



Exelixis Announces Third Quarter 2015 Financial Results and Provides Corporate Update

November 10, 2015

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

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 10, 2015-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the third quarter of 2015 and provided an update on progress toward delivering upon its key 2015 corporate objectives and clinical development milestones.

Key Priorities and Corporate Updates

Following release of positive results from the pivotal METEOR trial, Exelixis is focused on expediting its regulatory submissions and augmenting its commercial infrastructure to support the potential launch of its lead compound, cabozantinib, in advanced renal cell carcinoma (RCC) in the United States. At the same time, in support of its collaboration partner, Genentech, a member of the Roche Group, Exelixis is rolling out its portion of the U.S. sales force promoting COTELLIC™ (cobimetinib), a second Exelixis-discovered compound, following recent regulatory approvals for the compound in combination with vemurafenib for the treatment of BRAF V600 mutation-positive unresectable or metastatic melanoma in the United States and Switzerland.

Cabozantinib Highlights

METEOR Trial Delivers Positive Results in Advanced RCC; Cabozantinib Granted Breakthrough Therapy Designation. In July 2015, Exelixis announced that METEOR met its primary endpoint, demonstrating a statistically significant improvement in progression-free survival (PFS) for cabozantinib versus everolimus in a population of patients with advanced RCC who have experienced disease progression following treatment with at least one prior VEGFR tyrosine kinase inhibitor. Based on these data, the FDA granted Breakthrough Therapy Designation to cabozantinib as a potential treatment for patients with advanced RCC who have received one prior therapy. In September 2015, detailed data from METEOR were published in *The New England Journal of Medicine* and also presented during the Presidential Session I at the European Cancer Congress in Vienna, Austria.

Progress on U.S. and EU Regulatory Filings for Cabozantinib in Advanced RCC. Based on the data from the METEOR trial, in October 2015, Exelixis initiated the rolling submission of its New Drug Application (NDA) in the United States. Exelixis expects to complete the U.S. filing before the end of 2015. In the European Union, the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has granted accelerated assessment to cabozantinib for advanced RCC. As a result, when filed, the company's Marketing Authorization may be eligible for a 150-day review, versus the standard 210 days (excluding clock stops when written or oral information is requested from CHMP). Exelixis expects to complete the EU filing in early 2016.

Results from a Randomized Phase 2 Trial in First-Line RCC Expected in the First Half 2016. The randomized phase 2 trial comparing cabozantinib versus sunitinib in the treatment of first-line intermediate or poor risk RCC patients, CABOSUN, completed enrollment in early 2015 and results for the primary endpoint of PFS are now expected in the first half of 2016. CABOSUN is being conducted by The Alliance for Clinical Trials in Oncology as part of Exelixis' collaboration with the National Cancer Institute's Cancer Therapy Evaluation Program (NCI-CTEP).

Trial Underway Evaluating Cabozantinib with Immunotherapies. In July 2015, Exelixis' collaborators at NCI-CTEP initiated a phase 1 trial of cabozantinib in combination with nivolumab alone, or in combination with nivolumab plus ipilimumab, in patients with genitourinary tumors, including bladder cancer and RCC. The primary endpoint of the trial is the determination of dose-limiting toxicities and a recommended phase 2 dose for the combinations. Exelixis believes that there is a strong rationale for combining cabozantinib with immunotherapies, including clinical evidence of cabozantinib's ability to create a more immune-permissive environment, as well as preclinical data suggesting cabozantinib increases T-cell infiltration into tumors. Data from this trial could have relevance in other disease settings, including non-small cell lung cancer (NSCLC).

Cobimetinib Highlights

Regulatory Progress for COTELLIC in Europe, Including Approval in Switzerland and Positive Opinion Issued by the European Medicines Agency's CHMP. On August 27, 2015, Exelixis announced that Swissmedic, the Swiss licensing and supervisory authority, approved COTELLIC for use in combination with vemurafenib as a treatment for patients with advanced melanoma. In September 2015, the European Medicines Agency's CHMP adopted a positive opinion of Roche's Marketing Authorization Application for COTELLIC in combination with vemurafenib for the treatment of BRAF V600 mutation-positive unresectable or metastatic melanoma. The European Commission is expected to release its final opinion by the end of 2015. Under the terms of the collaboration agreement with Roche and Genentech, Exelixis will receive royalties on sales of COTELLIC outside of the United States.

Positive Overall Survival Data for Cobimetinib in Combination with Vemurafenib in Advanced Melanoma. In October 2015, Exelixis announced that the phase 3 coBRIM trial of cobimetinib in combination with vemurafenib met its secondary endpoint of demonstrating a statistically significant and clinically meaningful increase in overall survival for patients with unresectable locally advanced or metastatic melanoma carrying the BRAF V600 mutation. These data will be the subject of a presentation at the Society for Melanoma Research 2015 Congress taking place in San Francisco, November 18-21, 2015.

Regulatory Approval for COTELLIC in the United States. Today, Exelixis announced that the U.S. FDA approved cobimetinib for use in combination with vemurafenib as a treatment for patients with BRAF V600 mutation-positive advanced melanoma. COTELLIC is expected to be available within two weeks. Exelixis is entitled to an initial equal share of U.S. profits and losses, which will decrease as sales increase, and shares in the U.S. sales and marketing costs, including co-promoting COTELLIC in the U.S.

Corporate Highlights

Key Hires in Medical Affairs, Sales, and Marketing. In September 2015, the company announced three high-level appointments to support the commercialization of cabozantinib and cobimetinib: William Berg, M.D. joined the company as Senior Vice President of Medical Affairs, Jonathan Berndt as Vice President of Sales, and Gregg Bernier as Vice President of Marketing.

Public Offering of Stock Raises Net Proceeds of Approximately \$145.6 Million. In late July 2015, Exelixis launched and completed a public offering of common stock. The company issued 28,750,000 shares, including 3,750,000 shares issued under the underwriters' 30-day option to buy shares, at a price to the public of \$5.40 per share, receiving approximately \$145.6 million in net proceeds after deducting the underwriting discount and other estimated offering expenses payable by Exelixis. Exelixis currently expects to use the net proceeds from the offering for general corporate purposes, including for clinical trials, build-out of commercial infrastructure, research and development, capital expenditures and working capital.

"Over the last few months, we have made significant strides with our lead development program, cabozantinib in advanced RCC, including receiving Breakthrough Therapy Designation from the FDA, initiating our rolling NDA submission and obtaining accelerated assessment status from the European Medicines Agency's CHMP," said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. "At the same time, we have significantly strengthened our organization's capabilities, including the addition of high-level personnel in medical affairs, sales, and marketing in advance of the potential commercialization of cabozantinib in advanced RCC."

Dr. Morrissey continued: "Moreover, after the third quarter closed, Exelixis achieved a major milestone when COTELLIC became the second medicine to emerge from our research and development organization that has received FDA approval. We are excited to embark on the launch of COTELLIC in the U.S., working closely with our partners Genentech and Roche to commercialize the product, including fielding one quarter of the U.S. sales force."

2015 Financial Guidance. The company is refining its operating expense guidance for the second six months of 2015. We expect second half operating expenses to be at the upper end of the previously indicated \$80 million to \$90 million range including approximately \$10 million of incremental non-cash stock-based compensation expense related to the vesting of performance stock options tied to the read-out of METEOR top-line results. As a result, we anticipate that our full year 2015 operating expenses will be near the upper end of the previously-indicated \$150 million to \$160 million range.

Third Quarter 2015 Financial Results

Net revenues for the quarter ended September 30, 2015 were \$9.9 million, compared to \$6.3 million for the comparable period in 2014. Net revenues for the third quarter of 2015 consisted of \$6.9 million net product revenue related to the sale of COMETRIQ and \$3.0 million of contract revenues for a milestone payment received from Merck related to their worldwide license of our PI3K-delta program.

Research and development expenses for the quarter ended September 30, 2015 were \$26.1 million, compared to \$43.6 million for the comparable period in 2014. The decrease was primarily related to a net decrease in clinical trial costs related to COMET and METEOR, the company's phase 3 trials in metastatic castration-resistant prostate cancer and advanced RCC, and to a lesser degree, decreases in personnel related expenses resulting from an overall reduction in headcount. Those decreases were partially offset by an increase in stock-based compensation expense due to performance-based stock-options that vested as a result of the positive top-line data received from METEOR.

Selling, general and administrative expenses for the quarter ended September 30, 2015 were \$17.8 million, compared to \$9.9 million for the comparable period in 2014. The increase was primarily related to stock-based compensation expense due to the vesting of performance-based stock-options as a result of the positive top-line data received from the METEOR trial and higher marketing expenses, including expenses for cobimetinib under the company's collaboration agreement with Genentech. Those increases were partially offset by a decrease in facilities costs and consulting and outside services.

Other income (expense), net for the quarter ended September 30, 2015 was a net expense of (\$11.8) million compared to (\$11.0) million for the comparable period in 2014. The net expense is comprised primarily of interest expense which includes \$6.9 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 the Deerfield Notes for the quarter ended September 30, 2015, as compared to \$7.5 million for the comparable period in 2014.

Net loss for the quarter ended September 30, 2015 was (\$47.6) million, or (\$0.22) per share, basic, compared to (\$62.6) million, or (\$0.32) per share, basic, for the comparable period in 2014. The decreased net loss for the quarter was primarily due to decreases in research and development expenses and an increase in net revenues, partially offset by an increase in selling, general and administrative expenses.

Cash and cash equivalents, short- and long-term investments and short- and long-term restricted cash and investments totaled \$282.1 million at September 30, 2015 compared to \$242.8 million at December 31, 2014.

Conference Call and Webcast

Exelixis management will discuss the company's financial results for the second quarter of 2015 and provide a general business update during a conference call beginning at 5:00 p.m. EST/2:00 p.m. PST today, November 10, 2015. To listen to a live webcast of the conference call, visit the Event Calendar page under Investors & Media at www.exelixis.com. Alternatively, participants may dial (855) 793-2457 (domestic) or (631) 485-4921 (international) and provide the conference call passcode 62011541 to join by phone.

An archived replay of the webcast will be available on the Event Calendar page under Investors & Media at www.exelixis.com for one year. An audio-only phone replay will be available until 11:59 p.m. EST on November 12, 2015. Access numbers for the phone replay are: (855) 859-2056 (domestic) and (404) 537-3406 (international); the passcode is 62011541.

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 cabozantinib, its wholly owned inhibitor of multiple receptor tyrosine kinases. Positive results were recently announced for a phase 3 pivotal trial of cabozantinib in patients with advanced renal cell carcinoma who received at least one prior VEGF receptor tyrosine kinase inhibitor, and Exelixis expects to complete regulatory filings in the U.S. and European Union in late 2015 and early 2016, respectively. Another Exelixis-discovered compound, COTELLICTM, a selective inhibitor of MEK, received its first regulatory approvals in Switzerland and the United States, and 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 website at www.exelixis.com.

Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to: Exelixis' key 2015 corporate objectives and clinical development milestones; Exelixis' focus on expediting regulatory submissions for cabozantinib for the treatment of advanced RCC and augmenting its commercial infrastructure to support the potential launch of advanced RCC; Exelixis' continued support of Genentech, including fielding 25% of the U.S. sales force promoting COTELLIC; Exelixis' plan to complete regulatory filings for cabozantinib for the treatment of advanced RCC in the U.S. before the end of 2015 and in the EU in early 2016; the likelihood of expedited approval of cabozantinib for advanced RCC as a result Breakthrough Technology Designation in the U.S. and accelerated assessment status in the EU; the availability of results from the CABOSUN trial in the first half of 2016; Exelixis' belief that there is a strong rationale for combining cabozantinib with immunotherapies and that data from the phase 1 trial evaluating this approach in patients with genitourinary tumors could have relevance in other disease settings; the timing of a possible approval of cobimetinib in the EU; timing of the presentation of positive overall survival data from the coBRIM trial; the financial terms of Exelixis' collaboration with Genentech if cobimetinib successfully reaches the market, including Exelixis' entitlement to an initial equal share of U.S. profits and losses, with Exelixis' share decreasing as sales increase; the parties' plan to share equally in the U.S. sales and marketing costs and Exelixis' entitlement to receive royalties on sales of cobimetinib outside of the U.S.; Exelixis' plans for use of the net proceeds from the July 2015 public offering; and Exelixis' financial outlook for the second six months of 2015. Words such as "progress toward," "objectives," "priority," "expedite," "augment," "potential," "rolling out," "expects," "may be," "initiate," "believes," "suggesting," "could," "continues," "potential," "will be," "plan," "priority," "committed," "entitled," "trend," "embark" 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 uncertainties of FDA and EMA regulatory review and approval processes and Exelixis' compliance with applicable legal and regulatory requirements; Exelixis' ability to judge the proper size and level of experience of the commercialization teams required to support the launch of cabozantinib for advanced RCC; Exelixis' ability to roll out its portion of the U.S. sales force promoting COTELLIC; Exelixis' dependence on its relationship with Genentech/Roche with respect to cobimetinib and Exelixis' ability to maintain its rights under the collaboration; the availability of clinical trial data at the expected times; risks related to the potential failure of cabozantinib or cobimetinib to demonstrate safety and efficacy in clinical testing; the clinical, therapeutic and commercial value of cabozantinib and cobimetinib; the sufficiency of Exelixis' capital and other resources; the accuracy of Exelixis' financial guidance; the uncertain timing and level of expenses associated with the development of cabozantinib; Exelixis' ability to enter into new collaborations on acceptable terms; the risk that unanticipated developments could adversely affect the commercialization of Exelixis products; the degree of market acceptance of Exelixis products and the availability of coverage and reimbursement for them; 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 10, 2015 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.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenues:				
Net product revenues	\$ 6,854	\$ 6,291	\$ 24,234	\$ 17,758
Contract revenues	3,000	—	3,000	—
Total revenues	9,854	6,291	27,234	17,758
Operating expenses:				
Cost of goods sold	1,420	573	2,872	1,359
Research and development	26,091	43,628	72,879	149,451
Selling, general and administrative	17,842	9,906	40,162	41,063
Restructuring charge	282	3,758	1,142	4,135
Total operating expenses	45,635	57,865	117,055	196,008

Loss from operations	(35,781)	(51,574)	(89,821)	(178,250)
Other income (expense), net:								
Interest income and other, net	276		1,296		146		3,786	
Interest expense	(12,059)	(12,282)	(36,421)	(36,125)
Total other income (expense), net	(11,783)	(10,986)	(36,275)	(32,339)
Net loss	\$ (47,564)	\$ (62,560)	\$ (126,096)	\$ (210,589)
Net loss per share, basic and diluted	\$ (0.22)	\$ (0.32)	\$ (0.62)	\$ (1.09)
Shares used in computing basic and diluted net loss per share	217,587		195,126		203,153		193,855	

EXELIXIS, INC.

CONDENSED CONSOLIDATED BALANCE SHEET DATA

(in thousands)

	September 30, 2015	December 31, 2014 (1)
	(unaudited)	
Cash and investments (2)	\$ 282,061	\$ 242,760
Working capital (deficit)	\$ 151,429	\$ (4,619)
Total assets	\$ 363,241	\$ 327,960
Total stockholders' deficit	\$ (74,228)	\$ (114,829)

(1) Derived from the audited consolidated financial statements.

Cash and investments include cash and cash equivalents, short- and long-term investments and short- and long-term restricted cash and (2) investments. Long-term restricted cash and investments totaled \$2.7 million as of September 30, 2015. Short- and long-term restricted cash and investments totaled \$16.9 million as of December 31, 2014.

View source version on businesswire.com: <http://www.businesswire.com/news/home/20151110006958/en/>

Source: Exelixis, Inc.

Exelixis, Inc.

Chris Senner, 650-837-7240

Chief Financial Officer

csenner@exelixis.com

or

Susan Hubbard, 650-837-8194

Investor Relations & Corporate Communications

shubbard@exelixis.com