Exelixis Announces Second Quarter 2023 Financial Results and Provides Corporate Update

August 1, 2023

- Total Revenues of $469.8 million, Cabozantinib Franchise U.S. Net Product Revenues of $409.6 million -

- GAAP Diluted EPS of $0.25, Non-GAAP Diluted EPS of $0.31 -

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

ALAMEDA, Calif.--(BUSINESS WIRE)--Aug. 1, 2023-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the second quarter of 2023 and provided an update on progress toward achieving key corporate objectives, as well as commercial, clinical and pipeline development milestones.

"In the second quarter of 2023, the Exelixis team continued to make steady progress both on our commercial business and our rapidly advancing pipeline," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer, Exelixis. "It was another strong quarter for CABOMETYX®, which maintained its status as the leading tyrosine kinase inhibitor for the treatment of renal cell carcinoma, again driven by its use in combination with nivolumab in the first-line setting. Revenues from CABOMETYX and the broader cabozantinib franchise directly support the build-out of our differentiated pipeline, including zanzalintinib, our next-generation tyrosine kinase inhibitor, and XB002, our most advanced antibody-drug conjugate. During and after the quarter, we completed enrollment in multiple expansion cohorts of the phase 1 STELLAR-001 study for zanzalintinib, progressed the ongoing phase 3 pivotal trials and furthered our plans for additional pivotal trials of the compound. We also continued to advance the phase 1 JEWEL-101 study for XB002, selecting the single-agent dose from the dose-escalation stage of the study and initiating the cohort expansion stage, with the goal of moving the program into full development before year end. Our clinical collaborations with Cybrexa and Sairopa also advanced, including Cybrexa's recent clinical data update from the CBX-12 phase 1 program at the ASCO Annual Meeting in June."

Dr. Morrissey continued: "As we move through the second half of this year, we have much to look forward to, including the readout of the phase 3 CONTACT-02 study of cabozantinib and atezolizumab in patients with prostate cancer, the next overall survival analysis from the phase 3 COSMIC-313 study evaluating the triplet regimen of cabozantinib in combination with nivolumab and ipilimumab in renal cell carcinoma, and potential presentations of new data from our pipeline compounds. We also look forward to providing additional details around our discovery and development strategy and activities at an R&D Day planned for Tuesday, December 12th in New York City. As always, I want to thank the Exelixis team for their commitment, hard work and contributions during the second quarter as we advanced our mission to help cancer patients recover stronger and live longer."

Second Quarter 2023 Financial Results

Total revenues for the quarter ended June 30, 2023 were $469.8 million, as compared to $419.4 million for the comparable period in 2022.

Total revenues for the quarter ended June 30, 2023 included net product revenues of $409.6 million, as compared to $347.0 million for the comparable period in 2022. The increase in net product revenues was primarily due to an increase in sales volume and an increase in average net selling price.

Collaboration revenues, composed of license revenues and collaboration services revenues, were $60.2 million for the quarter ended June 30, 2023, as compared to $72.4 million for the comparable period in 2022. The decrease in collaboration revenues was primarily related to decreases in the recognition of milestone-related revenues and development cost reimbursements earned, which were partially offset by higher royalty revenues for the sales of cabozantinib outside of the U.S. generated by Exelixis' collaboration partners, Ipsen Pharma SAS and Takeda Pharmaceutical Company Limited.

Research and development expenses for the quarter ended June 30, 2023 were $232.6 million, as compared to $199.5 million for the comparable period in 2022. The increase in research and development expenses was primarily related to increases in manufacturing costs to support Exelixis' development candidates, personnel expenses, clinical trial costs and consulting and outside services, which were partially offset by lower license and other collaboration costs.

Selling, general and administrative expenses for the quarter ended June 30, 2023 were $141.7 million, as compared to $122.8 million for the comparable period in 2022. The increase in selling, general and administrative expenses was primarily related to increases in personnel expenses and legal and advisory fees related to the recent proxy contest.

Provision for income taxes for the quarter ended June 30, 2023 was $19.2 million, as compared to $17.8 million for the comparable period in 2022, primarily due to an increase in pre-tax income.

GAAP net income for the quarter ended June 30, 2023 was $81.2 million, or $0.25 per share, basic and diluted, as compared to GAAP net income of $70.7 million, or $0.22 per share, basic and diluted, for the comparable period in 2022.

Non-GAAP net income for the quarter ended June 30, 2023 was $100.3 million, or $0.31 per share, basic and diluted, as compared to non-GAAP net income of $89.7 million, or $0.28 per share, basic and diluted, for the comparable period in 2022.

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.

2023 Financial Guidance

Exelixis is maintaining the previously provided financial guidance for fiscal year 2023:

Total revenues	$1.775 billion - $1.875 billion
Net product revenues	$1.575 billion - $1.675 billion
Cost of goods sold	4.0% - 5.0% of net product revenues
Research and development expenses [(1)]	$1,000 million - $1,050 million
Selling, general and administrative expenses [(2)]	$475 million - $525 million
Effective tax rate	20% - 22%

(1) Includes $45 million of non-cash stock-based compensation expense.

(2) Includes $55 million of non-cash stock-based compensation expense.

Cabozantinib and Pipeline Highlights

Cabozantinib Franchise Net Product Revenues and Royalties. Net product revenues generated by the cabozantinib franchise in the U.S. were $409.6 million during the second quarter of 2023, with net product revenues of $403.3 million from CABOMETYX® (cabozantinib) and $6.4 million from COMETRIQ® (cabozantinib). Based upon cabozantinib-related net product revenues generated by Exelixis' collaboration partners during the quarter ended June 30, 2023, Exelixis earned $37.4 million in royalty revenues.

Cabozantinib and Pipeline Presentations at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting. In June, cabozantinib was the subject of 22 presentations at this year's ASCO Annual Meeting, which was held from June 2-6 in Chicago. Notable presentations included three-year quality-of-life follow-up data from CheckMate -9ER and detailed results from the CONTACT-03 phase 3 trial evaluating the combination of cabozantinib and atezolizumab vs. cabozantinib alone in metastatic RCC patients who have progressed following treatment with an immune checkpoint inhibitor therapy. Presentations featuring Exelixis pipeline compounds included updated phase 1 clinical data from the CBX-12 program in collaboration with Cybrexa, as well as an overview of the phase 3 STELLAR-303 study design evaluating zanzalintinib in combination with atezolizumab in patients with previously treated metastatic colorectal cancer.

Corporate Highlights

Settlement of CABOMETYX Patent Litigation with Teva Pharmaceuticals. In July, Exelixis announced that it entered into a Settlement and License Agreement (Agreement) with Teva Pharmaceuticals Development, Inc. and Teva Pharmaceuticals USA, Inc. (collectively "Teva"). This settlement resolves patent litigation brought by Exelixis in response to Teva's Abbreviated New Drug Application seeking approval to market a generic version of CABOMETYX prior to the expiration of the applicable patents. Pursuant to the terms of the Agreement, Exelixis will grant Teva a license to market its generic version of CABOMETYX in the U.S. beginning on January 1, 2031, if approved by the U.S. Food and Drug Administration and subject to conditions and exceptions common to agreements of this type. Additionally, in accordance with the Agreement, the parties will terminate all ongoing Hatch-Waxman litigation between Exelixis and Teva regarding CABOMETYX patents pending in the U.S. District Court for the District of Delaware.

Share Repurchase Program. As of June 30, Exelixis has repurchased $127.0 million of the company's common stock, at an average price of $19.22 per share. In March, Exelixis announced that the company's Board of Directors authorized the repurchase of up to $550 million of the company's common stock before the end of 2023. Share repurchases under the program may be made from time to time through a variety of methods, which may include open market purchases, in block trades, accelerated share repurchase transactions, exchange transactions, or any combination of such methods. The timing and amount of any share repurchases under the share repurchase program will be based on a variety of factors, including ongoing assessments of the capital needs of the business, alternative investment opportunities, the market price of Exelixis' common stock and general market conditions.

Exelixis Board of Directors Refreshment Plan. In May, upon the conclusion of its 2023 Annual Meeting of Stockholders, Exelixis announced the election of three new members to its Board of Directors, Mr. Thomas Heyman, Mr. Robert Oliver, Jr. and Mr. David Johnson, following the departure of prior board members Mr. Carl Feldbaum, Dr. Vincent Marchesi and Dr. Lance Willsey. Exelixis thanks Mr. Feldbaum and Drs. Marchesi and Willsey for their commitment and contributions to Exelixis during their tenure, and looks forward to working collaboratively with Messrs. Heyman, Oliver and Johnson to advance the company's mission to help patients recover stronger and live longer, and generate sustainable, long-term value for shareholders.

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 1, 2022 are indicated as being as of and for the periods ended June 30, 2022.

Conference Call and Webcast

Exelixis management will discuss the company's financial results for the second quarter of 2023 and provide a general business update during a conference call beginning at 5:00 p.m. ET / 2:00 p.m. PT today, Tuesday, August 1, 2023.

To access the conference call, please register using this link. Upon registration, a dial-in number and unique PIN will be provided to join the call. To access the live webcast link, log onto www.exelixis.com and proceed to the Event Calendar page under the Investors & News 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. A webcast replay of the conference call will also be archived on www.exelixis.com for one year.

About Exelixis

Exelixis is a globally ambitious oncology company innovating next-generation medicines and regimens at the forefront of cancer care. Powered by bi-coastal centers of discovery and development excellence, we are rapidly evolving our product portfolio to target an expanding range of tumor types and indications with our clinically differentiated pipeline of small molecules, antibody-drug conjugates and other biotherapeutics. This comprehensive approach harnesses decades of robust investment in our science and partnerships to advance our investigational programs and extend the impact of our flagship commercial product, CABOMETYX® (cabozantinib). Exelixis

is driven by a bold scientific pursuit to create transformational treatments that give more patients hope for the future. For information about the company and its mission to help cancer patients recover stronger and live longer, visit www.exelixis.com, follow @ExelixisInc on Twitter, like Exelixis, Inc. on Facebook and follow Exelixis on LinkedIn.

Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to: Exelixis' research and development expectations for 2023, including initiating additional pivotal trials for zanzalintinib, moving the XB002 program into full development before year end, readouts from the phase 3 CONTACT-02 and COSMIC-313 studies, and potential presentations of new data from its pipeline compounds; Exelixis' plans to provide additional details around its discovery and development strategy at an R&D Day in December 2023; Exelixis' 2023 financial guidance; Exelixis' and Teva's obligations under the Agreement and Exelixis' expectation that in accordance with the Agreement, Exelixis and Teva will terminate all ongoing Hatch-Waxman litigation regarding CABOMETYX patents; Exelixis' plan to repurchase up to $550 million of its common stock before the end of 2023; Exelixis' Board of Directors refreshment plan as part of its mission to help patients recover stronger and live longer, and generate sustainable, long-term value for shareholders; and Exelixis' scientific pursuit to create transformational treatments that give more patients hope for the future. 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 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, zanzalintinib 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 and other Exelixis product candidates; 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 9, 2023 and Annual Report on Form 10-K filed with the SEC on February 7, 2023, 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, 2023. 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenues:				
Net product revenues	$ 409,646	$ 347,044	$ 773,046	$ 657,342
License revenues	52,747	57,526	91,039	89,593
Collaboration services revenues	7,455	14,857	14,551	28,472
Total revenues	469,848	419,427	878,636	775,407
Operating expenses:				
Cost of goods sold	17,705	13,481	32,020	26,684
Research and development	232,570	199,481	466,816	356,152
Selling, general and administrative	141,723	122,759	273,120	225,622
Total operating expenses	391,998	335,721	771,956	608,458
Income from operations	77,850	83,706	106,680	166,949
Interest income	22,541	4,757	42,043	6,579
Other income (expense), net	(5)	45	(59)	209
Income before income taxes	100,386	88,508	148,664	173,737
Provision for income taxes	19,208	17,836	27,458	34,492
Net income	$ 81,178	$ 70,672	$ 121,206	$ 139,245
Net income per share:				
Basic	$ 0.25	$ 0.22	$ 0.37	$ 0.43
Diluted	$ 0.25	$ 0.22	$ 0.37	$ 0.43
Weighted-average common shares outstanding:				
Basic	324,205	321,117	324,312	320,349
Diluted	327,305	324,904	326,792	324,096

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,	
	2023	2022	2023	2022
GAAP net income	$ 81,178	$ 70,672	$ 121,206	$ 139,245
Adjustments:				
Stock-based compensation - research and development expenses [(1)]	9,589	9,549	12,841	18,448

Stock-based compensation - selling, general and administrative expenses [1]	15,311	15,073	28,720	25,933
Income tax effect of the above adjustments	(5,781)	(5,569)	(9,642)	(10,008)
Non-GAAP net income	$ 100,297	$ 89,725	$ 153,125	$ 173,618
GAAP net income per share:				
Basic	$ 0.25	$ 0.22	$ 0.37	$ 0.43
Diluted	$ 0.25	$ 0.22	$ 0.37	$ 0.43
Non-GAAP net income per share:				
Basic	$ 0.31	$ 0.28	$ 0.47	$ 0.54
Diluted	$ 0.31	$ 0.28	$ 0.47	$ 0.54
Weighted-average common shares outstanding:				
Basic	324,205	321,117	324,312	320,349
Diluted	327,305	324,904	326,792	324,096

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(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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