Exelixis Announces Second Quarter 2020 Financial Results and Provides Corporate Update

August 6, 2020

- Total Revenues of $259.5 Million, Cabozantinib Franchise Revenues of $178.7 Million -

- GAAP Diluted EPS of $0.21, Non-GAAP Diluted EPS of $0.25 -

- Conference Call and Webcast Today at 5:30 PM Eastern Time -

ALAMEDA, Calif.--(BUSINESS WIRE)--Aug. 6, 2020-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the second quarter of 2020 and provided an update on progress toward fulfilling its key corporate objectives, as well as commercial and clinical development milestones.

“Exelixis continued to execute on our key priorities and milestones in the second quarter of 2020,” said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. “The data flow in the quarter was headlined by the positive top-line results from the phase 3 pivotal CheckMate -9ER study evaluating the combination of cabozantinib and nivolumab in first-line renal cell carcinoma. We’re looking forward to the presentation of detailed results from the trial at the European Society for Medical Oncology’s Virtual Congress in September, where CheckMate -9ER has been selected for an oral presentation in the conference’s Presidential Symposium track. Working in tandem with Bristol Myers Squibb, the trial’s sponsor, and Ipsen and Takeda, our partners in cabozantinib’s global clinical development and commercialization, we’re quickly moving forward with the associated high-priority regulatory filings on a global basis. At the same time, the Exelixis commercial organization is well into their preparations for a potential launch in the United States.”

Dr. Morrissey continued: “As we move forward on the next commercial growth opportunity for cabozantinib, we’re also moving quickly to evaluate its potential utility in additional disease settings. Based on the results from COSMIC-021, we and our collaboration partner Roche recently initiated the CONTACT clinical trial program, which consists of three global phase 3 pivotal trials of cabozantinib in combination with atezolizumab in metastatic non-small cell lung cancer, castration-resistant prostate cancer, and renal cell carcinoma. In addition, as a result of our internal efforts complemented by the work of our research partners, we remain on track to file up to three new Investigational New Drug applications by the end of this year, including a CDK7 inhibitor from our Aurigene collaboration, a tissue factor-targeting antibody-drug conjugate from our Iconic collaboration, as well as XL265, a TAM kinase-focused kinase inhibitor from our own laboratories. I’m proud of the commitment demonstrated by the entire Exelixis team to continue to drive our business forward during these difficult times. We look forward to providing updates on our continued progress throughout the second half of the year.”

Second Quarter 2020 Financial Results

Total revenues for the quarter ended June 30, 2020 were $259.5 million, compared to $240.3 million for the comparable period in 2019.

Total revenues for the quarter ended June 30, 2020 included net product revenues of $178.7 million, compared to $193.7 million for the comparable period in 2019. The decrease in net product revenues was due to a decrease in sales volume, which was partially offset by an increase in the average net selling price. Net product revenues in the second quarter 2020 were negatively impacted by the COVID-19 pandemic and by an inventory build by wholesalers and end customers in the first quarter 2020, which generally reversed in the second quarter 2020.

Collaboration revenues, composed of license revenues and collaboration services revenues, were $80.7 million for the quarter ended June 30, 2020, compared to $46.6 million for the comparable period in 2019. The increase in collaboration revenues was primarily related to an increase in the recognition of milestone related revenues, increases in development cost reimbursements earned, and higher royalty revenues for the sales of cabozantinib outside of the U.S. generated by Exelixis’ collaboration partner, Ipsen Pharma SAS (Ipsen).

Research and development expenses for the quarter ended June 30, 2020 were $114.9 million, compared to $81.9 million for the comparable period in 2019. The increase in research and development expenses was primarily related to increases in clinical trial costs and personnel expenses, which were partially offset by decreases in license and other collaboration costs. The increase in clinical trial costs was primarily due to costs associated with expanding clinical trial programs for cabozantinib, which includes COSMIC-312, COSMIC-313, CONTACT-02 and COSMIC-021. The increase in personnel expenses was primarily due to an increase in headcount to support Exelixis’ expanding discovery and development efforts. Decreases in license and other collaboration costs were primarily due to upfront license fee payments made in the comparable period of 2019, offset by an increase in research funding commitments in this quarter.

Selling, general and administrative expenses for the quarter ended June 30, 2020 were $59.8 million, compared to $58.8 million for the comparable period in 2019. The increase in selling, general and administrative expenses was primarily related to increases in personnel expenses, which was offset by decreases in marketing costs. The increase in personnel expenses was primarily due to an increase in administrative headcount to support Exelixis’ commercial and research and development organizations.

Provision for income taxes for the quarter ended June 30, 2020 decreased to $13.9 million, compared to $20.7 million for the comparable period in 2019, primarily due to a decrease in pre-tax income.

GAAP net income for the quarter ended June 30, 2020 was $66.8 million, or $0.22 per share, basic and $0.21 per share, diluted, compared to GAAP net income of $79.0 million, or $0.26 per share, basic and $0.25 per share, diluted, for the comparable period in 2019. The decrease in GAAP net income was primarily related to an increase in research and development expenses and a decrease in net product revenues, which were partially offset by an increase in collaboration revenues.

Non-GAAP net income for the quarter ended June 30, 2020 was $79.4 million, or $0.26 per share, basic and $0.25 per share, diluted, compared to

non-GAAP net income of $90.7 million, or $0.30 per share, basic and $0.29 per share, diluted, for the comparable period in 2019. Non-GAAP net income excludes stock-based compensation, adjusted for the related income tax effect.

Cash and investments were $1.5 billion at June 30, 2020, compared to $1.4 billion at December 31, 2019.

Non-GAAP Financial Measures

To supplement Exelixis' financial results presented in accordance with U.S. Generally Accepted Accounting Principles (GAAP), Exelixis presents non-GAAP net income (and the related per share measures), which excludes from GAAP net income (and the related per share measures) stock-based compensation expense, adjusted for the related income tax effect for all periods presented.

Exelixis believes that the presentation of these non-GAAP financial measures provides useful supplementary information to, and facilitates additional analysis by, investors. In particular, Exelixis believes that these non-GAAP financial measures, when considered together with its financial information prepared in accordance with GAAP, can enhance investors' and analysts' ability to meaningfully compare Exelixis' results from period to period, and to identify operating trends in Exelixis' business. Exelixis has excluded stock-based compensation expense, adjusted for the related income tax effect, because it is a non-cash item that may vary significantly from period to period as a result of changes not directly or immediately related to the operational performance for the periods presented. Exelixis also regularly uses these non-GAAP financial measures internally to understand, manage and evaluate its business and to make operating decisions.

These non-GAAP financial measures are in addition to, not a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP. Exelixis encourages investors to carefully consider its results under GAAP, as well as its supplemental non-GAAP financial information and the reconciliation between these presentations, to more fully understand Exelixis' business. Reconciliations between GAAP and non-GAAP results are presented in the tables of this release.

2020 Financial Guidance

Exelixis is providing the following updated financial guidance for fiscal year 2020:

Total revenues (1)	$900 million - $950 million
Net product revenues	$725 million - $775 million
Cost of goods sold	4% - 5% of net product revenues
Research and development expenses (1)(2)	$500 million - $550 million
Selling, general and administrative expenses (1)(3)	$250 million - $270 million
Effective tax rate (1)	17% - 19%
Cash and investments (4)	$1.5 billion - $1.6 billion

(1) Guidance updated on August 6, 2020 from previously provided guidance on May 5, 2020.

(2) Includes $25 million of non-cash stock-based compensation expense.

(3) Includes $40 million of non-cash stock-based compensation expense.

(4) This cash guidance does not include any potential new business development activity, which remains a key priority for Exelixis as it continues to build toward becoming a multi-product oncology company.

Cabozantinib Highlights

Cabozantinib Franchise Net Product Revenues and Royalties. Net product revenues generated by the cabozantinib franchise in the U.S. were $178.7 million during the second quarter of 2020, with net product revenues of $173.6 million from CABOMETYX® (cabozantinib) and $5.1 million from COMETRIQ® (cabozantinib). Based upon cabozantinib-related revenues generated by Exelixis' partner Ipsen in the second quarter of 2020, Exelixis earned $16.3 million in royalty revenues.

Positive Top-line Results from Pivotal Phase 3 CheckMate -9ER Trial Evaluating Nivolumab in Combination with Cabozantinib in Previously Untreated Advanced Renal Cell Carcinoma (RCC). In April 2020, Exelixis and BMS announced that CheckMate -9ER, the phase 3 pivotal trial evaluating nivolumab in combination with cabozantinib compared to sunitinib in previously untreated advanced or metastatic RCC, met its primary endpoint of progression-free survival (PFS) at final analysis, as well as the secondary endpoints of overall survival (OS) at a pre-specified interim analysis, and objective response rate. This preliminary analysis of data showed a favorable safety profile for the combination of a 40 mg dose of cabozantinib with nivolumab.

Cabozantinib Data Presentations at the European Society for Medical Oncology Virtual Congress 2020 (ESMO 2020), including Oral Presentation of CheckMate -9ER in the Meeting's Presidential Symposium II. In September 2020, cabozantinib will be the subject of multiple presentations at ESMO 2020 (September 19-21). Notably, detailed results from CheckMate -9ER will be the subject of an oral presentation during the meeting's Presidential Symposium II. In addition, data from two cohorts of COSMIC-021 evaluating cabozantinib in combination with atezolizumab, expansion cohort 1 in first-line advanced clear cell RCC and cohort 10 in non-clear cell RCC, will be presented during ESMO 2020 as an oral and a poster presentation, respectively.

Initiation of Three Phase 3 Pivotal Trials of Cabozantinib in Combination with Atezolizumab in Previously Treated Metastatic Non-Small Cell Lung Cancer (NSCLC), Castration-Resistant Prostate Cancer (CRPC) and RCC. In June and July 2020, Exelixis announced the initiation of CONTACT-01, CONTACT-02 and CONTACT-03, three global phase 3 pivotal trials of cabozantinib in combination with atezolizumab in patients with previously treated, metastatic NSCLC, CRPC and RCC, respectively. The CONTACT program is part of a joint clinical research collaboration between Exelixis and F. Hoffmann-La Roche Ltd.

- CONTACT-01 is evaluating the combination of cabozantinib and atezolizumab in patients with metastatic NSCLC who have been previously treated with an immune checkpoint inhibitor (ICI) and platinum-containing chemotherapy.

- CONTACT-02 is evaluating the combination of cabozantinib and atezolizumab in patients with metastatic CRPC who have been previously treated with one novel hormonal therapy.
- CONTACT-03 is evaluating the combination of cabozantinib and atezolizumab in patients with metastatic RCC who progressed during or following treatment with an ICI as the immediate preceding therapy.

Completion of Patient Enrollment for COSMIC-312 Phase 3 Pivotal Trial in Previously Untreated Hepatocellular Carcinoma (HCC). Today, Exelixis is announcing the completion of patient enrollment in COSMIC-312, a global phase 3 pivotal trial of cabozantinib in combination with atezolizumab versus sorafenib in previously untreated advanced HCC, providing the patient population for the event-driven analyses of the study's endpoints. Separately, patient enrollment remains open in China with a focus on enrolling the necessary patient number to enable local registration, if supported by the clinical data. The co-primary endpoints of the trial are PFS and OS for the combination of cabozantinib and atezolizumab versus sorafenib. Based on current event rates, Exelixis anticipates announcing top-line results in the first half of 2021.

Announcement of Results from Phase 1b COSMIC-021 Trial of Cabozantinib in Combination with Atezolizumab in Multiple Advanced Solid Tumor Types. In May 2020, Exelixis announced encouraging results from three expansion cohorts of the phase 1b COSMIC-021 trial evaluating the combination of cabozantinib and atezolizumab in patients with metastatic NSCLC, CRPC and urothelial carcinoma. These data were subsequently presented during the 2020 American Society of Clinical Oncology Virtual Scientific Program.

Completion of Patient Enrollment for EXAMINER Phase 4 Trial of Cabozantinib in Metastatic Medullary Thyroid Cancer. In July 2020, Exelixis completed patient enrollment in EXAMINER, the phase 4 trial evaluating the safety and efficacy of the 60 mg tablet formulation of cabozantinib compared with the 140 mg capsule formulation, which is marketed as COMETRIQ, for the treatment of patients with progressive, metastatic medullary thyroid cancer. EXAMINER is a post-marketing requirement from the U.S. Food and Drug Administration (FDA) and the European Commission. The trial was designed to enroll up to 250 patients, and top-line results from the trial are anticipated later this year.

Corporate Updates

Takeda Pharmaceutical Company Limited (Takeda) Records First Commercial Sale of CABOMETYX in Japan. In March 2020, Takeda, Exelixis' partner responsible for the clinical development and commercialization of CABOMETYX in Japan, received approval from the Japanese Ministry of Health, Labour and Welfare to manufacture and market CABOMETYX as a treatment for patients with curatively unresectable or metastatic RCC. During the second quarter of 2020, Takeda launched CABOMETYX in Japan, triggering a $31.0 million milestone payment to Exelixis from Takeda upon the first commercial sale of CABOMETYX, of which $23.7 million was recognized as revenue in this quarter.

Exelixis Files Second Complaint in Patent Infringement Lawsuit against MSN Pharmaceuticals, Inc. (MSN). In May 2020, Exelixis filed a second complaint in the company's patent infringement lawsuit against MSN, following receipt of notice from MSN that it had amended its Abbreviated New Drug Application (ANDA), originally filed with the FDA in September 2019, to add two previously-unasserted CABOMETYX Orange Book-listed patents: U.S. Patent No. 7,579,473, the composition of matter patent, and U.S. Patent No. 8,497,284, a method of use patent. Exelixis is seeking, among other relief, an order that the effective date of any FDA approval of the ANDA would be a date no earlier than the expiration of all of U.S. Patent No. 7,579,473, U.S. Patent No. 8,497,284, and U.S. Patent No. 8,877,776, the latest of which expires on October 8, 2030, and equitable relief enjoining MSN from infringing this patent.

FDA Approves Tecentriq® (Atezolizumab) Plus COTELLIC® (Cobimetinib) and Zelboraf® (Vemurafenib) for Previously Untreated BRAF V600 Mutation-Positive Advanced Melanoma. In July 2020, the FDA approved the supplemental Biologics License Application (sBLA) submitted by Genentech, Inc. (a member of the Roche Group) (Genentech), for Tecentriq plus COTELLIC and Zelboraf for the treatment of BRAF V600-mutation positive advanced melanoma in previously untreated patients. The approval is based on positive results from the phase 3 IMspire150 study, which demonstrated that adding Tecentriq to COTELLIC and Zelboraf helped to reduce the risk of disease worsening or death, compared to placebo plus COTELLIC and Zelboraf. This is the second FDA approval for a regimen including COTELLIC, which was discovered by Exelixis and is now being developed by Genentech as part of a worldwide collaboration agreement between the two companies.

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 July 3, 2020, January 3, 2020 and June 28, 2019 are indicated as being as of and for the periods ended June 30, 2020, December 31, 2019 and June 30, 2019, respectively.

Conference Call and Webcast

Exelixis management will discuss the company's financial results for the second quarter of 2020 and provide a general business update during a conference call beginning at 5:30 p.m. EDT / 2:30 p.m. PDT today, Thursday, August 6, 2020.

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 6548897 to join by phone.

A telephone replay will be available until 8:00 p.m. EDT on August 8, 2020. Access numbers for the telephone replay are: 855-859-2056 (domestic) and 404-537-3406 (international); the passcode is 6548897. 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 system genetics, 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. Our discovery efforts have resulted in four approved products, CABOMETYX® (cabozantinib), COMETRIQ® (cabozantinib), COTELLIC® (cobimetinib) and MINNEBRO® (esaxerenone), and we 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. Exelixis is a member of 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: Exelixis' plans to present data from CheckMate -9ER and the clear cell RCC and non-clear cell RCC cohorts of COSMIC-021 at ESMO 2020; Exelixis' regulatory filing plans and launch readiness preparations with respect to the combination of nivolumab and cabozantinib as a treatment for patients with RCC; the potential utility of cabozantinib in additional disease settings; Exelixis' plans to file up to three new Investigational New Drug applications by the end of 2020; Exelixis' updated 2020 financial guidance; Exelixis' anticipated timelines for top-line results from COSMIC-312 and EXAMINER; 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. Any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements and 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 continuing COVID-19 pandemic and its impact on Exelixis' clinical trial, drug discovery and commercial activities; the degree of market acceptance of CABOMETYX and other Exelixis products in the indications for which they are approved and in the territories where they are approved, and Exelixis' and its partners' ability to obtain or maintain coverage and reimbursement for these products; the effectiveness of CABOMETYX and other Exelixis products in comparison to competing products; the level of costs associated with Exelixis' commercialization, research and development, in-licensing or acquisition of product candidates, and other activities; Exelixis' ability to maintain and scale adequate sales, marketing, market access and product distribution capabilities for its products or to enter into and maintain agreements with third parties to do so; the availability of data at the referenced times; the potential failure of cabozantinib and other Exelixis product candidates, both alone and in combination with other therapies, to demonstrate safety and/or efficacy in clinical testing; uncertainties inherent in the drug discovery and product development process; Exelixis' dependence on its relationships with its collaboration partners, including their pursuit of regulatory approvals for partnered compounds in new indications, their adherence to their obligations under relevant collaboration agreements and the level of their investment in the resources necessary to complete clinical trials or successfully commercialize partnered compounds in the territories where they are approved; complexities and the unpredictability of the regulatory review and approval processes in the U.S. and elsewhere; Exelixis' continuing compliance with applicable legal and regulatory requirements; unexpected concerns that may arise as a result of the occurrence of adverse safety events or additional data analyses of clinical trials evaluating cabozantinib, cobimetinib or esaxerenone; Exelixis' dependence on third-party vendors for the development, manufacture and supply of its products and product candidates; 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 Securities and Exchange Commission (SEC) on May 5, 2020, 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 6, 2020. All forward-looking statements in this press release are based on information available to Exelixis as of the date of this press release, and Exelixis undertakes no obligation to update or revise any forward-looking statements contained herein, except as required by law.

-see attached financial tables-

EXELIXIS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF INCOME
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenues:				
Net product revenues	$ 178,730	$ 193,675	$ 372,610	$ 373,256
License revenues	59,234	37,742	80,113	63,306
Collaboration services revenues	21,515	8,858	33,671	19,200
Total revenues	259,479	240,275	486,394	455,762
Operating expenses:				
Cost of goods sold	9,221	7,539	18,510	15,040
Research and development	114,933	81,932	216,810	145,221
Selling, general and administrative	59,791	58,815	122,731	118,953
Total operating expenses	183,945	148,286	358,051	279,214
Income from operations	75,534	91,989	128,343	176,548
Interest income	5,162	6,975	12,382	13,062
Other income, net	—	803	6	828
Income before income taxes	80,696	99,767	140,731	190,438
Provision for income taxes	13,875	20,725	25,298	35,621
Net income	$ 66,821	$ 79,042	$ 115,433	$ 154,817
Net income per share:				

Basic	$ 0.22	$ 0.26	$ 0.38	$ 0.51
Diluted	$ 0.21	$ 0.25	$ 0.36	$ 0.49
Weighted-average common shares outstanding:				
Basic	307,807	302,188	306,598	301,365
Diluted	318,144	314,911	316,992	314,786

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

	June 30, 2020	December 31, 2019
Cash and investments	$ 1,540,179	$ 1,388,628
Working capital	$ 1,251,982	$ 868,444
Total assets	$ 2,046,548	$ 1,885,670
Total stockholders' equity	$ 1,833,324	$ 1,685,970

EXELIXIS, INC.
RECONCILIATION OF GAAP NET INCOME TO NON-GAAP NET INCOME
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
GAAP net income	$ 66,821	$ 79,042	$ 115,433	$ 154,817
Adjustments:				
Stock-based compensation - research and development expenses (1)	6,112	5,138	11,198	9,444
Stock-based compensation - selling, general and administrative expenses (1)	10,042	9,941	18,938	18,164
Income tax effect of the above adjustments	(3,609)	(3,385)	(6,789)	(6,194)
Non-GAAP net income	$ 79,366	$ 90,736	$ 138,780	$ 176,231
GAAP net income per share:				
Basic	$ 0.22	$ 0.26	$ 0.38	$ 0.51
Diluted	$ 0.21	$ 0.25	$ 0.36	$ 0.49
Non-GAAP net income per share:				
Basic	$ 0.26	$ 0.30	$ 0.45	$ 0.58
Diluted	$ 0.25	$ 0.29	$ 0.44	$ 0.56
Weighted-average common shares outstanding:				
Basic	307,807	302,188	306,598	301,365
Diluted	318,144	314,911	316,992	314,786

(1) Non-cash stock-based compensation expense used for GAAP reporting in accordance with Accounting Standards Codification Topic 718, *Compensation—Stock Compensation*

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