



Exelixis Announces Second Quarter 2022 Financial Results and Provides Corporate Update

August 9, 2022

**- Total Revenues of \$419.4 million, Cabozantinib Franchise Revenues of \$347.0 million -
- GAAP Diluted EPS of \$0.22, Non-GAAP Diluted EPS of \$0.28 -
- Conference Call and Webcast Today at 5:00 PM Eastern Time -**

ALAMEDA, Calif.--(BUSINESS WIRE)--Aug. 9, 2022-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the second quarter of 2022 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 2022, Exelixis continued to execute across each of the core components of our business, highlighted in particular by our commercial and pipeline activities," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer, Exelixis. "The team drove strong commercial performance for CABOMETYX[®] (cabozantinib), resulting in a 22 percent growth in cabozantinib franchise net product revenues year-over-year. In addition, we achieved key cabozantinib milestones, including generating positive data for the progression-free survival primary endpoint of our COSMIC-313 clinical trial and supporting Ipsen as it successfully pursued its CABOMETYX label expansion for a differentiated thyroid cancer indication in the European Union and Canada."

Dr. Morrissey continued: "Exelixis also made significant pipeline advancements during and after the close of the quarter, initiating STELLAR-303, our first phase 3 pivotal study for XL092, as well as the first-in-human phase 1 study for XL114 in non-Hodgkin's lymphoma. Additionally, we signed new business development agreements with Biolnvent and Ryvu Therapeutics to further expand our biologics capabilities and portfolio of biotherapeutics candidates. Moving into the second half of this year, we have much to look forward to, including the potential to further augment the CABOMETYX label through upcoming clinical data readouts expected from the CONTACT-01 and CONTACT-03 pivotal studies in non-small cell lung cancer and renal cell carcinoma, respectively, as well as anticipated clinical updates from our XL092, XB002 and XL102 pipeline programs. I want to thank the Exelixis team for their continued hard work and dedication during the second quarter as we continue to advance our mission on behalf of the patients we serve."

Second Quarter 2022 Financial Results

Total revenues for the quarter ended June 30, 2022 were \$419.4 million, compared to \$385.2 million for the comparable period in 2021.

Total revenues for the quarter ended June 30, 2022 included net product revenues of \$347.0 million, compared to \$284.2 million for the comparable period in 2021. The increase in net product revenues was primarily due to an increase in sales volume, which was partially offset by increases in discounts and allowances, primarily from higher utilization in the 340B Drug Pricing Program.

Collaboration revenues, composed of license revenues and collaboration services revenues, were \$72.4 million for the quarter ended June 30, 2022, compared to \$100.9 million for the comparable period in 2021. The decrease in collaboration revenues was primarily related to a decrease in development cost reimbursements earned, which was partially offset by an increase in the recognition of milestone-related revenues, and higher royalty revenues for the sales of cabozantinib outside of the U.S. generated by Exelixis' collaboration partners, Ipsen Pharma SAS (Ipsen) and Takeda Pharmaceutical Company Limited (Takeda).

Research and development expenses for the quarter ended June 30, 2022 were \$199.5 million, compared to \$148.8 million for the comparable period in 2021. The increases in research and development expenses were primarily related to increases in personnel expenses, clinical trial costs, license and other collaboration costs, and consulting and outside services expenses, which were partially offset by a decrease in stock-based compensation expense.

Selling, general and administrative expenses for the quarter ended June 30, 2022 were \$122.8 million, compared to \$98.5 million for the comparable period in 2021. The increases in selling, general and administrative expenses were primarily related to increases in personnel expenses, marketing costs, business technology initiatives and legal costs.

Provision for income taxes for the quarter ended June 30, 2022 was \$17.8 million, compared to \$28.8 million for the comparable period in 2021, primarily due to a decrease in pre-tax income.

GAAP net income for the quarter ended June 30, 2022 was \$70.7 million, or \$0.22 per share, basic and diluted, compared to GAAP net income of \$96.1 million, or \$0.31 per share, basic and \$0.30 per share, diluted, for the comparable period in 2021.

Non-GAAP net income for the quarter ended June 30, 2022 was \$89.7 million, or \$0.28 per share, basic and diluted, compared to non-GAAP net income of \$117.9 million, or \$0.38 per share, basic and \$0.37 per share, diluted, for the comparable period in 2021.

Cash, cash equivalents, restricted cash equivalents and investments were \$2.0 billion at June 30, 2022, compared to \$1.9 billion at December 31, 2021.

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.

2022 Financial Guidance

Exelixis is maintaining the following previously provided financial guidance for fiscal year 2022:

Total revenues	\$1.525 billion - \$1.625 billion
Net product revenues	\$1.325 billion - \$1.425 billion
Cost of goods sold	5% - 6% of net product revenues
Research and development expenses ⁽¹⁾	\$725 million - \$775 million
Selling, general and administrative expenses ⁽²⁾	\$400 million - \$450 million
Effective tax rate	20% - 22%

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

(2) Includes \$50 million of non-cash stock-based compensation expense.

Cabozantinib Highlights

Cabozantinib Franchise Net Product Revenues and Royalties. Net product revenues generated by the cabozantinib franchise in the U.S. were \$347.0 million during the second quarter of 2022, up 12% over the prior quarter, comprised of net product revenues of \$339.2 million from CABOMETYX and \$7.9 million from COMETRIQ[®] (cabozantinib). In the second quarter of 2022, global cabozantinib franchise net product revenues generated by Exelixis and its partners were almost \$500 million. Exelixis earned \$30.2 million in royalty revenues during the quarter ended June 30, 2022, pursuant to collaboration agreements with its partners, Ipsen and Takeda.

Exelixis' Partner Ipsen Receives European Commission (EC) and Health Canada Approvals for CABOMETYX for Patients with Previously Treated Radioactive Iodine (RAI)-Refractory Differentiated Thyroid Cancer (DTC). In May, Exelixis announced its partner Ipsen received approval from the EC for CABOMETYX as a monotherapy for the treatment of adult patients with locally advanced or metastatic DTC, refractory or not eligible to RAI who have progressed during or after prior systemic therapy. This approval allows for the marketing of CABOMETYX in this indication in all 27 member states of the European Union, Norway, Liechtenstein and Iceland. Similarly, in late April 2022, Ipsen received approval from Health Canada to market CABOMETYX for a similar DTC indication in Canada. As a result of these approvals, Exelixis was eligible to receive \$27.0 million in milestone payments from Ipsen, of which \$25.7 million was recognized in license revenues and collaboration services revenues in the second quarter of 2022. Both approvals were based on the positive results of the phase 3 COSMIC-311 pivotal trial.

Cabozantinib Data Presentations at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting. In June, cabozantinib was the subject of 13 presentations at this year's ASCO Annual Meeting, held from June 3-7 in Chicago. Notable presentations included results from: cohorts 7 and 20 in non-small cell lung cancer; cohorts 3, 4 and 5 in urothelial carcinoma from the ongoing COSMIC-021 study evaluating cabozantinib in combination with atezolizumab across multiple tumor types; and a phase 2 investigator-sponsored trial from the Emory Winship Cancer Institute evaluating the combination of cabozantinib and pembrolizumab in recurrent metastatic head and neck squamous cell carcinoma.

Announcement of Top-line Results from the COSMIC-313 Phase 3 Pivotal Trial Evaluating Cabozantinib in Combination with Nivolumab and Ipilimumab in Previously Untreated Advanced Renal Cell Carcinoma (RCC). In July, Exelixis announced that COSMIC-313 met its primary endpoint, demonstrating significant improvement in progression-free survival (PFS) at the primary analysis. At a prespecified interim analysis for the secondary endpoint of overall survival (OS), the combination of cabozantinib, nivolumab and ipilimumab versus the combination of nivolumab and ipilimumab did not demonstrate a significant benefit. Therefore, the trial will continue to the next analysis of OS. COSMIC-313 is an ongoing phase 3 pivotal trial evaluating the combination of cabozantinib, nivolumab and ipilimumab versus the combination of nivolumab and ipilimumab in patients with previously untreated advanced intermediate- or poor-risk RCC. Exelixis intends to discuss the results with the U.S. Food & Drug Administration (FDA) to determine next steps toward a potential regulatory submission for the combination regimen for patients with previously untreated advanced intermediate- or poor-risk RCC. Detailed findings will be presented at a future medical meeting.

Pipeline Highlights

Initiation of First-In-Human Phase 1 Trial Evaluating XL114 Monotherapy in Patients with Non-Hodgkin's Lymphoma (NHL). In April, Exelixis announced the initiation of the dose-escalation stage of the first-in-human phase 1 trial of XL114, a novel anti-cancer compound that inhibits the CARD11-BCL10-MALT1 complex, as a monotherapy in patients with NHL who have received prior standard therapies. The objectives of the study are to determine the recommended dose and/or the maximum tolerated dose of XL114 and to evaluate the safety and preliminary efficacy of XL114 in patients with NHL. The dose-escalation stage will determine the recommended dose of XL114 in patients with advanced B- and T-cell NHL. In the cohort-expansion stage, the safety and preliminary efficacy of XL114 will be further evaluated in various B-cell NHL-specific expansion cohorts. The primary endpoint of the expansion stage will be objective response rate (ORR) based on lymphoma-specific response criteria as assessed by the investigator.

Initiation of the STELLAR-303 Phase 3 Pivotal Trial Evaluating XL092 in Patients with Metastatic Colorectal Cancer (CRC). In June, Exelixis

announced the initiation of STELLAR-303, a phase 3 pivotal trial evaluating XL092 in combination with atezolizumab versus regorafenib in patients with metastatic CRC that is not microsatellite instability-high or mismatch repair-deficient, who have progressed after or are intolerant to the standard of care therapy. STELLAR-303 is a global, multicenter, randomized phase 3 open-label study that will enroll approximately 600 patients with documented RAS status. The primary objective of the study is to evaluate the efficacy of the combination in patients with RAS wild-type disease, and outcomes in patients with RAS-mutated disease will also be evaluated. The primary endpoint is OS, and secondary endpoints include PFS, ORR and duration of response per Response Evaluation Criteria in Solid Tumors version 1.1 as assessed by the investigator. XL092 is Exelixis' next-generation tyrosine kinase inhibitor in development for multiple advanced tumor types.

Corporate Updates

Exclusive Option and License Agreement with BioInvent International AB (BioInvent) to Develop Novel Antibody-Based Oncology Therapies. In June, Exelixis and BioInvent entered into an option and license agreement focused on the identification and development of novel antibodies for use as oncology therapeutics. The collaboration is intended to expand Exelixis' portfolio of antibody-based therapies. Target and antibody discovery will be performed using BioInvent's proprietary n-CoDeR[®] antibody library and patient-centric F.I.R.S.T[™] screening platform, which together allow for parallel target and antibody discovery. Under the terms of the agreement, Exelixis paid BioInvent an upfront fee of \$25.0 million in exchange for rights to select three targets identified using BioInvent's proprietary F.I.R.S.T platform and n-CoDeR library, and will have the right to exercise an option to in-license any of the target programs upon identification of a development candidate directed to that target. Upon option exercise, Exelixis will assume responsibility for all future development and commercialization activities for the development candidate, including potential antibody-drug conjugate (ADC) and bispecific antibody engineering activities.

Exclusive License Agreement with Ryvu Therapeutics S.A. (Ryvu) to Develop Novel STING Agonist-Based Targeted Cancer Therapies. In July, Exelixis and Ryvu announced an exclusive license agreement focused on the development of novel targeted therapies utilizing Ryvu's STING (STimulator of INterferon Genes) technology. The collaboration is intended to expand Exelixis' portfolio of biotherapeutics by combining its tumor-specific targeting approaches with Ryvu's proprietary small molecule STING agonists and STING biology know-how. Under the terms of the agreement, Exelixis is obligated to pay Ryvu an upfront fee of \$3.0 million in exchange for certain rights to Ryvu's STING agonist small molecules, which Exelixis will seek to incorporate into targeted therapies such as ADCs. Exelixis will lead all research activities and, upon selection of each development candidate, will be responsible for all development and commercialization activities. Ryvu will provide expert guidance and know-how during the early research phase of the partnership.

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, and July 2, 2021, are indicated as being as of and for the periods ended June 30, 2022, and June 30, 2021, respectively.

Conference Call and Webcast

Exelixis management will discuss the company's financial results for the second quarter of 2022 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 9, 2022.

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 [888-338-9509](tel:888-338-9509) (domestic) or [412-902-4281](tel:412-902-4281) (international) and ask to be joined into the Exelixis conference call to participate by phone.

A telephone replay will be available until 8:00 p.m. ET on Thursday, August 11, 2022. Access numbers for the telephone replay are: [877-344-7529](tel:877-344-7529) (domestic) and [412-317-0088](tel:412-317-0088) (international); the passcode is 8698613. 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 commercially available 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 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.](https://www.facebook.com/ExelixisInc) on Facebook.

Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to: the potential for Exelixis to further augment the CABOMETYX label through upcoming clinical data readouts from the CONTACT-01 and CONTACT-03 pivotal studies, which are expected during the second half of 2022; Exelixis' expectation for clinical updates from its XL092, XB002 and XL102 pipeline programs during the second half of 2022; Exelixis' 2022 financial guidance; Exelixis' plans to discuss the COSMIC-313 results with the FDA to determine next steps toward a potential regulatory submission for cabozantinib in combination with nivolumab and ipilimumab for patients with previously untreated advanced intermediate- or poor-risk RCC; Exelixis' immediate and future financial and other obligations under its agreements with BioInvent and Ryvu; 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 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 and other Exelixis products; 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, including as a result of the COVID-19 pandemic and other global events; 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 10, 2022, 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 9, 2022. 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.

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EXELIXIS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF INCOME

(in thousands, except per share amounts)

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenues:				
Net product revenues	\$ 347,044	\$ 284,248	\$ 657,342	\$ 511,460
License revenues	57,526	39,640	89,593	67,168
Collaboration services revenues	14,857	61,289	28,472	76,779
Total revenues	<u>419,427</u>	<u>385,177</u>	<u>775,407</u>	<u>655,407</u>
Operating expenses:				
Cost of goods sold	13,481	14,884	26,684	28,082
Research and development	199,481	148,790	356,152	308,078
Selling, general and administrative	122,759	98,495	225,622	200,846
Total operating expenses	<u>335,721</u>	<u>262,169</u>	<u>608,458</u>	<u>537,006</u>
Income from operations	83,706	123,008	166,949	118,401
Interest income	4,757	1,891	6,579	4,573
Other income (expense), net	45	(11)	209	(101)
Income before income taxes	88,508	124,888	173,737	122,873
Provision for income taxes	17,836	28,796	34,492	25,180
Net income	<u>\$ 70,672</u>	<u>\$ 96,092</u>	<u>\$ 139,245</u>	<u>\$ 97,693</u>
Net income per share:				
Basic	\$ 0.22	\$ 0.31	\$ 0.43	\$ 0.31
Diluted	\$ 0.22	\$ 0.30	\$ 0.43	\$ 0.30
Weighted-average common shares outstanding:				
Basic	321,117	314,117	320,349	313,295
Diluted	324,904	322,941	324,096	322,114

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,	
	2022	2021	2022	2021
GAAP net income	\$ 70,672	\$ 96,092	\$ 139,245	\$ 97,693
Adjustments:				

Stock-based compensation - research and development expenses ⁽¹⁾	9,549	13,667	18,448	26,063
Stock-based compensation - selling, general and administrative expenses ⁽¹⁾	15,073	14,368	25,933	36,625
Income tax effect of the above adjustments	(5,569)	(6,235)	(10,008)	(14,024)
Non-GAAP net income	<u>\$ 89,725</u>	<u>\$ 117,892</u>	<u>\$ 173,618</u>	<u>\$ 146,357</u>
GAAP net income per share:				
Basic	\$ 0.22	\$ 0.31	\$ 0.43	\$ 0.31
Diluted	\$ 0.22	\$ 0.30	\$ 0.43	\$ 0.30
Non-GAAP net income per share:				
Basic	\$ 0.28	\$ 0.38	\$ 0.54	\$ 0.47
Diluted	\$ 0.28	\$ 0.37	\$ 0.54	\$ 0.45
Weighted-average common shares outstanding:				
Basic	321,117	314,117	320,349	313,295
Diluted	324,904	322,941	324,096	322,114

⁽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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