



## Exelixis Announces Third Quarter 2014 Financial Results and Provides Corporate Update

November 4, 2014

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

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 4, 2014-- Exelixis, Inc. (Nasdaq:EXEL) today reported financial results for the third quarter of 2014 and provided an update on its progress toward delivering upon its key corporate objectives and clinical development milestones.

### **Corporate Updates and Key Priorities for 2014/2015**

As detailed in early September, following the top-line results of the COMET-1 trial in metastatic castration-resistant prostate cancer (CRPC), Exelixis initiated a significant workforce reduction in order to focus its development efforts and financial resources on the opportunities for cabozantinib in metastatic renal cell carcinoma (RCC) and advanced hepatocellular carcinoma (HCC). The company also continues to support its partner Genentech, a member of the Roche Group, as it prepares for the potential commercialization of cobimetinib, an Exelixis-discovered compound.

**METEOR Trial Enrollment Nearly Complete.** Enrollment in METEOR, the phase 3 pivotal trial in metastatic RCC, is nearly complete. Exelixis expects the last patient to be enrolled before the end of 2014, setting the stage for top-line results for the trial's primary endpoint, progression-free survival (PFS), in the second quarter of 2015. Per the trial protocol, the primary endpoint analysis will be conducted once 259 events have occurred among the first 375 patients enrolled. This allows for sufficient follow-up for the primary PFS endpoint at the time of analysis. Enrollment for the first 375 patients in METEOR was completed in June 2014.

**Cobimetinib - Continued Development and Regulatory Progress.** In the third quarter of 2014, positive phase 3 results from the coBRIM study, the phase 3 pivotal trial evaluating cobimetinib in combination with vemurafenib in previously untreated patients with unresectable locally advanced or metastatic melanoma harboring a BRAF V600 mutation, were announced and subsequently presented in detail at the European Society for Medical Oncology 2014 Congress in Madrid, Spain. Roche has announced that it completed the Marketing Authorization Application for the combination of cobimetinib and vemurafenib in the European Union. In the United States, cobimetinib has received Fast Track Designation from the U.S. Food and Drug Administration, and Genentech expects to complete its New Drug Application filing for the combination before the end of this year. Exelixis and Genentech continue to make progress in their commercialization planning and preparations.

**COMET-2 Trial Top-Line Results Anticipated By Year-End.** Exelixis continues to anticipate top-line results from COMET-2 before the end of 2014. The trial is evaluating cabozantinib in men with metastatic CRPC who have moderate to severe bone pain despite optimized narcotics medication, and the primary endpoint is pain response in the absence of any increase in narcotics. As previously stated, Exelixis has deprioritized cabozantinib's development in metastatic CRPC, and based upon the totality of the data from the COMET program, Exelixis will discuss with regulatory authorities the potential regulatory path, if any, of cabozantinib in metastatic CRPC.

**Overall Survival (OS) Analysis for EXAM Trial in Medullary Thyroid Cancer (MTC).** EXAM is the phase 3 pivotal trial that served as the basis for the regulatory approval of COMETRIQ® (cabozantinib) to treat progressive, metastatic MTC in the U.S. (November 2012) and EU (March 2014). The primary endpoint of the study is PFS and the previously-reported data from this study demonstrated that treatment with cabozantinib resulted in a 2.8-fold increase in PFS compared with placebo. OS is the secondary endpoint of the trial, and the final analysis required at least 217 events to have occurred. Exelixis has now completed the OS analysis and the estimated median OS for the cabozantinib arm is 26.6 months versus 21.1 months for the placebo arm (HR = 0.85; 95% CI 0.64-1.12; p = 0.2409). These results are generally consistent with those observed in an earlier interim analysis conducted in 2012, and did not reach statistical significance. The subgroup analysis by RET M918T mutation status, a known negative prognostic factor in MTC, revealed a large and statistically significant improvement in OS of 25.4 months with cabozantinib for the RET M918T positive population (HR = 0.60, p = 0.0260). Exelixis will submit the final results for publication at an upcoming scientific forum, and to regulatory authorities to satisfy post-marketing commitments.

**XL888 Late-Breaking Oral Presentation at 2014 Society for Melanoma Research (SMR) Congress.** XL888 is a novel, synthetic orally bioavailable HSP90 inhibitor discovered and wholly owned by Exelixis. Exelixis advanced XL888 through phase 1 testing and then placed the program on hold to allow the company to focus its resources on the development of cabozantinib. Based on compelling preclinical data showing that resistance to vemurafenib can arise due to the activity of multiple HSP90 client proteins, investigators at the Moffitt Cancer Center initiated an ongoing phase 1 investigator-sponsored trial evaluating XL888 in combination with vemurafenib in BRAF inhibitor naïve patients with metastatic BRAF V600 mutant melanoma. Exelixis was recently notified by the investigators that results from this trial will be the subject of a late-breaking oral presentation at the 2014 SMR Congress (November 13-16, 2014, Zurich, Switzerland). Based upon these data, plans are underway by the investigators to initiate a phase 1b triple combination trial evaluating vemurafenib, cobimetinib, and XL888 in a similar patient population.

**Product Revenue from COMETRIQ.** Net product revenue from COMETRIQ sales was \$6.3 million for the third quarter of 2014, an increase of 32 percent over the third quarter of 2013, reflecting the continued ramp up in sales of the product following its commercial launch in the United States in January 2013. Net product revenue for the third quarter of 2014 includes the impact of a reduction to revenue for the recognition of a one-time project management fee of \$1.8 million payable to Exelixis' European distribution partner upon their anticipated achievement of a cumulative revenue goal by the end of 2014. The remaining portion of the one-time project management fee, or \$0.6 million, is expected to be recognized in the fourth quarter of 2014.

**Updated Financial Guidance.** Exelixis expects to end 2014 with greater than \$200 million in cash and cash equivalents, short- and long-term investments and short- and long-term restricted cash and investments. The company also now anticipates that full year 2014 operating expenses will be in the range of \$250 million to \$260 million. This range includes the employee termination benefits and asset impairments, but does not include any restructuring costs associated with potentially exiting certain of the company's buildings. Taking into account the company's cost saving measures,

including the restructuring activities referred to above, and an expected extension of the maturity date of the company's indebtedness under its note purchase agreement with Deerfield to July 1, 2018 from July 1, 2015. Exelixis expects that its current cash and cash equivalents, short- and long-term investments and product revenues are sufficient to fund its operations through the end of 2015. Exelixis has until March 31, 2015 to exercise its option to extend the maturity date of the Deerfield indebtedness, as provided for by the January 2014 amendment to the note purchase agreement. Any exercise of the extension option by Exelixis will be subject to customary conditions set forth in the note purchase agreement, as amended.

"Exelixis moved decisively and rapidly following the deprioritization of metastatic CRPC to refocus the company in support of the late-stage trials of cabozantinib in metastatic RCC and advanced HCC," said Michael M. Morrissey, Ph.D., the company's president and chief executive officer. "Over the past two months, the Exelixis team has worked diligently and made strong progress toward the clinical and business goals that will position us to realize the potential of cabozantinib."

Dr. Morrissey continued: "As we conclude 2014 and enter 2015, we continue to focus on the execution of the cabozantinib clinical development program, including the delivery of top-line results from the METEOR trial, now anticipated in the second quarter of 2015. Exelixis also remains committed to co-promoting cobimetinib for metastatic melanoma, pending regulatory filing and approval. Our continued cost-savings initiatives and ongoing financial discipline, together with the expected extension of the maturity of our Deerfield debt, have provided us with adequate resources to take us through the full year 2015, and we look forward to reporting on our progress in the coming weeks and months."

### **Third Quarter 2014 Financial Results**

**Net revenues** for the quarter ended September 30, 2014 were \$6.3 million, consisting entirely of product revenue related to the sale of COMETRIQ, compared to \$5.5 million for the comparable period in 2013, which consisted of \$4.8 million of product revenue related to the sale of COMETRIQ and \$0.7 million of license and contract revenue. Product revenues for the quarter ended September 30, 2014 were net of a \$1.8 million reduction to revenue for a project management fee payable to Exelixis' European distribution partner, as discussed above; no such fees were recognized during the comparable period in 2013. The decrease in contract and license revenue reflects the company's full recognition of all revenues from its collaboration agreements with Bristol-Myers Squibb Company in 2013.

**Research and development expenses** for the quarter ended September 30, 2014 were \$43.6 million, compared to \$47.4 million for the comparable period in 2013. The decrease was primarily related to the reversal of accrued employee bonuses and stock-based compensation recognized in prior periods on stock options that were granted subject to performance objectives, both as a result of the outcome of COMET-1. In addition, clinical trial costs decreased predominantly due to a reduction in costs related to COMET-1 that was offset in part by increases in costs related to METEOR and CELESTIAL, Exelixis' phase 3 pivotal trial in advanced HCC.

**Selling, general and administrative expenses** for the quarter ended September 30, 2014 were \$9.9 million, compared to \$13.6 million for the comparable period in 2013. The decrease was primarily related to a reduction in legal costs, and reversals of accrued employee bonuses and stock-based compensation recognized in prior periods on stock options that were granted subject to performance objectives, both as a result of the outcome of COMET-1. Those decreases were partially offset by increased personnel expenses, the majority of which is connected with the expansion of the company's U.S. sales force and marketing expenses, including an increase in expenses for cobimetinib under the company's collaboration agreement with Genentech.

**Restructuring charge** for the quarter ended September 30, 2014 was \$3.8 million compared to \$0.1 million for the comparable period in 2013. The restructuring charge for the quarter ended September 30, 2014 was primarily related to employee termination benefits and asset impairment charges resulting from the restructuring plan initiated in September 2014.

**Other income (expense), net** for the quarter ended September 30, 2014 was a net expense of (\$11.0) million compared to (\$11.2) million for the comparable period in 2013. Included in interest expense for the quarter ended September 30, 2014 was \$7.5 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 indebtedness under its note purchase agreement with Deerfield, as compared to \$6.7 million for the comparable period in 2013.

**Net loss** for the quarter ended September 30, 2014 was (\$62.6) million, or (\$0.32) per share, basic, compared to (\$67.1) million, or (\$0.36) per share, basic, for the comparable period in 2013. The decreased net loss was primarily due to decreases in research and development expenses and selling, general and administrative expenses, and an increase in product revenues, which was partially offset by an increase in restructuring charges.

**Cash** and cash equivalents, short- and long-term investments and short- and long-term restricted cash and investments totaled \$293.5 million at September 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 September 30, 2014 and provide a general business update during a conference call beginning at 5:00 p.m. EST/2:00 p.m. PST today, November 4, 2014. To join the call, participants may dial 1-866-270-6057 (domestic) or 1-617-213-8891 (international) and use passcode 72954080. 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 conference call 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. EST on December 4, 2014. Access numbers for the phone replay are: 888-286-8010 (domestic) and 617-801-6888 (international); the passcode is 91709998.

### **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](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 periods ended September 26, 2014 and September 27, 2013, and as of the fiscal year ended December 27, 2013, are indicated as ended September 30, 2014, September 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, cobimetinib and other Exelixis compounds; anticipated developments and timing with respect to Exelixis' ongoing phase 3 pivotal trials of cabozantinib; future cobimetinib regulatory filings and potential approvals; the progress of Exelixis' commercialization planning and preparation efforts with Genentech; future data presentations and clinical trial planning; expected timing for future revenue recognition; Exelixis' updated financial outlook for 2014, including 2014 year-end cash and cash equivalents, short- and long-term investments and short- and long-term restricted cash and investments balance and full year 2014 operating expenses; the sufficiency of Exelixis' cash resources to fund its operations through the end of 2015; the expected extension of the maturity date of Exelixis' indebtedness under its note purchase agreement with Deerfield to July 1, 2018 from July 1, 2015; and the timing of future reporting on Exelixis' progress. Words such as "continues," "expects," "anticipate," "will," "plan," "initiate," "potential," "focus," "delivery," "committed," "look forward," 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, cobimetinib and other Exelixis compounds to demonstrate safety and efficacy in clinical testing; the clinical, therapeutic and commercial value of cobimetinib, cabozantinib and other Exelixis compounds; 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; Exelixis' ability to extend the maturity date of its indebtedness under its note purchase agreement with Deerfield in accordance with, and subject to, the terms and conditions of the note purchase agreement; the risk that unanticipated developments could adversely affect the commercialization of COMETRIQ<sup>®</sup> (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 November 4, 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.

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## EXELIXIS, INC. CONDENSED 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>2014</u>	<u>2013</u>	<u>2014</u>	<u>2013</u>
Revenues:				
Net product revenues	\$ 6,291	\$ 4,771	\$ 17,758	\$ 10,670
License and contract revenues	—	695	—	16,321
Total revenues	<u>6,291</u>	<u>5,466</u>	<u>17,758</u>	<u>26,991</u>
Operating expenses:				
Cost of goods sold	573	290	1,359	855
Research and development	43,628	47,354	149,451	129,166
Selling, general and administrative	9,906	13,598	41,063	37,323
Restructuring charge	3,758	137	4,135	865
Total operating expenses	<u>57,865</u>	<u>61,379</u>	<u>196,008</u>	<u>168,209</u>
Loss from operations	<u>(51,574)</u>	<u>(55,913)</u>	<u>(178,250)</u>	<u>(141,218)</u>
Other income (expense), net:				
Interest income and other, net	1,296	219	3,786	930
Interest expense	(12,282)	(11,430)	(36,125)	(33,726)
Total other income (expense), net	<u>(10,986)</u>	<u>(11,211)</u>	<u>(32,339)</u>	<u>(32,796)</u>
Net loss	<u>\$ (62,560)</u>	<u>\$ (67,124)</u>	<u>\$ (210,589)</u>	<u>\$ (174,014)</u>

Net loss per share, basic and diluted	\$	(0.32)	\$	(0.36)	\$	(1.09)	\$	(0.95)
Shares used in computing basic and diluted net loss per share		195,126		184,149		193,855		183,957

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

	<b>September 30,</b>	<b>December 31,</b>
	<b>2014</b>	<b>2013 (1)</b>
	<u>(unaudited)</u>	<u></u>
Cash and investments (2)	\$ 293,485	\$ 415,862
Working capital	\$ 46,758	\$ 178,756
Total assets	\$ 383,656	\$ 503,287
Total stockholders' (deficit) equity	\$ (58,511)	\$ 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 \$16.9 million and \$29.1 million as of September 30, 2014 and December 31, 2013, respectively.



Source: Exelixis, Inc.

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