in 2012. The net loss was primarily due to increases in research and development, selling, general and administrative and interest expenses, slightly offset by increased revenues, as described above, and lower restructuring charges.

Cash and cash equivalents, short- and long-term investments and short- and long-term restricted cash and investments totaled $524.3 million at June 30, 2013, compared to $634.0 million at December 31, 2012.

Conference Call and Webcast

Exelixis' management will discuss the company's financial results for the quarter ended June 30, 2013, financial outlook and development program and plans for cabozantinib, and also provide a general business update, during a conference call beginning at 5:00 p.m. EDT/2:00 p.m. PDT today, Tuesday, August 6, 2013. 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 webcast 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 September 6, 2013. Access numbers for the phone replay are: 888-286-8010 (domestic) and 617-801-6888 (international); the passcode is 71509629.

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® (cabozantinib). 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 quarters ended June 29, 2012 and June 28, 2013, and as of the fiscal year ended December 28, 2012, are indicated as ended June 30, 2012 and 2013, and as ended December 31, 2012, 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; the design, plans and goals for the recently initiated phase 3 pivotal trial of cabozantinib in metastatic RCC; planning for the phase 3 pivotal trial of cabozantinib in metastatic HCC; the belief that Exelixis gained significant momentum in the second quarter of 2013; the continued focus on enrollment of the COMET pivotal trials in metastatic CRPC as Exelixis' top priority; the belief that the overall survival and post-hoc analyses from the phase 2 NRE metastatic CRPC cohort presented at the ASCO Annual Meeting continue to support the rationale for the COMET pivotal trials; and the continued expectation that top-line data for the COMET pivotal trials will be available in 2014. Words such as “expect,” “will,” “potential,” “activity,” “momentum,” “continue,” “focus,” “priority,” “planning,” “support,” “rationale,” 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: the availability of data at the expected times; 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; risks and uncertainties related to Exelixis' compliance with applicable regulatory requirements, including healthcare fraud and abuse laws; the sufficiency of Exelixis' capital and other resources; the uncertainty of the regulatory approval process; 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 three months ended June 28, 2013, filed with the Securities and Exchange Commission (SEC) on August 6, 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, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	**2012**	**2013**	**2012**
Revenues:				
License and contract revenues	$ 7,813	$ 7,813	$ 15,626	$ 26,323
Net product revenues	4,043	—	5,899	—
Total revenues	11,856	7,813	21,525	26,323
Operating expenses:				
Cost of goods sold	285	—	565	—
Research and development	49,077	32,610	81,812	65,706
Selling, general and administrative	13,180	6,760	23,725	14,665
Restructuring charge	609	1,166	728	971
Total operating expenses	63,151	40,536	106,830	81,342
Loss from operations	(51,295)	(32,723)	(85,305)	(55,019)
Other income (expense), net:				
Interest income and other, net	373	340	711	500
Interest expense	(11,239)	(4,092)	(22,296)	(8,096)
Total other income (expense), net	(10,866)	(3,752)	(21,585)	(7,596)
Loss before income taxes	(62,161)	(36,475)	(106,890)	(62,615)

Income tax provision	—	12	—	23
Net loss	$ (62,161)	$ (36,487)	$(106,890)	$(62,638)
Net loss per share, basic and diluted	$ (0.34)	$ (0.25)	$ (0.58)	$ (0.43)
Shares used in computing basic and diluted net loss per share	183,981	148,654	183,861	145,297

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

	June 30, 2013	**December 31, 2012** (1)
	(unaudited)	
Cash and investments (2)	$ 524,267	$ 633,961
Working capital	$ 300,356	$ 350,837
Total assets	$ 612,084	$ 721,097
Total stockholders' equity	$ 196,332	$ 296,434

(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 $34.2 million and $40.2 million as of June 30, 2013 and December 31, 2012, respectively.

Source: Exelixis, Inc.

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