Exelixis Announces Third Quarter 2017 Financial Results and Provides Corporate Update

November 1, 2017

- Cabozantinib Franchise Net Product Revenue of $96.4 million, Total Revenue of $152.5 million -

- Net Income of $81.4 million, Diluted EPS of $0.26 per Share -

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

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 1, 2017-- Exelixis, Inc. (NASDAQ: EXEL) today reported financial results for the third 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 ongoing 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 third quarter of 2017, CABOMETYX generated $90.4 million in net product revenue, while COMETRIQ® (cabozantinib) capsules for the treatment of patients with progressive, metastatic medullary thyroid cancer generated an additional $6.1 million in net product revenue, for a combined $96.4 million in net product revenue for the cabozantinib franchise.

"In addition to strong financial performance, the third quarter of 2017 was marked by significant clinical and regulatory milestones that continue to drive us forward in our mission to help cancer patients recover stronger and live longer," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. "In August, we completed the filing for CABOMETYX in previously untreated advanced RCC, which has been accepted by the FDA and granted Priority Review. With an upcoming FDA action date of February 15, 2018, our commercial team is fully prepared for a potential launch of CABOMETYX in this expanded indication to bring this much needed option to even more patients with advanced RCC as quickly as possible. In addition, based on the positive results from the CELESTIAL pivotal trial, demonstrating that cabozantinib provided a statistically significant and clinically meaningful improvement in overall survival for patients with advanced hepatocellular carcinoma, we are moving rapidly to complete our U.S. regulatory filing in the first quarter of next year."

Cabozantinib Highlights

Strong Growth in Cabozantinib Franchise Net Revenue. Cabozantinib generated $96.4 million in net product revenue during the third quarter of 2017, an increase of 10 percent from the second quarter of 2017 and an increase of 126 percent year-over-year.

Phase 3 CELESTIAL Trial Meets Primary Endpoint of Overall Survival (OS), with supplemental New Drug Application (sNDA) Filing Planned for Q1 2018. In October, Exelixis announced that the CELESTIAL trial met its primary endpoint of OS, with cabozantinib providing a statistically significant and clinically meaningful improvement in OS compared to placebo in patients with advanced hepatocellular carcinoma (HCC). The independent data monitoring committee for the study recommended that the trial should be stopped for efficacy following review of the second planned interim analysis. CELESTIAL is a randomized, global phase 3 trial of cabozantinib compared to placebo in patients with advanced HCC who have been previously treated with sorafenib. The safety data in the study were consistent with the established profile of cabozantinib. Based on these results, Exelixis plans to submit an sNDA to the U.S. Food and Drug Administration (FDA) in the first quarter of 2018. Detailed results from CELESTIAL will be submitted for presentation at a future medical conference.

Submission and Acceptance of sNDA for CABOMETYX for the Treatment of Previously Untreated Advanced RCC with FDA Priority Review. In August, Exelixis announced it had completed the submission of its sNDA to the FDA for CABOMETYX for the treatment of previously untreated advanced RCC. The sNDA submission is based on results from the CABOSUN randomized phase 2 trial of CABOMETYX compared to sunitinib in patients with previously untreated advanced RCC with intermediate- or poor-risk disease. After the quarter ended, the company announced the FDA had accepted the sNDA and granted Priority Review, assigning a Prescription Drug User Fee Act (PDUFA) action date of February 15, 2018.

Start of Phase 3 Trial of Cabozantinib in Combination with Nivolumab or with Nivolumab and Ipilimumab in Previously Untreated Advanced or Metastatic RCC. In July, Exelixis and Bristol-Myers Squibb (BMS) announced the initiation of CheckMate 9ER, the pivotal 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, with a primary endpoint of progression-free survival.

Cabozantinib and Cobimetinib Data Presentations at the European Society for Medical Oncology (ESMO) 2017 Congress. In September, Exelixis-discovered compounds were the subject of 10 presentations at the ESMO 2017 Congress held in Madrid, Spain. Data from CABOSUN, the randomized phase 2 trial of cabozantinib compared to sunitinib in patients with previously untreated advanced RCC with intermediate- or poor-risk disease, were the subject of a poster discussion which showed cabozantinib demonstrated a clinically meaningful and statistically significant reduction in the rate of disease progression or death. Other cabozantinib presentations included 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 phase 3 METEOR trial in advanced RCC. Cobimetinib presentations at the Congress included two data sets concerning forms of metastatic melanoma. The company, along with its collaboration partner Ipsen, also hosted an investor and media event in Madrid to discuss the data for cabozantinib presented at the Congress

and to take part in a question and answer session with Drs. Toni Choueiri, Sumanta Pal and Thomas Powles.

Cobimetinib Highlights

Settlement of Arbitration between Exelixis and Genentech Regarding Companies' Collaboration Agreement for Cobimetinib. In July, Exelixis announced a settlement of its 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.

Corporate Highlights

Updates from Partnered Programs with Daiichi Sankyo and BMS. In the third quarter and shortly after the quarter ended, Exelixis announced milestones for compounds from two of its partnered programs.

In September, collaborator Daiichi Sankyo announced positive top-line results from ESAX-HTN, a phase 3 pivotal trial of esaxerenone (formerly CS-3150) in patients with essential hypertension in Japan. As a result, Daiichi Sankyo plans to submit a Japanese regulatory application for esaxerenone for an essential hypertension indication in the first quarter of 2018. Daiichi Sankyo also announced the initiation of a pivotal trial of esaxerenone in patients with diabetic nephropathy. ESAX-DN is a phase 3 study in patients with type-2 diabetes with microalbuminuria who are taking an angiotensin II receptor blocker (ARB) or an angiotensin converting enzyme (ACE) inhibitor in Japan.

In October, Exelixis earned a $10 million milestone from BMS as part of the two companies' worldwide collaboration for compounds targeting retinoic acid-related orphan receptor (ROR), a family of nuclear hormone receptors implicated in inflammatory conditions. The milestone was triggered by BMS' filing of a Clinical Trial Authorization in Europe for a first-in-human study of a RORγt inverse agonist.

Debut of New Mission-Driven Corporate Branding and Website. In September, Exelixis introduced new corporate branding aligned with its mission, growth strategy and commitment to bring best-in-class oncology medicines to market. The new branding included a redesigned logo crafted as a wordmark with an extractable symbol that will become emblematic of Exelixis, as well as the revised corporate tagline, *Resilience.Results.Remission.* The new corporate branding celebrates the company's unwavering perseverance to deliver results, and its aspirational commitments to the diverse audiences it serves.

Third Quarter 2017 Financial Results

Total revenue for the quarter ended September 30, 2017 was $152.5 million, compared to $62.2 million for the comparable period in 2016. Total revenue includes $96.4 million and $56.1 million of net product revenue and collaboration revenue, respectively, compared to $42.7 million and $19.5 million for the comparable period in 2016. The increase in net product revenues primarily reflects the growth in product sales of CABOMETYX since the product's launch in late April 2016. Collaboration revenues for the quarter ended September 30, 2017 include two milestones totaling $45.0 million resulting from Ipsen's receipt of the validation from the European Medicines Agency for the application for variation to the CABOMETYX marketing authorization for the addition of a new indication in first-line treatment of advanced RCC in adults; we also recognized $11.1 million in additional revenue from the company's collaboration agreements with Ipsen, Takeda and Genentech during the quarter. Collaboration revenues for the comparable period in 2016 include the recognition of a $15.0 million milestone from Daiichi Sankyo and $4.5 million in revenue from the company's collaboration agreements with Ipsen, Takeda and Genentech.

Research and development expenses for the quarter ended September 30, 2017 were $28.5 million, compared to $20.3 million for the comparable period in 2016. The increase in research and development expenses was primarily a result of increases in personnel expenses, clinical trial costs and consulting and outside services. The increase in personnel-related expenses was primarily a result of an increase in headcount associated with the re-launch of the company's internal discovery program and the build-out of the company's medical affairs organization. The increase in clinical trial costs was predominantly due to start-up costs associated with CheckMate 9ER and start-up costs associated with the phase 1b trial of cabozantinib and atezolizumab in locally advanced or metastatic solid tumors; those increases were partially offset by decreases in costs related to METEOR, the company's completed phase 3 pivotal trial comparing CABOMETYX to everolimus in patients with advanced RCC. The increase in consulting and outside services was primarily in support of the company's medical affairs organization.

Selling, general and administrative expenses for the quarter ended September 30, 2017 were $38.1 million, compared to $32.5 million for the comparable period in 2016. The increase in selling, general and administrative expenses was primarily a result of increases in consulting and outside services to support the company's marketing activities and in personnel expenses resulting primarily from an increase in general and administrative headcount to support the company's commercial and research and development organizations. 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 December 2016.

Other income (expense), net for the quarter ended September 30, 2017 was $3.4 million compared to $(18.5) million for the comparable period in 2016. The increase in other income (expense), net, was primarily due to a $13.8 million loss on extinguishment of debt associated with the conversions of the 4.25% Convertible Subordinated Notes due 2019 (2019 Notes) during the third quarter of 2016, and a $7.8 million decrease in interest expense due to the conversions and the redemption of the 2019 Notes during the third and fourth quarters of 2016, the repayment of the Silicon Valley Bank term loan in March 2017 and the repayment of the Deerfield Notes in June 2017.

Net income for the quarter ended September 30, 2017 was $81.4 million, or $0.28 per share, basic and $0.26 per share, diluted, compared to a net loss of $(11.3) million, or $(0.04) per share, basic and diluted, for the comparable period in 2016. The transition to profitability was primarily due to the increase in net product revenues, reflecting the growth in product sales of CABOMETYX since the launch in late April 2016, which was supplemented by the growth in our collaboration revenues and 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 $422.3 million at September 30, 2017, as compared to $479.6 million at December 31, 2016.

2017 Financial Guidance

The company is updating its guidance that total costs and operating expenses for the full year will be between $285 million and $295 million. This guidance includes approximately $25 million of non-cash costs and expenses related primarily to stock-based compensation expense.

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 September 29, 2017, December 30, 2016 and September 30, 2016 are indicated as being as of and for the periods ended September 30, 2017, December 31, 2016 and September 30, 2016, respectively.

Conference Call and Webcast

Exelixis management will discuss the company's financial results for the third 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, November 1, 2017.

To access the webcast link, log onto *www.exelixis.com* and proceed to the News & Events / Event Calendar page under the Investors & Media heading. 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 96645455 to join by phone.

A telephone replay will be available until 8:00 p.m. EDT on November 3, 2017. Access numbers for the telephone replay are: 855-859-2056 (domestic) and 404-537-3406 (international); the passcode is 96645455. A webcast replay will also be archived on *www.exelixis.com* for one year.

About Exelixis

Founded in 1994, Exelixis, Inc. (NASDAQ: EXEL) is a commercially successful, oncology-focused biotechnology company that strives to accelerate the discovery, development and commercialization of new medicines for difficult-to-treat cancers. Following early work in model genetic systems, we established a broad drug discovery and development platform that has served as the foundation for our continued efforts to bring new cancer therapies to patients in need. We discovered our lead compounds, cabozantinib and cobimetinib, and advanced them into clinical development before entering into partnerships with leading biopharmaceutical companies in our efforts to bring them to patients globally. With growing revenues from the three resulting commercialized products - CABOMETYX®, COMETRIQ®, and COTELLIC® - we are reinvesting in our business to maximize the potential of our pipeline, which we intend to supplement with targeted business development activities and internal drug discovery, all to deliver the next generation of Exelixis medicines and help patients recover stronger and live longer. 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 CABOMETYX as Exelixis' top priority; the impact of the FDA's grant of Priority Review for Exelixis' sNDA for CABOMETYX as a treatment for patients with previously untreated advanced RCC and the positive results from the CELESTIAL pivotal trial on Exelixis' ability to improve treatment outcomes for patients with cancer; a potential commercial launch of CABOMETYX as a treatment for patients with previously untreated advanced RCC; Exelixis' plan to submit an sNDA in the first quarter of 2018 for cabozantinib as a treatment for HCC; data results from CELESTIAL at a future medical conference; Daiichi Sankyo's plans to submit a Japanese regulatory application for esaxerenone for an essential hypertension indication in the first quarter of 2018 and initiate a pivotal trial of esaxerenone in patients with diabetic nephropathy; the impact of Exelixis' new corporate branding; Exelixis' guidance for 2017 total costs and operating expenses, including non-cash costs and expenses; growing revenues from CABOMETYX, COMETRIQ, and COTELLIC and Exelixis' plans to reinvest in its business to maximize the potential of the company's pipeline, including through targeted business development activities and internal drug discovery; and Exelixis' mission to deliver the next generation of Exelixis medicines and help patients recover stronger and live longer. Words such as "focused," "priority," "mission," "upcoming," "potential," "moving," "plans," "planned," "future," "will," "forward," "promising," "guidance," "intend," "commitment," 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 CABOMETYX, COMETRIQ, and COTELLIC and the availability of coverage and reimbursement for these products; the risk that unanticipated developments could adversely affect the commercialization of CABOMETYX, 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 its relationship with Genentech/Roche with respect to cobimetinib and Exelixis' ability to maintain its rights under the collaboration; 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 August 2, 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 November 1, 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.

EXELIXIS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	**2016**	**2017**	**2016**
Revenues:				
Net product revenues	$ 96,416	$ 42,742	$ 253,297	$ 83,459
Collaboration revenues	56,094	19,452	79,108	30,414
Total revenues	152,510	62,194	332,405	113,873
Operating expenses:				
Cost of goods sold	4,658	2,455	10,875	4,700
Research and development	28,543	20,256	79,967	72,166
Selling, general and administrative	38,129	32,463	113,116	103,143
Restructuring (recovery) charge	—	(244)	(32)	871
Total operating expenses	71,330	54,930	203,926	180,880
Income (loss) from operations	81,180	7,264	128,479	(67,007)
Other income (expense), net:				
Interest income and other, net	3,408	3,059	6,098	4,010
Interest expense	—	(7,834)	(8,679)	(28,575)
Loss on extinguishment of debt	—	(13,773)	(6,239)	(13,773)
Total other income (expense), net	3,408	(18,548)	(8,820)	(38,338)
Income (loss) before income taxes	84,588	(11,284)	119,659	(105,345)
Income tax expense	3,206	—	3,921	—
Net income (loss)	$ 81,382	$ (11,284)	$ 115,738	$ (105,345)
Net income (loss) per share, basic	$ 0.28	$ (0.04)	$ 0.39	$ (0.44)
Net income (loss) per share, diluted	$ 0.26	$ (0.04)	$ 0.37	$ (0.44)
Shares used in computing basic net income (loss) per share	294,269	256,319	292,776	238,024
Shares used in computing diluted net income (loss) per share	312,940	256,319	311,555	238,024

EXELIXIS, INC.

CONDENSED CONSOLIDATED BALANCE SHEET DATA

(in thousands)

(unaudited)

	September 30, 2017	**December 31, 2016 (1)**
Cash and investments (2)	$ 422,317	$ 479,554
Working capital	$ 361,968	$ 200,215
Total assets	$ 609,772	$ 595,739
Total stockholders' equity	$ 238,715	$ 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 September 30, 2017 and $4.2 million as of December 31, 2016.

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