Exelixis Announces Second Quarter 2018 Financial Results and Provides Corporate Update

August 1, 2018

- Total Revenues of $186.1 million, Net Income of $87.5 million, Diluted EPS of $0.28 -

- Cabozantinib Franchise Net Product Revenues of $145.8 million -

- Ipsen Royalty Rate Increased to 22 Percent upon Reaching $150.0 million in Cumulative Net Sales -

- Conference Call and Webcast Today at 5:00 P.M. Eastern Daylight Time -

ALAMEDA, Calif.--(BUSINESS WIRE)--Aug. 1, 2018-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the second quarter of 2018 and provided an update on progress toward fulfilling its key corporate objectives, as well as commercial and clinical development milestones.

“The second quarter of 2018 was highlighted by the strong commercial performance of CABOMETYX® (cabozantinib) in advanced renal cell carcinoma and continued regulatory progress for cabozantinib across multiple indications,” said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. “We are pleased with our partner Ipsen’s progress as it launches CABOMETYX in the first-line setting following their recent label expansion in the European Union and the achievement of key commercial sales milestones. In advanced hepatocellular carcinoma, acceptance of our supplemental New Drug Application by the U.S. Food and Drug Administration brought us a step closer to offering CABOMETYX as a treatment to another patient population in need of new options.”

Dr. Morrissey continued: “Our strong financial performance in the second quarter was driven primarily by an increase in U.S. sales of CABOMETYX, as well as a milestone recognized from our collaborative partnerships, leading to net income of $87.5 million or $0.28 per share on a fully diluted basis. The progress we made in the second quarter put us in position for continued momentum across the business in the second half of 2018.”

Second Quarter 2018 Financial Results

Total revenues for the quarter ended June 30, 2018 were $186.1 million, compared to $99.0 million for the comparable period in 2017.

Total revenues include net product revenues of $145.8 million for the quarter ended June 30, 2018, compared to $88.0 million for the comparable period in 2017, representing a 66 percent increase year-over-year. The increase in net product revenues reflects the continued growth of CABOMETYX for the treatment of advanced renal cell carcinoma (RCC).

Total revenues also include collaboration revenues of $40.3 million for the quarter ended June 30, 2018 compared to $11.0 million for the comparable period in 2017. The increase in collaboration revenues was primarily the result of a $25.0 million commercial milestone from Ipsen Pharma SAS (Ipsen) that we earned in the second quarter of 2018 upon Ipsen’s achievement of $100.0 million of net sales cumulatively over four consecutive quarters. Royalties from Ipsen on their ex-U.S. sales of cabozantinib and, to a lesser extent, royalties from Genentech on their ex-U.S. sales of COTELLIC® (cobimetinib), also increased in the second quarter of 2018, contributing $6.9 million in collaboration revenues compared to $1.6 million for the comparable period in 2017. These increases were partially offset by a decrease of $3.1 million in the recognition of deferred revenue due to our adoption of Accounting Standards Update No. 2014-09 *Revenue from Contracts with Customers (Accounting Standards Codification Topic 606)* on January 1, 2018. For more information on our adoption of the new revenue standard, see “Note 1. Organization and Summary of Significant Accounting Policies - Recently Adopted Accounting Pronouncements - Revenue” contained in Part I, Item 1 of Exelixis’ Quarterly Report on Form 10-Q expected to be filed with the Securities and Exchange Commission (SEC) on August 1, 2018.

Research and development expenses for the quarter ended June 30, 2018 were $42.5 million, compared to $28.2 million for the comparable period in 2017. The increase in research and development expenses was primarily related to increases in personnel expenses and license costs. The increase in personnel expenses was primarily due to increases in headcount to support our development and discovery efforts. The increase in license costs was primarily a result of the collaboration and license agreement we entered into with Invenra, Inc. (Invenra) in May 2018.

Selling, general and administrative expenses for the quarter ended June 30, 2018 were $51.9 million, compared to $40.7 million for the comparable period in 2017. The increase in selling, general and administrative expenses was primarily related to increases in consulting and outside services and personnel expenses. The increase in consulting and outside services was primarily due to an increase in marketing activities. The increase in personnel expenses was primarily due to increases in general and administrative headcount to support the company’s commercial and research and development organizations.

Net income for the quarter ended June 30, 2018 was $87.5 million, or $0.29 per share, basic and $0.28 per share, diluted, compared to a $17.7 million, or $0.06 per share, basic and diluted, for the comparable period in 2017. The increase in net income was primarily the result of increases in net product revenues and collaboration revenues, which was partially offset by the increases in research and development and selling, general and administrative expenses.

Cash and cash equivalents, short- and long-term investments and short- and long-term restricted cash and investments totaled $595.9 million at June 30, 2018, as compared to $457.2 million at December 31, 2017.

2018 Financial Guidance

The company is maintaining its 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.

Cabozantinib Highlights

Strong Growth in Cabozantinib Franchise Net Revenues. Net product revenues generated by the cabozantinib franchise were $145.8 million during the second quarter of 2018, an increase of 66 percent year-over-year. During the second quarter of 2018, CABOMETYX generated $141.1 million in net product revenues and COMETRIQ® (cabozantinib) capsules for the treatment of patients with progressive, metastatic medullary thyroid cancer generated an additional $4.7 million in net product revenues.

Cabozantinib Royalty Rate Increased to 22 Percent of Net Sales by Ipsen. During the second quarter of 2018, Ipsen reached $150.0 million in cumulative net sales of cabozantinib, which resulted in an increase in royalty revenues earned by Exelixis to 22 percent of net sales by Ipsen. Previously we had been entitled to receive a tiered royalty of 2 percent to 12 percent. Moving forward, we are now entitled to receive a tiered royalty of 22 percent to 26 percent of annual net sales.

European Commission (EC) Approves CABOMETYX for Previously Untreated Intermediate- or Poor-Risk Advanced RCC. In May, Exelixis announced its partner Ipsen received approval from the EC for CABOMETYX 20 mg, 40 mg and 60 mg for an expanded indication that includes the first-line treatment of adults with intermediate- or poor-risk advanced RCC in the European Union (EU). Under the terms of the Collaboration Agreement with Ipsen, Exelixis is entitled to receive a milestone payment of $50 million for the EC approval, of which approximately $46 million was recognized as collaboration revenue in the first quarter of 2018.

U.S. Food and Drug Administration (FDA) Accepts Supplemental New Drug Application (sNDA) for CABOMETYX in Previously Treated Advanced Hepatocellular Carcinoma (HCC). In May, Exelixis announced that the FDA accepted for filing the company's sNDA for CABOMETYX tablets as a treatment for patients with previously treated advanced HCC. The FDA completed its filing review, determining that the application was sufficiently complete to permit a substantive review and assigning a Prescription Drug User Fee Act (PDUFA) action date of January 14, 2019.

Second Expansion to Clinical Research Protocol for Phase 1b COSMIC-021 Trial. In June, Exelixis announced a planned amendment to the protocol for COSMIC-021, the phase 1b trial of cabozantinib in combination with atezolizumab (TECENTRIQ®), an anti-PDL1 antibody discovered and developed by Genentech, in patients with locally advanced or metastatic solid tumors, to add 10 new expansion cohorts to the trial. There are now a total of 18 cohorts in the expansion stage of the study, for which the primary goal remains to determine the objective response rate in each cohort.

Cabozantinib Data at the American Society of Clinical Oncology (ASCO) 2018 Annual Meeting. In June, data from clinical trials of cabozantinib were featured in 15 presentations at the ASCO Annual Meeting in Chicago. Presentations included sub-group analyses of the CELESTIAL phase 3 pivotal trial in advanced HCC comparing outcomes by duration of sorafenib treatment in patients whose only prior treatment was sorafenib, as well as outcomes based on age. The findings showed that cabozantinib improved overall survival (OS) and progression-free survival compared with placebo irrespective of duration of prior sorafenib treatment or age category.

CELESTIAL Phase 3 Pivotal Trial Results Published in *The New England Journal of Medicine (NEJM)*. In July, Exelixis announced that *NEJM* published positive results from the CELESTIAL phase 3 pivotal trial of cabozantinib in patients with previously treated advanced HCC. As previously announced and presented, the data demonstrate that cabozantinib provided a statistically significant and clinically meaningful improvement in OS versus placebo.

Cobimetinib Highlights

Update on IMblaze370 Phase 3 Trial of Atezolizumab and Cobimetinib in Patients with Heavily Pretreated Locally Advanced or Metastatic Colorectal Cancer (CRC). In May, Exelixis' collaborator Genentech informed the company that IMblaze370, the phase 3 pivotal trial evaluating cobimetinib in combination with atezolizumab in patients with heavily pretreated locally advanced or metastatic CRC, did not meet its primary endpoint. Genentech continues to pursue the cobimetinib development program with two additional ongoing phase 3 pivotal trials (IMspire150 and IMspire170) of combination regimens containing cobimetinib, and is also conducting a series of early-stage clinical trials investigating the combination of cobimetinib and atezolizumab in multiple tumor settings.

Corporate Highlights

Appointment of Dr. Maria Freire to Exelixis' Board of Directors. In April, Exelixis announced the appointment of biomedical research executive Maria C. Freire, Ph.D., to the company's Board of Directors. Dr. Freire currently serves as President and Executive Director and as a member of the board of directors of the Foundation for the National Institutes of Health, an independent 501(c)(3) charitable organization established by Congress to support the National Institutes of Health by raising private funds for biomedical research and fostering partnerships and alliances around the world.

Collaboration with Invenra to Discover and Develop Novel Biologics to Treat Cancer. In May, Exelixis announced it had entered into a collaboration with Invenra, a Madison, Wisconsin-based biotechnology firm focused on developing next-generation biologics, to discover and develop multispecific antibodies for the treatment of cancer. Under the collaboration agreement, Invenra is responsible for antibody lead discovery and generation, while Exelixis will lead Investigational New Drug enabling studies, manufacturing, clinical development and future regulatory and commercialization activities. The collaboration agreement also provides that Exelixis will receive an exclusive, worldwide license to one preclinical asset, and that Exelixis and Invenra intend to pursue up to six additional discovery projects during the term of the collaboration, which in total are directed to three discovery programs.

Move of Company Headquarters to Alameda. As of June 11, Exelixis officially moved its headquarters from South San Francisco to Alameda, California. The new facilities include state-of-the-art labs and additional office space, providing a strong foundation for Exelixis' long-term vision and growth.

Inclusion on Standard & Poor's (S&P) MidCap 400 Index. In June, Exelixis announced it had been added to the S&P MidCap 400 classified under S&P's Global Industry Classification Standard Biotechnology Sub-Industry index, effective prior to the open of trading on July 2. The index, which is distinct from the large-cap S&P 500®, measures the performance of profitable mid-sized companies, reflecting the distinctive risk and return characteristics of this market segment.

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 June 29, 2018, June 30, 2017 and December 29, 2017, are indicated as being as of and for the periods ended June 30, 2018, June 30, 2017 and December 31, 2017, respectively.

Conference Call and Webcast

Exelixis management will discuss the company's financial results for the second quarter of 2018 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 1, 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 5668207 to join by phone.

A telephone replay will be available until 8:30 p.m. EDT on August 3, 2018. Access numbers for the telephone replay are: 855-859-2056 (domestic) and 404-537-3406 (international); the passcode is 5668207. 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 three commercially available products, CABOMETYX® (cabozantinib), COMETRIQ® (cabozantinib) and COTELLIC® (cobimetinib), and have entered into partnerships with leading pharmaceutical companies to bring these important medicines to patients worldwide. Supported by revenues from our marketed products and collaborations, we are committed to prudently reinvesting in our business to maximize the potential of our pipeline. We are supplementing 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. In July 2018, Exelixis was added to the Standard & Poor's (S&P) MidCap 400 index, which measures the performance of profitable mid-sized companies. For more information about Exelixis, please visit *www.exelixis.com*, follow @ExelixisInc on Twitter or like Exelixis,Inc on Facebook.

Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to: the impact of the FDA's acceptance of Exelixis' sNDA for CABOMETYX as a treatment option for patients with previously treated HCC; Exelixis' belief that the progress the company made in the second quarter of 2018 puts it in a position for continued momentum across the business in the second half of 2018; Exelixis' guidance for 2018 total costs and operating expenses, including non-cash costs and expenses; Exelixis' plans to conduct future clinical studies, including the planned expansion to the COSMIC-021 trial, for which the goal remains to determine the objective response rate in each of the 18 cohorts; Exelixis' planned discovery activities under the collaboration with Invenra; Exelixis' belief that the company's new headquarters in Alameda will provide a strong foundation for Exelixis' long-term vision and growth; 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 "continued," "expected," "guidance," "will," "planned," "goal," "focused," "future," "intend," "vision," "committed," "potential," "mission," 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 sufficient coverage and adequate 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; Exelixis' dependence on its relationships with its collaboration partners, including the level of their investment in the resources necessary to successfully commercialize partnered compounds 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 for the development, manufacture and supply of its products; 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 May 2, 2018, 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 1, 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 June 30,		Six Months Ended June 30,	
	2018	**2017**	**2018**	**2017**
Revenues:				
Net product revenues	$ 145,836	$ 88,004	$ 280,108	$ 156,881
Collaboration revenues	40,272	11,004	119,719	23,014
Total revenues	186,108	99,008	399,827	179,895
Operating expenses:				
Cost of goods sold	5,997	3,014	11,636	6,217
Research and development	42,488	28,214	80,245	51,424
Selling, general and administrative	51,853	40,667	105,869	74,955
Total operating expenses	100,338	71,895	197,750	132,596
Income from operations	85,770	27,113	202,077	47,299
Other income (expense), net:				
Interest income	2,697	1,251	4,592	2,364
Interest expense	—	(4,259)	—	(8,679)
Other, net	(72)	(5,868)	97	(5,913)
Total other income (expense), net	2,625	(8,876)	4,689	(12,228)
Income before income taxes	88,395	18,237	206,766	35,071
Provision for income taxes	901	581	3,415	715
Net income	$ 87,494	$ 17,656	$ 203,351	$ 34,356
Net income per share, basic	$ 0.29	$ 0.06	$ 0.68	$ 0.12
Net income per share, diluted	$ 0.28	$ 0.06	$ 0.65	$ 0.11
Shares used in computing net income per share, basic	297,336	293,188	296,874	292,029
Shares used in computing net income per share, diluted	312,241	311,219	313,024	310,759

EXELIXIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEET DATA

(in thousands)

(unaudited)

	June 30, 2018	**December 31, 2017 (1)**
Cash and investments (2)	$ 595,923	$ 457,176
Working capital	$ 586,342	$ 369,704
Total assets	$ 911,158	$ 655,294
Total stockholders' equity	$ 774,968	$ 284,961

(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 $1.6 million as of June 30, 2018 and $5.2 million as of December 31, 2017.

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