



## Exelixis Announces Third Quarter 2013 Financial Results

October 30, 2013

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

### Q3 2013 Highlights and Recent Events

- Reported net product revenue for COMETRIQ® (cabozantinib) of \$4.8 million in the third quarter of 2013.
- Reached the enrollment target of 960 patients for COMET-1, the phase 3 pivotal trial of cabozantinib in patients with metastatic castration-resistant prostate cancer (mCRPC). The primary endpoint of COMET-1 is overall survival (OS). Top-line data from COMET-1 and a second pivotal trial in mCRPC, COMET-2, with the primary endpoint of pain response in patients with bone pain associated with bone metastases, are expected in 2014.
- Initiated CELESTIAL, a phase 3 pivotal trial comparing cabozantinib to placebo in patients with advanced hepatocellular carcinoma (HCC) who have previously been treated with sorafenib. The trial is expected to enroll 760 patients at up to 200 sites globally in up to 30 countries. The primary endpoint is OS, and the secondary endpoints include objective response rate (ORR) and progression-free survival (PFS).
- Announced updated results from BRIM7, an ongoing phase 1b clinical trial conducted by Roche and Genentech, Exelixis' collaborator and a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY) at the European Cancer Congress 2013. The study is evaluating the BRAF inhibitor (BRAFi) vemurafenib in combination with the MEK inhibitor cobimetinib (GDC-0973/XL518) in patients with locally advanced/unresectable or metastatic melanoma carrying a BRAF<sup>V600</sup> mutation. The ORR (comprising complete or partial responses) was 85% in the cohort of BRAFi-naïve patients. As previously announced, Genentech is conducting a phase 3 pivotal trial evaluating vemurafenib alone or in combination with cobimetinib in previously untreated patients with malignant melanoma and the BRAF<sup>V600</sup> mutation, for which data are expected in 2014.

"The continued progress of our clinical development program is illustrated by the five ongoing pivotal trials investigating cabozantinib in multiple indications, including the METEOR trial in metastatic renal cell cancer (RCC) and the CELESTIAL trial in advanced HCC," said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. "Top-line data from COMET-1 and COMET-2 and the overall survival analysis for EXAM are expected in 2014. Additionally, the phase 3 pivotal trial of vemurafenib alone or in combination with cobimetinib is also expected to report data in 2014. Thus, we believe 2014 will be an important year for Exelixis with the potential read out of a total of four phase 3 pivotal trials for the Exelixis-discovered compounds cabozantinib and cobimetinib."

**Net revenues** for the quarter ended September 30, 2013 were \$5.5 million, compared to \$13.3 million for the comparable period in 2012. Revenues for the quarter included net product revenues of \$4.8 million from the sale of COMETRIQ, which became commercially available in late January 2013. The overall decrease in revenues during the quarter as compared to the same period in 2012 was due to a decrease in contract and license revenue relating to the depletion of deferred revenues from Bristol-Myers Squibb and a \$5.5 million milestone payment received from Daiichi Sankyo in August 2012.

**Research and development expenses** for the quarter ended September 30, 2013 were \$47.4 million, compared to \$30.7 million for the comparable period in 2012. The increases were predominantly driven by clinical trial costs, primarily related to clinical trial activities for COMET-1 as well as costs incurred in connection with the start-up of the METEOR phase 3 pivotal trial in metastatic RCC and the CELESTIAL phase 3 pivotal trial in advanced HCC.

**Selling, general and administrative expenses** for the quarter ended September 30, 2013 were \$13.6 million, compared to \$7.3 million for the comparable period in 2012. Approximately half of the increase was a result of an increase in expenses related to consulting and outside services provided by our U.S. sales force and our European distribution partner for the sale of COMETRIQ. The remaining increase was related to legal and accounting fees, wages and benefits, employee stock-based compensation expense, and patent costs. These increases were partially offset by decreases in facilities costs.

**Other income (expense), net** for the quarter ended September 30, 2013 was a net expense of \$(11.2) million compared to \$(7.4) million for the comparable period in 2012. The increase in expense 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 September 30, 2013 was \$6.7 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 Management Company, L.P.

**Net loss** for the quarter ended September 30, 2013 was \$(67.1) million, or \$(0.36) per share, basic, compared to \$(32.8) million, or \$(0.20) per share, basic, for the comparable period in 2012. The increased net loss was primarily due to increases in research and development expenses, selling, general and administrative expenses and decreases in license and contract revenues, which were slightly offset by increases in product revenues, as described above.

**Cash** and cash equivalents, short- and long-term investments and short- and long-term restricted cash and investments totaled \$464.7 million at September 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 September 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, Wednesday, October 30, 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. PST on November 30, 2013. Access numbers for the phone replay are: 888-286-8010 (domestic) and 617-801-6888 (international); the passcode is 62077154.

### 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](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 September 28, 2012 and September 27, 2013, and as of the fiscal year ended December 28, 2012, are indicated as ended September 30, 2012, September 30, 2013, and 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 and cobimetinib (GDC-0973/XL518); the designs, plans and goals for the COMET-1 and COMET-2 trials of cabozantinib in mCRPC, and the timing (including for the readout of top-line data) thereof; the design, plans and goals for the CELESTIAL trial of cabozantinib in advanced HCC; the design, plans and goals for the phase 3 pivotal trial of cobimetinib in locally advanced/unresectable or metastatic melanoma, and the timing (including for the readout of top-line data) thereof; the continued progress of Exelixis' development program; and the expectation that 2014 will be an important year for Exelixis, with the potential read out of a total of four phase 3 pivotal trials for cabozantinib and cobimetinib. Words such as "expected," "endpoint," "continued," "progress," "believe," "will," "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: risks related to the potential failure of cabozantinib or cobimetinib (GDC-0973/XL518) 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; Exelixis' dependence on its relationship with Genentech/Roche for the development of cobimetinib (GDC-0973/XL518) and Exelixis' ability to maintain its rights under the collaboration; the uncertainty of regulatory approval processes; 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; 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 September 27, 2013, filed with the Securities and Exchange Commission (SEC) on October 30, 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, the Exelixis logo, and COMETRIQ are registered U.S. trademarks.*

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2013</u>	<u>2012</u>	<u>2013</u>	<u>2012</u>
Revenues:				
License and contract revenues	\$ 695	\$ 13,313	\$ 16,321	\$ 39,636
Net product revenues	4,771	—	10,670	—
Total revenues	<u>5,466</u>	<u>13,313</u>	<u>26,991</u>	<u>39,636</u>
Operating expenses:				
Cost of goods sold	290	—	855	—
Research and development	47,354	30,680	129,166	96,386
Selling, general and administrative	13,598	7,343	37,323	22,008
Restructuring charge	137	733	865	1,704

Total operating expenses	61,379	38,756	168,209	120,098
Loss from operations	(55,913)	(25,443)	(141,218)	(80,462)
Other income (expense), net:				
Interest income and other, net	219	318	930	818
Interest expense	(11,430)	(7,679)	(33,726)	(15,775)
Total other income (expense), net	(11,211)	(7,361)	(32,796)	(14,957)
Loss before income taxes	(67,124)	(32,804)	(174,014)	(95,419)
Income tax provision	—	10	—	33
Net loss	<u>\$ (67,124)</u>	<u>\$ (32,814)</u>	<u>\$ (174,014)</u>	<u>\$ (95,452)</u>
Net loss per share, basic and diluted	\$ (0.36)	\$ (0.20)	\$ (0.95)	\$ (0.63)
Shares used in computing basic and diluted net loss per share	184,149	166,354	183,957	152,316

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

	<b>September 30, 2013</b>		<b>December 31, 2012 (1)</b>
	<b>(unaudited)</b>		
Cash and investments (2)	\$ 464,721	\$	633,961
Working capital	\$ 228,284	\$	350,837
Total assets	\$ 555,959	\$	721,097
Total stockholders' equity	\$ 132,763	\$	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 totaled \$28.1 million and \$40.2 million as of September 30, 2013 and December 31, 2012, respectively.



Source: Exelixis, Inc.

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