



## Exelixis Announces Second Quarter 2015 Financial Results and Provides Corporate Update

August 11, 2015

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

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Aug. 11, 2015-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the second 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

Exelixis is focused on expediting its regulatory submissions for cabozantinib in advanced renal cell carcinoma (RCC) based on the positive outcome from the METEOR pivotal trial and building its commercial infrastructure to support the launch of cabozantinib in advanced RCC in the United States, pending approval. In addition, Exelixis continues to support its partner Genentech, a member of the Roche Group, as it prepares for the potential worldwide commercialization of cobimetinib, a second Exelixis-discovered compound.

**METEOR Trial Delivers Positive Top-Line Results in Advanced RCC.** 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 renal cell carcinoma who have experienced disease progression following treatment with at least one prior VEGFR tyrosine kinase inhibitor. The primary analysis was conducted on the first 375 patients enrolled, and the hazard ratio (HR) was 0.58 (95% CI 0.45-0.75,  $p < 0.0001$ ), equating to a 42% decrease in the risk of disease progression or death for the cabozantinib arm. As expected, data pertaining to overall survival (OS) for the entire 658-patient study population were not mature at the data cut-off, but a pre-planned interim analysis showed a trend favoring cabozantinib (HR=0.67, unadjusted 95 percent CI 0.51-0.89;  $p=0.005$ ). At the time of the interim analysis, the pre-specified p-value of 0.0019 to achieve statistical significance was not reached. The trial will continue to the final OS analysis anticipated in 2016. The frequency of serious adverse events of any grade, regardless of causality, was approximately balanced between study arms, and the rate of discontinuations for adverse events was low (10%) in both arms.

**U.S. and EU Regulatory Filings for Cabozantinib in Advanced RCC Planned for Early 2016.** Having obtained positive top-line results for METEOR, Exelixis' highest corporate priority is the completion of regulatory filings for cabozantinib in advanced RCC. Based on the data from the trial, the company intends to complete regulatory filings in the U.S. and European Union in early 2016. Earlier this year, cabozantinib received Fast Track designation by the U.S. Food and Drug Administration.

**Recently Initiated Trial Combines Cabozantinib with Immunotherapies.** In July 2015, Exelixis' collaborators at the National Cancer Institute's Cancer Therapy Evaluation Program (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).

**Data at ASCO Underscore Potential of Cabozantinib in NSCLC.** Oral presentations at the American Society of Clinical Oncology's 2015 Annual Meeting, May 29 - June 2, highlighted positive data from two trials of cabozantinib in molecularly-defined subtypes of NSCLC. An investigator-sponsored phase 2 trial of cabozantinib in RET-rearranged NSCLC met its primary endpoint, exceeding the predefined number of objective responses. A second trial, conducted by the ECOG-ACRIN Cancer Research Group under Exelixis' cooperative research and development agreement with NCI-CTEP, also met its primary endpoint, extending PFS for cabozantinib and the combination of cabozantinib and erlotinib versus erlotinib alone in EGFR wild-type NSCLC. Exelixis is committed to working with its collaborators at the NCI and at ECOG-ACRIN to explore further development of cabozantinib in lung cancer.

**Cobimetinib Commercialization Planning Continues Ahead of Anticipated Regulatory Decisions.** Also at ASCO, investigators presented updated data from coBRIM, the phase 3 pivotal trial of cobimetinib in combination with vemurafenib in patients with advanced melanoma harboring a BRAF V600 mutation. coBRIM formed the basis for Genentech's and Roche's regulatory filings in the U.S. and EU, respectively, for which both companies anticipate decisions later this year. In the U.S., Genentech's New Drug Application received priority review, and the Prescription Drug User Fee Act action date is now November 11, 2015. Cobimetinib, a selective MEK inhibitor discovered by Exelixis, is the subject of a worldwide collaboration agreement between Exelixis and Genentech. Pursuant to this agreement, Exelixis is entitled to an initial equal share of U.S. profits and losses, with Exelixis' share decreasing as sales increase. The parties will share equally in the U.S. marketing and commercialization costs, and, if approved, Exelixis will co-promote the compound in the U.S. Outside the U.S., Exelixis is entitled to receive royalties on sales of cobimetinib.

**Christopher J. Senner Joins Exelixis as EVP and Chief Financial Officer.** In July 2015, Exelixis appointed Chris Senner to the role of Executive Vice President and Chief Financial Officer. Mr. Senner has nearly 25 years of experience in biopharmaceutical finance. He joined Exelixis following five years at Gilead Sciences, where he most recently served as Vice President, Corporate Finance. Prior to joining Gilead, Mr. Senner spent eighteen years at Wyeth in a variety of financial roles with increasing responsibility for many of the company's divisions and regions.

**Extension of Maturity Date of Indebtedness Under the Note Purchase Agreement with Deerfield.** On July 1, 2015, Exelixis extended the maturity

date of the Deerfield Notes from July 1, 2015 to July 1, 2018. The Deerfield Notes will bear interest on and after July 2, 2015, at the rate of 7.5% per annum to be paid in cash, quarterly in arrears, and 7.5% per annum to be paid in kind, quarterly in arrears, for a total interest rate of 15% per annum and will mature on July 1, 2018.

**Public Offering of Stock Raises Net Proceeds of \$146 Million.** After the second quarter ended, 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 \$146 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.

"The second quarter, and the weeks following it, are some of the most significant in Exelixis history," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of the company. "As announced in July, cabozantinib delivered impressive results in the METEOR trial, including a statistically significant and clinically meaningful improvement in PFS, along with a strong trend toward improving overall survival, as compared to everolimus, a widely-used agent in the second and later lines of advanced RCC treatment. The data will serve as the foundation for regulatory filings in the U.S. and EU, which we intend to complete in early 2016."

Dr. Morrissey continued: "As we move into the third quarter with METEOR data in hand, all of us at Exelixis share an even greater sense of urgency and focus around maximizing the potential of our pipeline to help patients with cancer. This is illustrated by our recent activities, including the recruitment of a new chief financial officer with global commercial finance expertise, advancement of our discussions around a potential partnership for ex-U.S. rights to cabozantinib, and the initiation of a new trial evaluating cabozantinib in combination with immunotherapies. At the same time, alongside our partners Roche and Genentech, we have completed our commercial readiness for the potential U.S. regulatory approval of cobimetinib later this year."

**COMETRIQ Product Revenue.** Net product revenue from COMETRIQ® (cabozantinib capsules) sales was \$8.0 million for the second quarter of 2015.

**2015 Financial Guidance.** The company anticipates that operating expenses for the second six months of 2015 will be in a range of \$80 million to \$90 million, 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.

## **Second Quarter 2015 Financial Results**

**Net revenues** for the quarter ended June 30, 2015 were \$8.0 million, compared to \$6.6 million for the comparable period in 2014. Net revenues consisted entirely of product revenue related to the sale of COMETRIQ.

**Research and development expenses** for the quarter ended June 30, 2015 were \$24.5 million, compared to \$51.0 million for the comparable period in 2014. The decrease was primarily related to a net decrease in clinical trial costs, predominantly due to decreases in costs related to COMET-1 and COMET-2, the company's phase 3 trials in metastatic castration-resistant prostate cancer, and decreases in personnel related expenses resulting from an overall reduction in headcount.

**Selling, general and administrative expenses** for the quarter ended June 30, 2015 were \$12.8 million, compared to \$16.5 million for the comparable period in 2014. The decrease was primarily related to a decrease in personnel and stock-based compensation expenses resulting from an overall reduction in headcount, consulting and outside services, and legal and patent costs. Those decreases were partially offset by higher marketing expenses, including expenses for cobimetinib under the company's collaboration agreement with Genentech.

**Restructuring charge** for the quarter ended June 30, 2015 was \$1.3 million. The restructuring charge was primarily related to the exit of certain facilities, the partial termination of one of Exelixis' building leases and subleasing activities during the period.

**Other income (expense), net** for the quarter ended June 30, 2015 was a net expense of (\$12.1) million compared to (\$11.7) million for the comparable period in 2014. The net expense is comprised primarily of interest expense which includes \$7.2 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 June 30, 2015, as compared to \$7.3 million for the comparable period in 2014.

**Net loss** for the quarter ended June 30, 2015 was (\$43.4) million, or (\$0.22) per share, basic, compared to (\$73.4) million, or (\$0.38) 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 selling, general and administrative expenses and an increase in product revenues.

**Cash** and cash equivalents, short- and long-term investments and short- and long-term restricted cash and investments totaled \$167.0 million at June 30, 2015 compared to \$242.8 million at December 31, 2014. The June 30, 2015 cash position was prior to the launch of the company's public offering of stock on July 21, 2015, as noted above.

## **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. EDT/2:00 p.m. PDT today, August 11, 2015. To join the call, participants may dial 855-793-2457 (domestic) or 631-485-4921 (international) and provide the conference call passcode 94776699 to join by phone. 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) for one year. An audio-only phone replay will be available until 11:59 p.m. EDT on August 13, 2015. Access numbers for the phone replay are: 855-859-2056 (domestic) and 404-537-3406 (international); the passcode is 94776699.

## **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. Another Exelixis-

discovered compound, cobimetinib, a 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).

## 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 building a commercial infrastructure to support the launch of advanced RCC, pending approval; Exelixis' continued support of Genentech, as it prepares for the potential worldwide commercialization of cobimetinib; the continuation of the METEOR trial to the final OS analysis anticipated in 2016; Exelixis' plan to complete regulatory filings for cabozantinib for the treatment of advanced RCC in the U.S. and EU in early 2016; Exelixis' belief that there is a strong rationale for combining cabozantinib with immunotherapies and that data from the phase 1 trial of cabozantinib in combination nivolumab alone, or in combination with nivolumab plus ipilimumab, in patients with genitourinary tumors, including bladder cancer and RCC, could have relevance in other disease settings; Exelixis' commitment to working with its collaborators at NCI and at ECOG-ACRIN to explore further development of cabozantinib in lung cancer; the continued commercialization planning for cobimetinib ahead of anticipated regulatory decisions; 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. marketing and commercialization costs, Exelixis' plans to co-promote the compound in the U.S. and Exelixis' entitlement to receive royalties on sales of cobimetinib outside of the U.S.; Exelixis' expectations for use of the net proceeds from the public offering; the strong trend toward improving OS, as compared to everolimus, reflected in the METEOR trial results; Exelixis' plan to use the data from the METEOR trial results as the foundation for regulatory filings in the U.S. and EU; Exelixis' plan to maximize the potential of its pipeline to help patients with cancer; Exelixis' commercial readiness for the potential U.S. regulatory approval of cobimetinib later this year; and Exelixis' financial outlook for the second six months of 2015, including non-cash charges for stock-based compensation. Words such as "objectives," "focused," "continues," "potential," "will," "anticipated," "planned," "priority," "intends," "believes," "could," "committed," "entitled," "expects," "trend," 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 the regulatory review and approval processes and Exelixis' compliance with applicable legal and regulatory requirements; Exelixis' ability to correctly judge the proper size and level of experience of the sales and marketing force required to support the launch of advanced RCC, if approved; 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 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 uncertain timing and level of expenses associated with the development of cabozantinib; Exelixis' ability to enter into new collaborations on acceptable terms; Exelixis' ability to conduct clinical trials of cabozantinib sufficient to achieve a positive completion; the risk that unanticipated developments could adversely affect the commercialization of COMETRIQ; the degree of market acceptance of COMETRIQ and the availability of coverage and reimbursement for COMETRIQ; 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 August 11, 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.

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## EXELIXIS, INC.

### CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Revenues:				
Net product revenues	\$ 7,992	\$ 6,562	\$ 17,380	\$ 11,467
Operating expenses:				
Cost of goods sold	686	477	1,452	786
Research and development	24,506	50,976	46,788	105,823
Selling, general and administrative	12,789	16,466	22,320	31,157
Restructuring charge	1,291	331	860	377
Total operating expenses	39,272	68,250	71,420	138,143
Loss from operations	(31,280)	(61,688)	(54,040)	(126,676)
Other income (expense), net:				

Interest income and other, net	(123	)	359	(130	)	2,490	
Interest expense	(11,959	)	(12,081	)	(24,362	)	(23,843
Total other income (expense), net	(12,082	)	(11,722	)	(24,492	)	(21,353
Net loss	\$ (43,362	)	\$ (73,410	)	\$ (78,532	)	\$ (148,029
Net loss per share, basic and diluted	\$ (0.22	)	\$ (0.38	)	\$ (0.40	)	\$ (0.77
Shares used in computing basic and diluted net loss per share	196,201		194,929		196,052		193,323

## EXELIXIS, INC.

### CONDENSED CONSOLIDATED BALANCE SHEET DATA

(in thousands)

	<b>June 30, 2015</b>	<b>December 31, 2014 (1)</b>
	(unaudited)	
Cash and investments (2)	\$ 166,988	\$ 242,760
Working capital (deficit)	\$ 31,487	\$ (4,619 )
Total assets	\$ 248,778	\$ 327,960
Total stockholders' deficit	\$ (188,188 )	\$ (114,829 )

(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 \$8.8 million and \$16.9 million as of June 30, 2015 and December 31, 2014, respectively.

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