



Exelixis Announces Second Quarter 2017 Financial Results and Provides Corporate Update

August 2, 2017

- Cabozantinib Franchise Net Product Revenue of \$88.0 million, Total Revenue of \$99.0 million -

- Net Income of \$17.7 million, Diluted EPS of \$0.06 per Share -

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

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Aug. 2, 2017-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the second quarter of 2017 and provided an update on progress toward fulfilling its key corporate objectives, as well as commercial and clinical development milestones.

Exelixis is focused on maximizing the opportunity for its two internally discovered compounds, cabozantinib and cobimetinib, to improve care and outcomes for people with cancer around the world. The company's top priority remains the commercialization of CABOMETYX[®] (cabozantinib) tablets as a treatment for patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy. During the second quarter of 2017, CABOMETYX generated \$80.9 million in net product revenue, while COMETRIQ[®] (cabozantinib) capsules for the treatment of patients with progressive, metastatic medullary thyroid cancer generated an additional \$7.1 million in net product revenue, for a combined \$88.0 million in net product revenue for the cabozantinib franchise.

While continuing to execute on the commercialization of CABOMETYX, Exelixis made further progress this quarter on drivers for the company's future growth. Importantly, an analysis of progression-free survival (PFS) based on the independent radiology review committee (IRC) review of radiographic images from the CABOSUN trial confirmed results per investigator assessment reported earlier. The IRC review was conducted in support of a supplemental New Drug Application (sNDA) filing for cabozantinib as a treatment for patients with previously untreated advanced RCC planned for submission in the third quarter of 2017. In addition, several new trials combining cabozantinib with leading immunotherapies were recently initiated in genitourinary cancer indications. The company also retired the final tranche of its remaining corporate debt, and shortly after the close of the second quarter, announced the favorable settlement of its dispute with Genentech (a member of the Roche Group) concerning cobimetinib, which Exelixis initiated in June 2016.

"The second quarter of 2017 was highlighted by the growth of the cabozantinib franchise, and the significant clinical development, financial and regulatory progress made by the Exelixis team," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. "With increasing revenues and disciplined financial management, Exelixis is now funding our growth from our operations, giving us the flexibility to invest in clinical trials, evaluate business development opportunities, and reinstate measured discovery operations that can build long-term value and benefit the patients we serve."

Dr. Morrissey continued: "Shortly after the quarter closed, Exelixis made an important step forward when we and our partner Genentech agreed to a revised revenue and cost-sharing arrangement for cobimetinib's commercialization in the United States. The new terms provide an equitable foundation for our work with Genentech on this important Exelixis-discovered compound that is now the subject of three phase 3 pivotal trials and multiple earlier stage trials."

Cabozantinib Highlights

Strong Growth in Cabozantinib Franchise Net Revenue. Cabozantinib generated \$88.0 million in net product revenue during the second quarter of 2017, an increase of 28 percent from the first quarter of 2017 and an increase of 178 percent year-over-year. The year-over-year increase was driven primarily by the continued U.S. uptake of CABOMETYX following U.S. Food and Drug Administration approval in April 2016 as a treatment for patients with advanced RCC who have received prior anti-angiogenic therapy.

Start of Phase 3 Trial of Cabozantinib in Combination with Nivolumab or with Nivolumab and Ipilimumab in Previously Untreated Advanced or Metastatic RCC. Shortly after the quarter ended, Exelixis and Bristol-Myers Squibb Company (BMS) announced the initiation of CheckMate 9ER, the phase 3 trial evaluating cabozantinib in combination with two of BMS' leading immunotherapies, nivolumab and ipilimumab, compared to sunitinib. The trial is planned to enroll 1,014 treatment-naïve patients, and the primary endpoint is PFS.

Launch of Phase 1b Trial of Cabozantinib with Atezolizumab in Patients with Locally Advanced or Metastatic Solid Tumors. In June, Exelixis announced the initiation of the dose-escalation stage of a phase 1b trial of cabozantinib in combination with atezolizumab in patients with locally advanced or metastatic urothelial carcinoma (UC) or RCC. The primary objective is to determine the optimal dose and schedule of daily oral administration of cabozantinib when given in combination with atezolizumab to inform the trial's subsequent expansion stage. Expansion cohorts will evaluate the selected dose and schedule in four settings, including previously untreated RCC patients, previously untreated, both cisplatinum eligible and ineligible UC patients, and previously treated UC patients.

Continued Progress on Filing in Previously Untreated Advanced RCC. During the second quarter, Exelixis announced that the analysis of the review by a blinded IRC had confirmed the primary efficacy endpoint results of investigator-assessed PFS from the CABOSUN randomized phase 2 trial in patients with previously untreated advanced RCC with intermediate- or poor-risk disease. The company remains on track to file its sNDA for cabozantinib in the third quarter of 2017.

CELESTIAL Data Anticipated in the Second Half of 2017. CELESTIAL, the ongoing phase 3 pivotal trial of cabozantinib in patients with advanced hepatocellular carcinoma (HCC), continues to progress. Exelixis is tracking events closely and continues to anticipate that the second interim analysis at 75 percent of the required events will be completed in the second half of 2017.

Cabozantinib and Cobimetinib Data Presentations at the ESMO 2017 Congress. Exelixis-discovered compounds will be the subject of 10 presentations at the ESMO 2017 Congress, which is being held September 8-12, 2017 in Madrid, Spain. Data from CABOSUN, the randomized phase 2 trial of cabozantinib versus sunitinib in patients with previously untreated advanced RCC, have been accepted as a late-breaking abstract at the meeting and will be the subject of a poster discussion on Sunday, September 10th. Other cabozantinib presentations will include an oral presentation of data from the phase 1b trial of cabozantinib, nivolumab, and ipilimumab in advanced genitourinary malignancies, as well as additional analyses of the METEOR trial in advanced RCC. Cobimetinib presentations at the Congress will include two data sets concerning forms of metastatic melanoma.

Cobimetinib Highlights

Settlement of Arbitration Between Exelixis and Genentech Regarding Companies' Collaboration Agreement for Cobimetinib. After the quarter ended, Exelixis announced a settlement of our arbitration with Genentech concerning claims asserted by Exelixis against Genentech related to the development and commercialization of cobimetinib, the Exelixis-discovered medicine that is marketed as COTELLIC[®]. The revised revenue and cost-sharing arrangement resolves the companies' dispute pursuant to the arbitration demand filed on June 3, 2016, and aligns both companies' interests in advancing cobimetinib as a promising therapy for patients with multiple forms of cancer. Moving forward, the revenue applied to the profit and loss statement for the COTELLIC collaboration (Collaboration P&L) will now be calculated using the average of the quarterly net selling prices of COTELLIC and any additional branded Genentech product(s) prescribed with COTELLIC. Exelixis will continue to share U.S. commercialization costs, while Genentech's portion of these costs will now be allocated to the Collaboration P&L in proportion to the number of Genentech products in any given combination including COTELLIC. For more detail on the terms, please see Exelixis' press release and corresponding Form 8-K filed with the U.S. Securities and Exchange Commission (SEC), both issued on July 20, 2017.

Cobimetinib Now the Subject of Three Phase 3 Pivotal Trials. Roche recently confirmed it anticipates enrolling the first patient in IMspire170, the phase 3 pivotal trial of cobimetinib and atezolizumab versus pembrolizumab in first-line BRAF wild-type metastatic or unresectable locally advanced melanoma, in the third quarter of 2017. Alongside the fully enrolled IMblaze370 trial (third-line advanced or metastatic colorectal cancer) and the currently recruiting IMspire150 TRILOGY (first-line BRAF V600 mutation-positive metastatic or unresectable locally advanced melanoma), cobimetinib is now the subject of three phase 3 pivotal trials where it is being evaluated in combination with other anticancer therapies.

Corporate Highlights

Last Source of Indebtedness Retired Through Repayment of the Deerfield Notes. In June 2017, Exelixis retired a series of Secured Convertible Notes originally issued in July 2010 to entities associated with Deerfield Management Company, L.P. (Deerfield Notes). Exelixis retired the Deerfield Notes by making a \$123.8 million payment to the Deerfield entities. Repaying the Deerfield Notes a year ahead of their July 2018 maturity date will save Exelixis approximately \$12 million in interest expense.

Significant Presence for Cabozantinib and Cobimetinib at the 2017 ASCO Annual Meeting. Exelixis-discovered compounds were the subject of 13 presentations, including further analysis of the METEOR study in advanced RCC, as well as updated results from the phase 1b combination trial of cabozantinib plus immunotherapy in genitourinary tumors. Additional cabozantinib data presentations included results from trials in endometrial cancer and uterine carcinosarcoma. Cobimetinib data included updates from the early stage combination trials of cobimetinib plus atezolizumab, and plus atezolizumab and vemurafenib, which have informed the design of several of Roche's ongoing phase 3 pivotal trials.

2017 Financial Guidance

The company is reiterating its previously provided guidance that total costs and operating expenses for the full year will be between \$290 million and \$310 million. This guidance includes approximately \$25 million of non-cash costs and expenses related primarily to stock-based compensation expense.

Second Quarter 2017 Financial Results

Total revenue for the quarter ended June 30, 2017 was \$99.0 million, compared to \$36.3 million for the comparable period in 2016. Total revenue includes \$88.0 million and \$11.0 million of net product revenue and collaboration revenue, respectively, compared to \$31.6 million and \$4.6 million for the comparable period in 2016. The increase in net product revenues primarily reflects the impact of the commercial launch of CABOMETYX in late April 2016. Collaboration revenues for the quarter ended June 30, 2017 include \$5.5 million, \$4.1 million and \$1.4 million earned under our collaboration agreements with Ipsen, Takeda and Genentech, respectively. In comparison, during the quarter ended June 30, 2016, collaboration revenues include \$3.6 million and \$1.0 million earned under our collaboration agreements with Ipsen and Genentech, respectively.

Research and development expenses for the quarter ended June 30, 2017 were \$28.2 million, compared to \$23.0 million for the comparable period in 2016. The increase in research and development expenses was primarily a result of increases in clinical trial costs and personnel expenses. The clinical trial cost increase was predominantly due to increases in costs related to CABOSUN, start-up costs associated with CheckMate 9ER, and start-up costs associated with Exelixis' phase 1b trial of cabozantinib and atezolizumab in locally advanced or metastatic solid tumors, and were partially offset by a decrease in costs related to METEOR. The increase in personnel-related expenses was primarily a result of an increase in headcount associated with the re-launch of our discovery program and the build-out of our medical affairs organization.

Selling, general and administrative expenses for the quarter ended June 30, 2017 were \$40.7 million, compared to \$35.8 million for the comparable period in 2016. The increase in selling, general and administrative expenses was primarily a result of increases in personnel expenses resulting primarily from an increase in headcount connected with the build-out and support of the Exelixis U.S. commercial organization, an increase in legal costs, and an increase in consulting and outside services to support our marketing activities. Those increases were partially offset by a decrease in losses under the collaboration agreement with Genentech driven by Genentech's change in cost allocation approach in January 2017.

Other expense, net for the quarter ended June 30, 2017 was a net expense of \$8.9 million, compared to \$9.7 million for the comparable period in 2016. The decrease in other expense, net, was primarily due to a decrease in interest expense as a result of the 2016 conversions and redemption of the 4.25% Convertible Subordinated Notes due 2019 and the repayment of the Silicon Valley Bank term loan in March 2017. The decrease in interest expense was partially offset by a \$6.2 million loss on extinguishment primarily related to the prepayment penalty associated with the early repayment of the Deerfield Notes on June 28, 2017.

Net income for the quarter ended June 30, 2017 was \$17.7 million, or \$0.06 per share, basic and diluted, compared to a net loss of \$(34.8) million, or \$(0.15) per share, basic and diluted, for the comparable period in 2016. The decrease in net loss was primarily due to the increase in net product and

collaboration revenues, partially offset by the increase in operating expenses.

Cash and cash equivalents, short- and long-term investments and long-term restricted cash and investments totaled \$380.3 million at June 30, 2017, as compared to \$479.6 million at December 31, 2016.

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 periods ended June 30, 2017, December 30, 2016 and July 1, 2016 are indicated as being as of and for the periods ended June 30, 2017, December 31, 2016 and June 30, 2016, respectively.

Conference Call and Webcast

Exelixis management will discuss the company's financial results for the second quarter of 2017 and provide a general business update during a conference call beginning at 5:00 p.m. EDT/2:00 p.m. PDT today, Wednesday, August 2, 2017.

To access the webcast link, log onto www.exelixis.com and proceed to the Event Calendar page under Investors & Media. Please connect to the company's website at least 15 minutes prior to the conference call to ensure adequate time for any software download that may be required to listen to the webcast. Alternatively, please call (855) 793-2457 (domestic) or (631) 485-4921 (international) and provide the conference call passcode 49002905 to join by phone.

A telephone replay will be available until 11:59 p.m. EDT on Friday, August 4, 2017. Access numbers for the telephone replay are: (855) 859-2056 (domestic) and (404) 537-3406 (international); the passcode is 49002905. A webcast replay will also be archived on www.exelixis.com for one year.

About Exelixis

Exelixis, Inc. (Nasdaq: EXEL) is a biopharmaceutical company committed to the discovery, development and commercialization of new medicines to improve care and outcomes for people with cancer. Since its founding in 1994, three products discovered at Exelixis have progressed through clinical development, received regulatory approval, and entered the marketplace. Two are derived from cabozantinib, an inhibitor of multiple tyrosine kinases including VEGF, MET, AXL and RET receptors: CABOMETRYX[®] tablets approved for previously treated advanced renal cell carcinoma and COMETRIQ[®] capsules approved for progressive, metastatic medullary thyroid cancer. The third product, COTELLIC[®], is a formulation of cobimetinib, a reversible inhibitor of MEK, is marketed under a collaboration with Genentech (a member of the Roche Group), and is approved as part of a combination regimen to treat advanced melanoma. Both cabozantinib and cobimetinib have shown potential in a variety of forms of cancer and are the subjects of broad clinical development programs. For more information about Exelixis, please visit www.exelixis.com or follow @ExelixisInc on Twitter.

Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to: Exelixis' focus on maximizing the opportunity for cabozantinib and cobimetinib to help patients with cancer around the world; the commercialization of CABOMETRYX as Exelixis' top priority; the drivers for Exelixis' future growth; Exelixis' plan to submit a sNDA in the third quarter of 2017 for cabozantinib as a treatment for previously untreated patients with advanced RCC; the anticipated timing for the second interim analysis of CELESTIAL in the second half of 2017; future data presentations from clinical trials of cabozantinib and cobimetinib at the ESMO 2017 Congress; the anticipated timing of enrollment for IMspire170; Exelixis' guidance for 2017 total costs and operating expenses, including non-cash costs and expenses; and the therapeutic potential and continued development of cabozantinib and cobimetinib. Words such as "focused," "priority," "future," "planned," "anticipated," "will," "guidance," "committed," "potential," 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. 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 degree of market acceptance of CABOMETRYX, COMETRIQ, and COTELLIC and the availability of coverage and reimbursement for these products; the risk that unanticipated developments could adversely affect the commercialization of CABOMETRYX, COMETRIQ, and COTELLIC; Exelixis' dependence on its relationship with its collaboration partners, including, the level of their investment in the resources necessary to successfully commercialize cabozantinib and cobimetinib in the territories where they are approved; risks and uncertainties related to regulatory review and approval processes and Exelixis' compliance with applicable legal and regulatory requirements; Exelixis' ability and the ability of its collaborators to conduct clinical trials of cabozantinib and cobimetinib both alone and in combination with other therapies sufficient to achieve a positive completion; risks related to the potential failure of cabozantinib and cobimetinib, both alone and in combination with other therapies, to demonstrate safety and efficacy in clinical testing; the level of costs associated with Exelixis' commercialization, research and development and other activities; Exelixis' dependence on third-party vendors; Exelixis' ability to protect the company's intellectual property rights; 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 SEC on May 1, 2017, and in Exelixis' future filings with the SEC, including, without limitation, Exelixis' quarterly report on Form 10-Q expected to be filed with the SEC on August 2, 2017. 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,

	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Revenues:				
Net product revenues	\$ 88,004	\$ 31,618	\$ 156,881	\$ 40,717
Collaboration revenues	11,004	4,634	23,014	10,962
Total revenues	<u>99,008</u>	<u>36,252</u>	<u>179,895</u>	<u>51,679</u>
Operating expenses:				
Cost of goods sold	3,014	1,560	6,217	2,245
Research and development	28,214	22,984	51,424	51,910
Selling, general and administrative	40,727	35,823	74,987	70,680
Restructuring (recovery) charge	(60)	1,021	(32)	1,115
Total operating expenses	<u>71,895</u>	<u>61,388</u>	<u>132,596</u>	<u>125,950</u>
Income (loss) from operations	<u>27,113</u>	<u>(25,136)</u>	<u>47,299</u>	<u>(74,271)</u>
Other expense, net:				
Interest income and other, net	1,622	749	2,690	951
Interest expense	(4,259)	(10,451)	(8,679)	(20,741)
Loss on extinguishment of debt	(6,239)	—	(6,239)	—
Total other expense, net	<u>(8,876)</u>	<u>(9,702)</u>	<u>(12,228)</u>	<u>(19,790)</u>
Income (loss) before income taxes	18,237	(34,838)	35,071	(94,061)
Income tax expense	581	—	715	—
Net income (loss)	<u>\$ 17,656</u>	<u>\$ (34,838)</u>	<u>\$ 34,356</u>	<u>\$ (94,061)</u>
Net income (loss) per share, basic	\$ 0.06	\$ (0.15)	\$ 0.12	\$ (0.41)
Net income (loss) per share, diluted	\$ 0.06	\$ (0.15)	\$ 0.11	\$ (0.41)
Shares used in computing basic net income (loss) per share	293,188	229,310	292,029	228,860
Shares used in computing diluted net income (loss) per share	311,219	229,310	310,759	228,860

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

	<u>June 30,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u> ⁽¹⁾
Cash and investments ⁽²⁾	\$ 380,319	\$ 479,554
Working capital	\$ 304,568	\$ 200,215
Total assets	\$ 516,532	\$ 595,739
Total stockholders' equity	\$ 148,511	\$ 89,318

(1) Derived from the audited consolidated financial statements.

(2) Cash and investments include cash and cash equivalents, short- and long-term investments and long-term restricted cash and investments. Long-term restricted cash and investments totaled \$4.7 million as of June 30, 2017 and \$4.2 million as of December 31, 2016.



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Source: Exelixis, Inc.

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