Exelixis Announces Third Quarter 2022 Financial Results and Provides Corporate Update

November 1, 2022

– Total Revenues of $411.7 million, Cabozantinib Franchise Revenues of $366.5 million –
– GAAP Diluted EPS of $0.23, Non-GAAP Diluted EPS of $0.31 –
– Conference Call and Webcast Today at 5:00 PM Eastern Time –

ALAMEDA, Calif.--(BUSINESS WIRE)--Nov. 1, 2022-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the third quarter of 2022 and provided an update on progress toward achieving key corporate objectives, as well as commercial, clinical and pipeline development milestones.

"Exelixis focused its efforts toward the progress and expansion of our clinical and early-stage pipeline during the third quarter of 2022, fueled by the growing revenues from our cabozantinib franchise," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer, Exelixis. "The team continued to drive strong commercial performance for cabozantinib, resulting in 39 percent year-over-year net product revenue growth for our flagship franchise. The team was also highly active on the business development front evaluating various opportunities and executing on multiple deals, including new option deals with Cybrexa and Sairopa announced today, which highlight our strategic efforts to access clinical- or near-clinical-stage assets that have the potential to be first- or best-in-class medicines and may provide differentiated benefits to patients with cancer."

Dr. Morrissey continued: "In addition, we achieved key clinical milestones, including presenting detailed results from our pivotal COSMIC-313 clinical trial and dose-escalation data from the phase 1b STELLAR-001 trial of XL092 at the ESMO 2022 Congress, as well as sharing the first clinical update from our phase 1 XB002 tissue factor ADC program at the 34th ENA Symposium in October. I'd like to thank the entire Exelixis team for their continued hard work and dedication in the third quarter as we made significant progress in commitment of the patients we serve."

Third Quarter 2022 Financial Results

Total revenues for the quarter ended September 30, 2022 were $411.7 million, as compared to $328.4 million for the comparable period in 2021.

Total revenues for the quarter ended September 30, 2022 included net product revenues of $366.5 million, as compared to $263.1 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 an increase in chargebacks related to the 340B Drug Pricing Program.

Collaboration revenues, composed of license revenues and collaboration services revenues, were $45.3 million for the quarter ended September 30, 2022, as compared to $65.3 million for the comparable period in 2021. The decrease in collaboration revenues was primarily related to decreases in the recognition of milestone-related revenues and development cost reimbursements earned, which was partially offset by 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 September 30, 2022 were $198.8 million, as compared to $163.4 million for the comparable period in 2021. The increase in research and development expenses were primarily related to increases in clinical trial costs, personnel expenses, consulting and outside services expenses, and stock-based compensation expense, which were partially offset by a decrease in other development costs.

Selling, general and administrative expenses for the quarter ended September 30, 2022 were $115.0 million, as compared to $101.6 million for the comparable period in 2021. The increase in selling, general and administrative expenses was primarily related to increases in personnel expenses, business technology initiatives, and rent and utilities expenses.

Provision for income taxes for the quarter ended September 30, 2022 was $18.8 million, as compared to $15.1 million for the comparable period in 2021, primarily due to an increase in pre-tax income.

GAAP net income for the quarter ended September 30, 2022 was $73.2 million, or $0.23 per share, basic and diluted, as compared to GAAP net income of $38.2 million, or $0.12 per share, basic and diluted, for the comparable period in 2021.

Non-GAAP net income for the quarter ended September 30, 2022 was $102.0 million, or $0.32 per share, basic and $0.31 per share, diluted, as compared to non-GAAP net income of $64.5 million, or $0.20 per share, basic and diluted, for the comparable period in 2021.

Cash, cash equivalents, restricted cash equivalents and investments were $2.1 billion at September 30, 2022, as 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 providing the following updated financial guidance for fiscal year 2022:

Total revenues	$1.575 billion - $1.600 billion
Net product revenues	$1.375 billion - $1.400 billion
Cost of goods sold	~5% of net product revenues
Research and development expenses (1)	$875 million - $900 million
Selling, general and administrative expenses (2)	$450 million - $475 million
Effective tax rate	20% - 22%

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

(2) Includes $60 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 $366.5 million during the third quarter of 2022, up 6% over the prior quarter, comprised of net product revenues of $361.4 million from CABOMETYX® (cabozantinib) and $5.1 million from COMETRIQ® (cabozantinib). In the third quarter of 2022, global cabozantinib franchise net product revenues generated by Exelixis and its partners were almost $500 million. Exelixis earned $30.3 million in royalty revenues during the quarter ended September 30, 2022, pursuant to collaboration agreements with its partners, Ipsen and Takeda.

Detailed Results from Phase 3 COSMIC-313 Pivotal Trial in Patients with Previously Untreated Advanced Renal Cell Carcinoma (RCC) Presented at the 2022 European Society for Medical Oncology (ESMO) Congress. In September, Exelixis presented detailed results from the pivotal phase 3 COSMIC-313 trial evaluating the triplet combination of cabozantinib, nivolumab and ipilimumab versus the combination of nivolumab and ipilimumab in patients with previously untreated advanced intermediate- or poor-risk RCC, at the 2022 ESMO Congress. The data included detailed results of the primary endpoint of progression-free survival (PFS) demonstrating a positive PFS benefit for the triplet combination of cabozantinib, nivolumab and ipilimumab compared to the combination of nivolumab and ipilimumab, as well as encouraging objective response rates in the PFS intent-to-treat population. The safety profile observed in the trial was reflective of the known safety profiles for each single agent as well as the combination regimens used in this study. Previously, in July, Exelixis announced that COSMIC-313 met its primary endpoint, demonstrating significant improvement in 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 did not demonstrate a significant benefit over the combination of nivolumab and ipilimumab. Therefore, the trial will continue to the next analysis of OS.

Pipeline Highlights

Presentation of Dose-Escalation Results from Phase 1b STELLAR-001 Trial Evaluating XL092 Monotherapy and in Combination with Atezolizumab in Patients with Advanced Solid Tumors at the 2022 ESMO Congress. In September, Exelixis presented results from the dose-escalation stage of STELLAR-001, an ongoing phase 1b trial evaluating XL092 as a single agent and in combination with atezolizumab in patients with locally advanced or metastatic solid tumors. The data showed that XL092 demonstrated preliminary clinical activity similar to that observed with cabozantinib in phase 1 across a range of solid tumors and dose levels, with a manageable safety profile. Of note, both single-agent XL092 and XL092 in combination with atezolizumab demonstrated encouraging efficacy and safety in a heavily pretreated patient population, including clear cell RCC patients previously treated with cabozantinib. Tumor reduction was seen in a majority of patients along with a high disease control rate. The maximum tolerated dose was determined to be 120 mg, and the recommended dose for the expansion stage is 100 mg for both single-agent XL092 and XL092 in combination with atezolizumab. The cohort-expansion stage of the study is currently ongoing and enrolling patients across multiple solid tumor types.

Expanded Clinical Trial Collaboration and Supply Agreement with Bristol-Myers Squibb (BMS) to Include Fixed-Dose Combination of Nivolumab and Relatlimab in Combination with XL092 in Phase 1b STELLAR-002 Trial. In October, Exelixis announced the expansion of its June 2021 Clinical Trial Collaboration and Supply Agreement with BMS to include the use of the fixed-dose combination of nivolumab and relatlimab in the ongoing phase 1b STELLAR-002 clinical trial, which is evaluating XL092 in combination with multiple immune checkpoint inhibitors in advanced solid tumors. Relatlimab is a lymphocyte activation gene-3 (LAG-3)-blocking antibody. LAG-3 is an inhibitory immune checkpoint expressed on the surface of T-cells. The STELLAR-002 trial is divided into two parts: a dose-escalation stage and a cohort-expansion stage. Enrollment and dosing in the dose-escalation portion of STELLAR-002 is ongoing. The dose-escalation stage will determine the recommended dose in patients with advanced solid tumors for each of the combination therapy regimens, including: XL092 and nivolumab; XL092, nivolumab and ipilimumab; and XL092 and the fixed-dose combination of nivolumab and relatlimab. The novel triplet combination of XL092 and the fixed-dose combination of nivolumab and relatlimab has the potential to be used in multiple expansion cohorts.

Presentation of Initial Dose-Escalation Results from the First-in-Human Phase 1 JEWEL-101 Trial Evaluating XB002 in Patients with Advanced Solid Tumors at the 34th EORTC-NCI-AACR (ENA) Symposium. In October, Exelixis presented promising initial results from the ongoing dose-escalation stage of JEWEL-101, a phase 1 study evaluating Exelixis' XB002 next-generation tissue factor targeting antibody-drug conjugate (ADC), at the 34th ENA Symposium. The data demonstrated that XB002 was well-tolerated across multiple dose levels, with no

dose-limiting toxicities observed as of the data cutoff. A pharmacokinetic analysis demonstrated that XB002 exposure increased more than or proportionately to dose increases. XB002 total antibody and intact ADC pharmacokinetics were similar, suggesting XB002 is stable after infusion. Consistent with this, levels of free circulating payload remained low at all dose levels. JEWEL-101 is enrolling patients with advanced solid tumors for which therapies are unavailable, ineffective or intolerable. The dose-escalation stage of the study is currently ongoing and will progress to the cohort-expansion stage once the recommended dose and/or maximum tolerated dose for XB002 have been determined. In the upcoming cohort-expansion stage, the efficacy of XB002 will be further evaluated as a single agent and in combination with nivolumab.

Corporate Updates

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 paid 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 period ended October 1, 2021, is indicated as being as of and for the period ended September 30, 2021.

Conference Call and Webcast

Exelixis management will discuss the company's financial results for the third 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, November 1, 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 (domestic) or 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, November 3, 2022. Access numbers for the telephone replay are: 877-344-7529 (domestic) and 412-317-0088 (international); the passcode is 6992264. 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. on Facebook.

Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to: Exelixis' belief that new business development deals further its strategy to access clinical- or near-clinical-stage assets that have the potential to be first- or best-in-class medicines and may provide differentiated benefits to patients with cancer; Exelixis' updated 2022 financial guidance; the potential for the triplet combination of XL092 and the fixed-dose combination of nivolumab and ipilimumab to be used in multiple expansion cohorts in the STELLAR-002 trial; Exelixis' immediate and future financial and other obligations under its agreement with 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, XL092 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 August 9, 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 November 1, 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenues:				
Net product revenues	$ 366,482	$ 263,117	$ 1,023,824	$ 774,577
License revenues	34,384	49,694	123,977	116,862
Collaboration services revenues	10,872	15,612	39,344	92,391
Total revenues	411,738	328,423	1,187,145	983,830
Operating expenses:				
Cost of goods sold	15,305	11,874	41,989	39,956
Research and development	198,837	163,370	554,989	471,448
Selling, general and administrative	114,983	101,558	340,605	302,404
Total operating expenses	329,125	276,802	937,583	813,808
Income from operations	82,613	51,621	249,562	170,022
Interest income	9,498	1,658	16,077	6,231
Other income (expense), net	(69)	(19)	140	(120)
Income before income taxes	92,042	53,260	265,779	176,133
Provision for income taxes	18,832	15,056	53,324	40,236
Net income	$ 73,210	$ 38,204	$ 212,455	$ 135,897
Net income per share:				
Basic	$ 0.23	$ 0.12	$ 0.66	$ 0.43
Diluted	$ 0.23	$ 0.12	$ 0.65	$ 0.42
Weighted-average common shares outstanding:				
Basic	322,148	315,380	320,949	313,990
Diluted	325,066	322,022	324,420	322,084

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
GAAP net income	$ 73,210	$ 38,204	$ 212,455	$ 135,897
Adjustments:				
Stock-based compensation – research and development expenses [(1)]	16,438	11,487	34,886	37,550
Stock-based compensation – selling, general and administrative expenses [(1)]	20,899	22,479	46,832	59,104
Income tax effect of the above adjustments	(8,506)	(7,631)	(18,514)	(21,655)
Non-GAAP net income	$ 102,041	$ 64,539	$ 275,659	$ 210,896
GAAP net income per share:				
Basic	$ 0.23	$ 0.12	$ 0.66	$ 0.43
Diluted	$ 0.23	$ 0.12	$ 0.65	$ 0.42
Non-GAAP net income per share:				
Basic	$ 0.32	$ 0.20	$ 0.86	$ 0.67

Diluted	$ 0.31	$ 0.20	$ 0.85	$ 0.65
Weighted-average common shares outstanding:				
Basic	322,148	315,380	320,949	313,990
Diluted	325,066	322,022	324,420	322,084

(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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Chris Senner
Chief Financial Officer
Exelixis, Inc.
650-837-7240
csenner@exelixis.com

Susan Hubbard
EVP, Public Affairs & Investor Relations
Exelixis, Inc.
650-837-8194
shubbard@exelixis.com

Source: Exelixis, Inc.