



Exelixis Announces Fourth Quarter and Full Year 2013 Financial Results

February 20, 2014

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Feb. 20, 2014-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the fourth quarter and year ended December 31, 2013.

Q4 2013 Highlights and Recent Events

- Completed enrollment in COMET-1, the phase 3 study of cabozantinib versus prednisone with the primary endpoint of overall survival in patients with advanced metastatic castration-resistant prostate cancer (CRPC). The study reached its enrollment target of 960 patients in September 2013 and the enrollment was closed in November 2013.
- Received a positive opinion from the European Committee for Medicinal Products for Human Use (CHMP) on the Marketing Authorization Application (MAA) for COMETRIQ® (cabozantinib) for the treatment of adult patients with progressive, unresectable locally advanced or metastatic medullary thyroid cancer (MTC). The opinion is now being reviewed by the European Commission, which has the authority to approve medicines for the European Union.
- Initiated a phase 2 clinical trial comparing cabozantinib plus abiraterone and prednisone versus abiraterone/prednisone in patients with CRPC who have bone metastases and have not been previously treated with chemotherapy. The primary endpoint for the randomized, open-label trial is radiographic progression-free survival (PFS). The company believes that the results of this trial could provide important insight into the role that cabozantinib might play in earlier lines of therapy, including patients who have not yet received chemotherapy.
- 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.
- Reported net product revenue for COMETRIQ (cabozantinib) of \$4.3 million in the fourth quarter of 2013.
- 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.

"We made significant progress in 2013 by launching COMETRIQ in MTC in the U.S. and substantially advancing our cabozantinib clinical development efforts by completing enrollment in COMET-1 and initiating pivotal trials in metastatic renal cell cancer (RCC) and advanced hepatocellular cancer (HCC). Building off that success, 2014 has the potential to be a transformational year in advancing our mission to help patients with cancer. We started the year with two internally-discovered compounds in six ongoing pivotal trials, with four of these trials expected to deliver top-line data in 2014," said Michael M. Morrissey, Ph.D., the company's president and chief executive officer. "These include the COMET-1 and COMET-2 trials for cabozantinib in metastatic CRPC, and a pivotal trial of cobimetinib conducted by Roche and Genentech in patients with malignant melanoma, in addition to the overall survival readout for EXAM in MTC. While we look forward to these results, we continue to advance the other components of our global clinical development program, which is focused on identifying additional opportunities for cabozantinib to expand its clinical and commercial potential."

Net revenues for the quarter ended December 31, 2013 were \$4.3 million, compared to \$7.8 million for the comparable period in 2012; and for the year ended December 31, 2013 were \$31.3 million compared to \$47.5 million for the year ended December 31, 2012. Revenues included net product revenues of \$4.3 million and \$15.0 million for the quarter and year ended December 31, 2013, respectively, from the sale of COMETRIQ, which became commercially available in late January 2013. The overall decrease in revenues during both the quarter and the year as compared to the same periods in 2012 was due to a decrease in contract and license revenue as a result of having fully recognized all revenues from the company's collaboration agreements with Bristol-Myers Squibb Company. The decrease in revenues during the year was also due to \$10.7 million in license revenue recognized in 2012 resulting from the completion of the technology transfer under the company's December 2011 license agreement with Merck for the company's PI3K-delta program, and a \$5.5 million milestone payment received in August 2012 under the company's collaboration agreement with Daiichi Sankyo for XL550.

Research and development expenses for the quarter ended December 31, 2013 were \$49.6 million, compared to \$32.5 million for the comparable period in 2012; and for the year ended December 31, 2013 were \$178.8 million compared to \$128.9 million for the year ended December 31, 2012. The increase during both the quarter and the year was predominantly driven by clinical trial costs, primarily related to clinical trial activities for COMET-1 and METEOR, the company's phase 3 pivotal trials in metastatic CRPC and metastatic RCC, respectively, as well as costs incurred in connection with the start-up of the CELESTIAL phase 3 pivotal trial in advanced HCC. For the year, the increases in costs for those trials were partially offset by lower clinical trial costs related to the continued wind down of various phase 2 studies for cabozantinib, most notably the randomized

discontinuation trial, as well as the EXAM trial for cabozantinib in patients with MTC.

Selling, general and administrative expenses for the quarter ended December 31, 2013 were \$13.6 million, compared to \$9.8 million for the comparable period in 2012; and for the year ended December 31, 2013 were \$51.0 million compared to \$31.8 million for the year ended December 31, 2012. The increase during both the quarter and the year was primarily a result of an increase in expenses related to the company's U.S. sales force and the company's European distribution partner for the sale of COMETRIQ, personnel expenses and employee stock-based compensation expense. The increase during the year was also due to increases in legal and accounting fees, patent costs, and lower overhead allocations to research and development, which were partially offset by a decrease in facilities costs.

Other income (expense), net for the quarter ended December 31, 2013 was a net expense of (\$11.3) million compared to (\$10.1) million for the comparable period in 2012; and for the year ended December 31, 2013 was (\$44.1) million compared to (\$25.1) million for the year ended December 31, 2012. The increase in expense for the quarter was primarily related to the gain on sale of excess property and equipment in 2012 and for the year end 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 and year ended December 31, 2013 was \$6.8 million and \$26.3 million, respectively, 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.

Net loss for the quarter ended December 31, 2013 was (\$70.7) million, or (\$0.38) per share, basic, compared to (\$52.2) million, or (\$0.28) per share, basic, for the comparable period in 2012; and for the year ended December 31, 2013 was (\$244.8) million, or (\$1.33) per share, compared to (\$147.6) million, or (\$0.92) per share, basic, for the year ended December 31, 2012. The increased net loss during both the quarter and the year 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 \$415.9 million at December 31, 2013, compared to \$634.0 million at December 31, 2012.

Financial Outlook

For the full year 2014, Exelixis does not expect any significant contract and license revenue in 2014 and is not providing guidance on expected revenue from COMETRIQ product sales at this time. Exelixis expects total costs and expenses in the range of \$250 million to \$280 million, including non-cash expenses of approximately \$16 million to \$18 million related primarily to stock-based compensation expense. Exelixis further expects interest expense of approximately \$47 million, which includes non-cash charges of \$28 million. Exelixis expects its cash and cash equivalents, short- and long-term investments and short- and long-term restricted cash and investments to be greater than \$200 million at the end of 2014.

Conference Call and Webcast

Exelixis' management will discuss the company's financial results for the quarter ended December 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. EST/2:00 p.m. PST today, Thursday, February 20, 2014. 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 8:59 p.m. PST on March 20, 2014. Access numbers for the phone replay are: 888-286-8010 (domestic) and 617-801-6888 (international); the passcode is 59600043.

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 and years ended December 28, 2012 and December 27, 2013 are indicated as ended December 31, 2012 and December 31, 2013, respectively.

Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to: the review by the European Commission of the CHMP's referenced positive opinion on the MAA for COMETRIQ® (cabozantinib); the belief that the referenced phase 2 clinical trial of cabozantinib in combination with other agents in patients with CRPC could provide insight into the role cabozantinib might play in earlier lines of therapy; the potential for 2014 to be a transformational year for Exelixis; the expected timing of various trials, including expected top-line data from four pivotal trials in 2014; the continued development and clinical, therapeutic and commercial potential of, and opportunities for, cabozantinib; and Exelixis' financial outlook for 2014, including expected contract and license revenue, total costs and expenses, including non-cash expenses, interest expense, including non-cash charges, and 2014 year-end cash and cash equivalents, short- and long-term investments and short- and long-term restricted cash and investments balance. Words such as "being," "believes," "could," "provide," "might," "potential," "transformational," "expect," "look forward," "continue," "advance," "focused," "opportunities," "expand," "outlook," 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' annual report on Form 10-K filed with the Securities and Exchange Commission (SEC) on February 20, 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, the Exelixis logo, and COMETRIQ are registered U.S. trademarks.

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

	<u>Three Months Ended December 31,</u>		<u>Year Ended December 31,</u>	
	<u>2013</u>	<u>2012</u>	<u>2013</u>	<u>2012</u>
	(Unaudited)			
Revenues:				
License and contract revenues	\$ —	\$ 7,814	\$ 16,321	\$ 47,450
Net product revenues	4,347	—	15,017	—
Total revenues	<u>4,347</u>	<u>7,814</u>	<u>31,338</u>	<u>47,450</u>
Operating expenses:				
Cost of goods sold	263	—	1,118	—
Research and development	49,597	32,492	178,763	128,878
Selling, general and administrative	13,635	9,829	50,958	31,837
Restructuring charge	366	7,467	1,231	9,171
Total operating expenses	<u>63,861</u>	<u>49,788</u>	<u>232,070</u>	<u>169,886</u>
Loss from operations	<u>(59,514)</u>	<u>(41,974)</u>	<u>(200,732)</u>	<u>(122,436)</u>
Other income (expense), net:				
Interest income and other, net	293	1,168	1,223	1,986
Interest expense	(11,621)	(11,313)	(45,347)	(27,088)
Total other income (expense), net	<u>(11,328)</u>	<u>(10,145)</u>	<u>(44,124)</u>	<u>(25,102)</u>
Loss before income taxes	(70,842)	(52,119)	(244,856)	(147,538)
Income tax (benefit) provision	(96)	74	(96)	107
Net loss	<u>\$ (70,746)</u>	<u>\$ (52,193)</u>	<u>\$ (244,760)</u>	<u>\$ (147,645)</u>
Net loss per share, basic and diluted	\$ (0.38)	\$ (0.28)	\$ (1.33)	\$ (0.92)
Shares used in computing basic and diluted net loss per share	184,376	183,605	184,062	160,138

EXELIXIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEET DATA (1)
(in thousands)

	<u>December 31,</u>	<u>December 31,</u>
	<u>2013</u>	<u>2012</u>
Cash and investments (2)	\$ 415,862	\$ 633,961
Working capital	\$ 178,756	\$ 350,837
Total assets	\$ 503,287	\$ 721,097

Total stockholders' equity \$ 66,238 \$ 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 \$29.1 million and \$40.2 million as of December 31, 2013 and 2012, respectively.



Source: Exelixis, Inc.

Exelixis, Inc.

Frank Karbe, 650-837-7565

Chief Financial Officer

fkarbe@exelixis.com

Charles Butler, 650-837-7277

Vice President

Investor Relations & Corporate Communications

cbutler@exelixis.com