



## Exelixis Announces First Quarter 2013 Financial Results

May 7, 2013

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May. 7, 2013-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the quarter ended March 31, 2013.

### Q1 2013 Highlights and Recent Events

- Commercial launch of COMETRIQ™ (cabozantinib) in the United States on January 24, 2013 for the treatment of progressive, metastatic medullary thyroid cancer (MTC).
- Reported net product revenue for COMETRIQ of \$1.9 million in the first quarter of 2013.
- Announced in February 2013 a three-year agreement with Swedish Orphan Biovitrum (Sobi) to support the distribution and commercialization of COMETRIQ for metastatic MTC primarily in the European Union and potentially other countries, initially under a Named Patient Use Program and then more broadly only if approved by the European Medicines Agency.
- Presentation of data at the American Association for Cancer Research Annual Meeting 2013 detailing the mechanism of action of cabozantinib in a preclinical castration-resistant prostate cancer (CRPC) bone metastasis model. Treatment of animals with cabozantinib resulted in substantial inhibition of tumor growth, induction of tumor cell death, and blockade of cancer-induced bone remodeling as determined by bioluminescence imaging, MRI, micro-CT, and histological analyses. In addition, imaging studies showed that early reductions in the uptake of the bone scan tracer <sup>99</sup>Tc-MDP were associated with the anti-tumor activity of cabozantinib in mice.
- Announced that nine abstracts have been accepted for presentation at the 2013 Annual Meeting of the American Society of Clinical Oncology (ASCO) this June in Chicago, Illinois. At the meeting, investigators will present updates from clinical trials of cabozantinib in MTC, CRPC, uveal melanoma, and bladder cancer, among other tumor types.
- Received notice from Genentech, Exelixis' collaborator in the development of cobimetinib (GDC-0973/XL518) and a member of the Roche Group, in January 2013 that the first patient was dosed in a phase 3 pivotal trial evaluating the BRAF inhibitor Zelboraf (vemurafenib) alone or in combination with cobimetinib (GDC-0973/XL518) in previously untreated patients with malignant melanoma harboring the BRAF V600 mutation.

"The first quarter of 2013 began on a significant note with the successful U.S. launch of COMETRIQ for the treatment of progressive, metastatic MTC. We are gratified to provide an important new treatment option for patients with this disease," said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. "While we continue to execute on the commercial launch, we remain focused on advancing the cabozantinib clinical development program. The majority of sites for the COMET program, consisting of two pivotal trials in CRPC, are now open, and we continue to expect top-line data in 2014. Beyond prostate cancer, we expect to start additional pivotal trials in metastatic renal cell carcinoma (RCC) and metastatic hepatocellular carcinoma (HCC) in the third quarter 2013. In addition, we have a broad and expanding program of earlier stage trials, and updates on some of these trials will be provided at the ASCO Annual Meeting in June."

**Net revenues** for the quarter ended March 31, 2013 were \$9.7 million, compared to \$18.5 million for the comparable period in 2012. Net revenues for the quarter included \$1.9 million resulting from the sale of COMETRIQ, which became commercially available on January 24, 2013. The quarterly decrease in non-product revenues, when compared to the same period in 2012, is primarily due to \$10.7 million in revenue recognized in 2012 resulting from the completion of the technology transfer under Exelixis' December 2011 license agreement with Merck for Exelixis' PI3K-delta program.

**Research and development expenses** for the quarter ended March 31, 2013 were \$32.7 million, compared to \$33.1 million for the comparable period in 2012. The decrease was primarily due to lower personnel expenses, lower allocations of general corporate costs to research and development and lower depreciation and amortization expenses. These decreases were largely offset by increased clinical trial costs as well as increased expenses for consulting and outside services. The increase in clinical trial costs was primarily related to clinical trial activities for COMET-1 and COMET-2, Exelixis' phase 3 pivotal trials in CRPC, as well as costs incurred in preparation for phase 3 trials for metastatic HCC and metastatic RCC. These increases are largely offset by lower costs related to the continued wind down of Exelixis' phase 2 randomized discontinuation trial, EXAM, Exelixis' phase 3 pivotal trial for cabozantinib in progressive, metastatic MTC, as well as a decrease in chemistry, manufacturing and control expenses.

**Selling, general and administrative expenses** for the quarter ended March 31, 2013 were \$10.5 million, compared to \$7.9 million for the comparable period in 2012. The increase was primarily due to an increase in expenses for consulting and outside services related to both the sale of COMETRIQ in the United States and the preparation for making COMETRIQ available to patients primarily in the European Union and potentially other countries, as well as an increase in marketing expense and lower allocations of general corporate costs to research and development.

**Other income (expense), net** for the quarter ended March 31, 2013 was a net expense of (\$10.7) million compared to (\$3.8) million in the quarter ended March 31, 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 March 31, 2012 was (\$6.3) 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 March 31, 2013 was (\$44.7) million, or (\$0.24) per share, compared to (\$26.2) million, or (\$0.18) per share, basic, for the comparable period in 2012. The net loss was primarily due to decreases in revenues, increases in selling, general and administrative expenses and increased interest expenses as described above.

**Cash** and cash equivalents, short- and long-term investments and short- and long-term restricted cash and investments totaled \$566.8 million at March 31, 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 March 31, 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, May 7, 2013. To listen to a live webcast of the conference call, visit the Event Calendar page under Investors & Media at [www.exelixis.com](http://www.exelixis.com).

An archived replay of the webcast will be available on the Event Calendar page under Investors & Media at [www.exelixis.com](http://www.exelixis.com) and via phone until 11:59 p.m. PDT on June 7, 2013. Access numbers for the phone replay are: 888-286-8010 (domestic) and 617-801-6888 (international); the passcode is 84660665.

#### **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](http://www.exelixis.com).

#### **Basis of Presentation**

Exelixis adopted a 52- or 53-week fiscal year that generally ends on the Friday closest to December 31<sup>st</sup>. For convenience, references in this press release as of and for the fiscal quarters ended March 30, 2012 and March 29, 2013, and as of the fiscal year ended December 28, 2012, are indicated as ended March 31, 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 referenced distribution and commercialization of COMETRIQ in the European Union and potentially other countries, initially under a Named Patient Use Program and then more broadly only if approved by the European Medicines Agency; expected data presentations from clinical trials of cabozantinib in MTC, CRPC, uveal melanoma and bladder cancer at the 2013 ASCO Annual Meeting; Exelixis' continued execution on the commercial launch of COMETRIQ; Exelixis' focus on advancing the cabozantinib clinical development program; Exelixis' continued expectation for top-line data for the COMET program in 2014; Exelixis' plans to initiate phase 3 pivotal trials of cabozantinib in metastatic RCC and metastatic HCC in the third quarter 2013; Exelixis' expanding cabozantinib development program of earlier stage trials and updated data presentations on such trials at the 2013 ASCO Annual Meeting; and the continued development and clinical, therapeutic and commercial potential of, and opportunities for, cabozantinib. Words such as "support," "potentially," "will," "continue," "remain," "focused," "expect," "expanding," "believes," "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: the uncertainty of the regulatory approval processes; 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; 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; 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 three months ended March 29, 2013, filed with the Securities and Exchange Commission (SEC) on May 7, 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.

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#### **EXELIXIS, INC.**

#### **CONSOLIDATED STATEMENTS OF OPERATIONS**

(in thousands, except per share data)

(unaudited)

	<b>Three Months Ended March 31,</b>	
	<b>2013</b>	<b>2012</b>
Revenues:		
License and contract revenues	\$ 7,813	\$ 18,510
Net product revenues	1,856	—
Total revenues	9,669	18,510
Operating expenses:		
Cost of goods sold	280	—
Research and development	32,735	33,096
Selling, general and administrative	10,545	7,905
Restructuring charge (credit)	119	(195 )
Total operating expenses	43,679	40,806
Loss from operations	(34,010 )	(22,296 )
Other income (expense), net:		
Interest income and other, net	338	160
Interest expense	(11,057 )	(4,004 )
Total other income (expense), net	(10,719 )	(3,844 )
Loss before income taxes	(44,729 )	(26,140 )
Income tax provision	—	11
Net loss	\$ (44,729 )	\$ (26,151 )
Net loss per share, basic and diluted	\$ (0.24 )	\$ (0.18 )
Shares used in computing basic and diluted net loss per share	183,742	141,940

## **EXELIXIS, INC.**

### **CONDENSED CONSOLIDATED BALANCE SHEET DATA**

(in thousands)

	<b>March 31,</b>	<b>December 31,</b>
	<b>2013</b>	<b>2012 (1)</b>
	(unaudited)	
Cash and investments (2)	\$ 566,757	\$ 633,961
Working capital	\$ 316,146	\$ 350,837
Total assets	\$ 659,527	\$ 721,097
Total stockholders' equity	\$ 254,852	\$ 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 \$34.1 million and \$40.2 million as of March 31, 2013 and December 31, 2012, respectively.

Source: Exelixis, Inc.

*Exelixis, Inc.*

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