Exelixis Announces Fourth Quarter and Full Year 2017 Financial Results and Provides Corporate Update

February 26, 2018

- Total Revenue of $120.1 million for the Fourth Quarter of 2017, $452.5 million for the Full Year 2017 -

- Cabozantinib Franchise Net Product Revenue of $95.7 million for the Fourth Quarter of 2017, $349.0 million for the Full Year 2017 -

- Diluted EPS of $0.12 per Share for the Fourth Quarter of 2017, $0.49 for the Full Year 2017 -

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

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Feb. 26, 2018-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the fourth quarter and full year 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. In 2017, the company's top priority was continuing to execute on the launch of CABOMETYX ® (cabozantinib) tablets, which saw added momentum in December when the U.S. Food and Drug Administration (FDA) expanded the product's indication to encompass all patients with advanced renal cell carcinoma (RCC). CABOMETYX generated $90.4 million and $324.0 million in net product revenue during the fourth quarter and full year of 2017, respectively. COMETRIQ® (cabozantinib) capsules for the treatment of patients with progressive, metastatic medullary thyroid cancer generated an additional $5.3 million and $25.0 million in net product revenue during the fourth quarter and full year of 2017, respectively. Total revenue was $120.1 million and $452.5 million for the fourth quarter and full year of 2017, respectively.

"2017 was an important year for Exelixis, underscored by substantial progress in the commercial, clinical, regulatory and financial components of our business, all of which fuel our mission to help cancer patients recover stronger and live longer," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. "Supported by revenue from the CABOMETYX franchise, we reinvested in our business by initiating new clinical trials, planning for future studies, and taking concrete steps to build a new generation of Exelixis medicines beyond cabozantinib and cobimetinib through resuming our internal drug discovery activities and pursuing targeted business development opportunities."

Dr. Morrissey continued: "Exelixis is already off to a productive start in 2018. We continue to make progress on our supplemental New Drug Application for cabozantinib as a treatment for advanced hepatocellular carcinoma, which we expect to complete in the first quarter. And earlier this month, at ASCO-GU, an updated analysis from the trial evaluating cabozantinib, in combination with nivolumab or with nivolumab plus ipilimumab, demonstrated high rates of durable responses in patients with previously treated metastatic urothelial carcinoma and metastatic RCC. We also continue to expect top-line results in the first half of this year from IMblaze370, Genentech's phase 3 pivotal trial of cobimetinib in combination with atezolizumab in advanced colorectal cancer. At the same time, other Exelixis-discovered compounds are moving forward in the hands of our partners, including esaxerenone, for which Daiichi Sankyo plans to file a Japanese regulatory application for an essential hypertension indication in the first quarter. As we move through the year, we remain deeply committed to doing all we can to help the patients we serve and are grateful for the continued support of our stockholders."

Cabozantinib Highlights

FDA Approval of CABOMETYX Tablets for Previously Untreated Advanced RCC. In December, approximately two months ahead of the assigned Prescription Drug User Fee Act (PDUFA) action date, the FDA approved CABOMETYX tablets for an expanded indication for patients with advanced RCC. The FDA's priority review and early approval of CABOMETYX for this indication was based on results from the randomized phase 2 CABOSUN trial in patients with previously untreated RCC, which demonstrated a statistically significant and clinically meaningful improvement in progression-free survival (PFS) versus sunitinib, a current standard of care.

Strong Growth in Cabozantinib Franchise Net Revenue. Cabozantinib generated $95.7 million in net product revenue during the fourth quarter of 2017, an increase of 84 percent year-over-year. Full-year 2017 net product revenue was $349.0 million, an increase of 158 percent year-over-year.

Following Positive Top-Line Results, Phase 3 CELESTIAL Data in Advanced Hepatocellular Carcinoma (HCC) Presented at American Society of Clinical Oncology (ASCO) 2018 Gastrointestinal Cancers Symposium (ASCO-GI). In October, Exelixis announced the CELESTIAL trial met its primary endpoint of overall survival (OS), with cabozantinib providing a statistically significant and clinically meaningful improvement in OS compared to placebo in patients with advanced HCC who had been previously treated with sorafenib and up to one additional therapy. Detailed results of the trial were later presented in a late-breaking oral session at ASCO-GI in January 2018. Based on these results, Exelixis plans to submit a supplemental New Drug Application (sNDA) to the FDA in the first quarter of 2018.

Amendment to Clinical Research Protocol for Phase 1b Trial of Cabozantinib in Combination with Atezolizumab in Patients with Locally Advanced or Metastatic Solid Tumors. In January 2018, Exelixis announced an amendment to the protocol for the phase 1b trial of cabozantinib in combination with atezolizumab in patients with locally advanced or metastatic solid tumors. The amendment added four new expansion cohorts to the trial, which now includes patients with non-small cell lung cancer and castration-resistant prostate cancer, in addition to previously included patients

with RCC and urothelial carcinoma (UC). The primary objective in the expansion stage of this trial remains to determine the objective response rate (ORR) in each cohort.

Cabozantinib Data at the ASCO 2018 Genitourinary Cancers Symposium (ASCO-GU). In February, cabozantinib was the subject of 14 presentations at the 2018 ASCO-GU Symposium in San Francisco. Updated results from the ongoing phase 1 trial of cabozantinib in combination with nivolumab, with or without ipilimumab, in patients with refractory genitourinary tumors were the subject of a poster presentation with the two combination regimens demonstrating an acceptable tolerability profile, and high rates of durable responses in the previously treated metastatic UC and metastatic RCC cohorts. This phase 1 trial informed the design of CheckMate 9ER, the ongoing phase 3 pivotal trial of cabozantinib plus immunotherapy in patients with previously untreated RCC that is being conducted with Bristol-Myers Squibb (BMS).

Cabozantinib Data at the 2018 Multidisciplinary Head and Neck Cancers Symposium. In February, cabozantinib was the subject of an oral presentation at this medical meeting held in Scottsdale, Arizona. Investigators presented results from the ongoing investigator-sponsored phase 2 trial of cabozantinib in patients with radioiodine-refractory differentiated thyroid carcinoma (DTC) in the first-line setting. Exelixis plans to initiate a pivotal phase 3 study with cabozantinib in patients with advanced DTC later this year.

Cobimetinib Highlights

Phase 1b Results for the Combination of Cobimetinib and Atezolizumab in Metastatic Colorectal Cancer (CRC) at ASCO-GI. In January 2018, updated safety and efficacy results from the Genentech-sponsored phase 1b clinical trial of cobimetinib in combination with atezolizumab in patients with metastatic CRC were presented at ASCO-GI. The primary objectives for the study are the evaluation of the safety and tolerability of the combination. Secondary endpoints include investigator-assessed ORR, PFS by RECIST 1.1, and OS. Initial results reported from this study at ASCO 2016 led to the initiation of IMblaze370 (formerly COTEZO), a phase 3 pivotal trial of the combination or atezolizumab alone versus regorafenib in patients with unresectable locally advanced or metastatic CRC, for which Genentech has guided it expects top-line results in the first half of 2018. More information about IMblaze370 is available at www.clinicaltrials.gov.

First Patient Enrolled in Phase 3 Pivotal Trial in First-Line BRAF Wild-Type Melanoma. In December, Genentech confirmed enrollment of the first patient in IMspire170, the pivotal phase 3 trial studying the combination of cobimetinib and atezolizumab versus pembrolizumab in previously untreated BRAF wild-type melanoma. In addition to this study, in January 2017, Genentech initiated IMspire150 TRILOGY, a phase 3 pivotal trial evaluating the combination of cobimetinib, vemurafenib and atezolizumab versus cobimetinib plus vemurafenib in previously untreated BRAF V600 mutation positive patients with metastatic or unresectable locally advanced melanoma.

Corporate Highlights

Exclusive Licensing Agreement with StemSynergy Therapeutics, Inc. (StemSynergy) for the Discovery and Development of Novel Anticancer Therapies. In January 2018, Exelixis announced it had entered into an exclusive collaboration and license agreement with StemSynergy for the discovery and development of novel oncology compounds targeting Casein Kinase 1 alpha (CK1α), a component of the Wnt signaling pathway implicated in key oncogenic processes. Under the terms of the agreement, Exelixis will partner with StemSynergy to conduct preclinical and clinical studies with compounds from StemSynergy's CK1α Activator Program. Exelixis paid StemSynergy aggregate upfront payments of $3.0 million and will pay up to $3.5 million in initial research and development funding. StemSynergy will be eligible for a variety of milestone payments for the first product to emerge from the collaboration, as well as single-digit royalties on worldwide sales.

Financial Community Briefing at ASCO-GI. In January 2018, Exelixis and Ipsen hosted a live briefing event for the financial community to discuss cabozantinib data presented at ASCO-GI. The replay of the briefing is now available on the News & Events / Event Calendar page at www.exelixis.com.

Update on Partnered Program with BMS. In October, Exelixis earned a $10.0 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.

Fourth Quarter and Full Year 2017 Financial Results

Total revenue for the quarter ended December 31, 2017 was $120.1 million, compared to $77.6 million for the comparable period in 2016. Total revenue for the year ended December 31, 2017 was $452.5 million, compared to $191.5 million for the comparable period in 2016.

Total revenue for the quarter and year ended December 31, 2017 includes net product revenue of $95.7 million and $349.0 million, respectively, compared to $51.9 million and $135.4 million for the comparable periods in 2016. The increase in net product revenue primarily reflects the growth in product sales of CABOMETYX since the product's launch in late April 2016.

Total revenue for the quarter and year ended December 31, 2017 also includes collaboration revenue of $24.4 million and $103.5 million, respectively, compared to $25.7 million and $56.1 million for the comparable periods in 2016. Collaboration revenue includes milestones earned for the quarter and year ended December 31, 2017 of $10.0 million and $57.5 million, respectively, compared to $20.0 million and $40.0 million for the comparable periods in 2016. Additional license, development, royalty and product supply revenue was recognized from the company's collaboration agreements totaling $14.4 million and $46.0 million for the quarter and year ended December 31, 2017, respectively, as compared to $5.7 million and $16.1 million for the comparable periods in 2016.

Research and development expenses for the quarter ended December 31, 2017 were $32.2 million, compared to $23.8 million for the comparable period in 2016. Research and development expenses for the year ended December 31, 2017 were $112.2 million, compared to $96.0 million for the comparable period in 2016. The increase in research and development expenses for both the quarter and the year were 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 increases in headcount associated with our development efforts, our internal discovery program, and our 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 our 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, our completed phase 3 pivotal trial comparing CABOMETYX to everolimus in patients with previously treated advanced RCC. The increase in consulting and outside services was primarily in support of the company's discovery and medical affairs organizations.

Selling, general and administrative expenses for the quarter ended December 31, 2017 were $46.2 million, compared to $13.0 million for the comparable period in 2016. Selling, general and administrative expenses for the year ended December 31, 2017 were $159.4 million, compared to $116.1 million for the comparable period in 2016. The increase in selling, general and administrative expenses for both the quarter and the year were primarily a result of increases in personnel expenses resulting primarily from an increase in general and administrative headcount to support the company's commercial and research and development organizations, marketing activities and an increase in losses under the collaboration agreement with Genentech. In December 2016, Genentech changed its cost allocation approach under the agreement and accordingly selling, general and administrative expenses were offset with a recovery of $23.1 million and $13.3 million, during the quarter and year ended December 31, 2016, respectively, for disputed losses that had been recognized and recorded in prior periods.

Other income (expense), net for the quarter ended December 31, 2017 was $1.5 million compared to ($3.8) million for the comparable period in 2016. Other income (expense), net for the year ended December 31, 2017 was ($7.3) million compared to ($42.1) million for the comparable period in 2016. The increase in other income (expense), net, was primarily due to a $4.5 million and $24.4 million decrease in interest expense for the quarter and year ended December 31, 2017, respectively, as compared to the comparable periods in 2016, as a result of the repayment of the Secured Convertible Notes due 2018 (Deerfield Notes) in June 2017, the repayment of the Silicon Valley Bank term loan in March 2017, and the conversions and the redemption of the 4.25% Convertible Senior Subordinated Notes due 2019 (2019 Notes) during the third and fourth quarters of 2016. Other income (expense), net was also impacted by losses on extinguishment of debt of $6.2 million associated with the repayment of the Deerfield Notes in 2017 and $13.9 million associated with conversions and the redemption of the 2019 Notes during 2016.

Net income for the quarter ended December 31, 2017 was $38.5 million, or $0.13 per share, basic and $0.12 per share, diluted, compared to $35.1 million, or $0.12 per share, basic and diluted, for the comparable period in 2016. Net income for the year ended December 31, 2017 was $154.2 million, or $0.52 per share, basic and $0.49 per share, diluted, compared to a net loss of ($70.2) million, or ($0.28) per share, basic and diluted, for the comparable period in 2016. The transition to profitability was primarily due to the increase in net product revenue, reflecting the growth in product sales of CABOMETYX since the product's launch in late April 2016, which was supplemented by the growth in our collaboration revenue and partially offset by the increase in operating expenses.

Cash and cash equivalents, short- and long-term investments and short- and long-term restricted cash and investments totaled $457.2 million at December 31, 2017, as compared to $479.6 million at December 31, 2016.

2018 Financial Guidance

The company is providing guidance that total costs and operating expenses for the full year will be between $430 million and $460 million. This guidance includes approximately $50 million of non-cash costs and expenses related primarily to stock-based compensation expense.

Basis of Presentation

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

Conference Call and Webcast

Exelixis management will discuss the company's financial results for the fourth quarter and full year of 2017 and provide a general business update during a conference call beginning at 5:00 p.m. EST / 2:00 p.m. PST today, Monday, February 26, 2018.

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 6857848 to join by phone.

A telephone replay will be available until 8:00 p.m. EST on February 28, 2018. Access numbers for the telephone replay are: 855-859-2056 (domestic) and 404-537-3406 (international); the passcode is 6857848. 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 these medicines to patients globally. We are steadfast in our commitment to prudently reinvest in our business to maximize the potential of our pipeline. We intend to supplement our existing therapeutic assets 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. Exelixis recently earned a spot on Deloitte's Technology Fast 500 list, a yearly award program honoring the 500 fastest-growing companies over the past four years. 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; Exelixis' plans to conduct future clinical studies; Exelixis' reinvestment in its business to build a new generation of Exelixis medicines beyond cabozantinib and cobimetinib, including through resuming internal drug discovery activities and pursuing targeted business development opportunities; Exelixis' plans to submit an sNDA for cabozantinib as a treatment for HCC in the first quarter of 2018; Exelixis' expectation of top-line results in the first half of 2018 from the phase 3 pivotal trial of cobimetinib in combination with Genentech's atezolizumab in advanced CRC; Daiichi Sankyo's plans to submit a Japanese regulatory application for esaxerenone for an essential hypertension indication in the first quarter of 2018; Exelixis' plans to initiate a pivotal phase 3 study with cabozantinib in patients with advanced DTC later this year; Exelixis' plans to conduct preclinical and clinical studies with compounds from StemSynergy's CK1α Activator Program,

as well as Exelixis' immediate and potential future financial obligations under the collaboration and license agreement with StemSynergy; Exelixis' guidance for 2018 total costs and operating expenses, including non-cash costs and expenses; 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," "planning," "future," "expect," "plans," "committed," "will," "guidance," "commitment," "potential," "intend," 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; risks and uncertainties related to regulatory review and approval processes and Exelixis' compliance with applicable legal and regulatory requirements; 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 availability of data at the referenced times; 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; 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; the level of costs associated with Exelixis' commercialization, research and development, in-licensing or acquisition of product candidates, and other activities; Exelixis' dependence on third-party vendors; Exelixis' ability to protect its intellectual property rights; market competition, including the potential for competitors to obtain approval for generic versions of Exelixis' marketed products; 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 November 1, 2017, and in Exelixis' future filings with the SEC, including, without limitation, Exelixis' Annual Report on Form 10-K expected to be filed with the SEC on February 26, 2018. 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 December 31,		Year Ended December 31,	
	2017	**2016**	**2017**	**2016**
Revenues:				
Net product revenues	$ 95,711	$ 51,916	$ 349,008	$ 135,375
Collaboration revenues	24,361	25,665	103,469	56,079
Total revenues	120,072	77,581	452,477	191,454
Operating expenses:				
Cost of goods sold	4,191	1,852	15,066	6,552
Research and development	32,204	23,801	112,171	95,967
Selling, general and administrative	46,246	13,002	159,362	116,145
Restructuring (recovery) charge	—	43	(32)	914
Total operating expenses	82,641	38,698	286,567	219,578
Income (loss) from operations	37,431	38,883	165,910	(28,124)
Other income (expenses), net:				
Interest income	1,387	831	4,883	2,578
Interest expense	—	(4,485)	(8,679)	(33,060)
Other, net	100	(106)	(3,537)	(11,616)
Total other income (expenses), net	1,487	(3,760)	(7,333)	(42,098)
Income (loss) before income taxes	38,918	35,123	158,577	(70,222)
Provision for income taxes	429	—	4,350	—
Net income (loss)	$ 38,489	$ 35,123	$ 154,227	$ (70,222)
Net income (loss) per share, basic	$ 0.13	$ 0.12	$ 0.52	$ (0.28)
Net income (loss) per share, diluted	$ 0.12	$ 0.12	$ 0.49	$ (0.28)
Shares used in computing basic net income (loss) per share	296,021	288,158	293,588	250,531
Shares used in computing diluted net income (loss) per share	313,342	301,324	312,003	250,531

EXELIXIS, INC.

CONDENSED CONSOLIDATED BALANCE SHEET DATA

(in thousands)

(unaudited)

	December 31, 2017	December 31, 2016 (1)
Cash and investments (2)	$ 457,176	$ 479,554
Working capital	$ 369,704	$ 200,215
Total assets	$ 655,294	$ 595,739
Total stockholders' equity	$ 284,961	$ 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 short- and long-term restricted cash and investments. Short- and long-term restricted cash and investments totaled $5.2 million as of December 31, 2017 and $4.2 million as of December 31, 2016.

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