Exelixis Announces First Quarter 2022 Financial Results and Provides Corporate Update

May 10, 2022

- Total Revenues of $356.0 million, Cabozantinib Franchise Revenues of $310.3 million -

- GAAP Diluted EPS of $0.21, Non-GAAP Diluted EPS of $0.26 -

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

ALAMEDA, Calif.--(BUSINESS WIRE)--May 10, 2022-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the first quarter of 2022 and provided an update on progress toward achieving key corporate objectives, as well as commercial, clinical and pipeline development milestones.

“Exelixis had a strong start to 2022 as we continued to gain momentum across all components of our business,” said Michael M. Morrissey, Ph.D., President and Chief Executive Officer, Exelixis. “We are pleased with the growth of the cabozantinib franchise, driven by increased demand for CABOMETYX® (cabozantinib) in combination with OPDIVO® (nivolumab) in the first-line renal cell carcinoma setting, as well as by the initial impact of the drug’s most recent U.S. label expansion into differentiated thyroid cancer. As we strive to help as many eligible cancer patients as possible benefit from cabozantinib, we look forward to top-line results from the COSMIC-313, CONTACT-01 and CONTACT-03 pivotal phase 3 clinical trials expected over the course of this year.”

Dr. Morrissey continued: “Cabozantinib franchise revenues fuel the growth of our expanding pipeline, which now comprises four differentiated clinical-stage programs. We are on track to initiate the pivotal trial series for XL092 beginning in the second quarter of 2022 with the first phase 3 trial, STELLAR-303, which will evaluate the compound in combination with atezolizumab in a form of colorectal cancer, and we expect to advance the ongoing phase 1 studies of XL092, XB002 and XL102, and to present initial data from these trials later this year. Additionally, in April we initiated the first-in-human phase 1 trial of XL114, our small molecule inhibitor of the CARD11-BCL10-MALT1 complex. As our pipeline advances, we are building out our infrastructure, both on our Alameda campus as well as in the Greater Philadelphia area through our Exelixis East expansion. I look forward to providing further updates on our progress throughout the year and want to thank the Exelixis team for their collective hard work and execution as we advance our mission to help cancer patients recover stronger and live longer.”

First Quarter 2022 Financial Results

Total revenues for the quarter ended March 31, 2022 were $356.0 million, compared to $270.2 million for the comparable period in 2021.

Total revenues for the quarter ended March 31, 2022 included net product revenues of $310.3 million, compared to $227.2 million for the comparable period in 2021. The increase in net product revenues was due to an increase in sales volume, primarily as a result of the growth in the number of units sold following the FDA’s approval of CABOMETYX in combination with OPDIVO as a first-line treatment of patients with advanced RCC in January 2021 and in part due to the longer duration of therapy for this combination. The increase in net product revenues was partially offset by increases in discounts and allowances, primarily from higher utilization by covered entities in the 340B Drug Pricing Program, an increase in Medicaid utilization and an increase in Exelixis’ co-pay assistance for commercially insured patients.

Collaboration revenues, composed of license revenues and collaboration services revenues, were $45.7 million for the quarter ended March 31, 2022, compared to $43.0 million for the comparable period in 2021. The increase in collaboration revenues was primarily related to 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), which was partially offset by a decrease in development cost reimbursements.

Research and development expenses for the quarter ended March 31, 2022 were $156.7 million, compared to $159.3 million for the comparable period in 2021. The decrease in research and development expenses was primarily related to decreases in license and other collaboration costs and stock-based compensation expense, which was partially offset by increases in personnel expenses.

Selling, general and administrative expenses for the quarter ended March 31, 2022 were $102.9 million, compared to $102.4 million for the comparable period in 2021. The increase in selling, general and administrative expenses was primarily related to increases in personnel expenses and marketing costs, which was partially offset by a decrease in stock-based compensation expense.

Provision for (benefit from) income taxes for the quarter ended March 31, 2022 was $16.7 million, compared to $(3.6) million for the comparable period in 2021, primarily due to the change in pre-tax income (loss).

GAAP net income for the quarter ended March 31, 2022 was $68.6 million, or $0.21 per share, basic and diluted, compared to GAAP net income of $1.6 million, or $0.01 per share, basic and $0.00 per share, diluted, for the comparable period in 2021.

Non-GAAP net income for the quarter ended March 31, 2022 was $83.9 million, or $0.26 per share, basic and diluted, compared to non-GAAP net income of $28.5 million, or $0.09 per share, basic and diluted, for the comparable period in 2021.

Cash, cash equivalents, restricted cash equivalents and investments were $2.0 billion at March 31, 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 $310.3 million during the first quarter of 2022, up 3% over the prior quarter, with net product revenues of $302.8 million from CABOMETYX and $7.5 million from COMETRIQ® (cabozantinib). Exelixis earned $27.0 million in royalty revenues during the quarter ended March 31, 2022, pursuant to collaboration agreements with its partners, Ipsen and Takeda.

Completion of Enrollment in CONTACT-03 Pivotal Trial of Cabozantinib in Combination with Atezolizumab in Previously Treated Metastatic Renal Cell Carcinoma (RCC). In January 2022, Exelixis announced that enrollment was complete for CONTACT-03, the global phase 3 pivotal trial evaluating cabozantinib in combination with atezolizumab versus cabozantinib alone in patients with locally advanced or metastatic clear cell or non-clear cell RCC who progressed during or following treatment with an immune checkpoint inhibitor (ICI). CONTACT-03 enrolled 523 patients who were randomized 1:1 to the experimental arm of cabozantinib in combination with atezolizumab and the control arm of cabozantinib alone. The primary endpoints of the trial are progression-free survival (PFS) per Response Evaluation Criteria in Solid Tumors v. 1.1 as assessed by independent radiology review and overall survival (OS). Secondary endpoints include PFS, objective response rate (ORR) and duration of response as assessed by study investigators. CONTACT-03 is sponsored by F. Hoffmann-La Roche Limited and co-funded by Exelixis. Interim data from the trial are anticipated in the second half of 2022.

Cabozantinib Data at the 2022 American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium (ASCO GI 2022). In January 2022, investigators presented encouraging data from two trials of cabozantinib in combination with ICIs for the treatment of advanced colorectal cancer (CRC) at ASCO GI 2022. The results reinforce Exelixis' decision to pursue clinical development of XL092, which pairs a target profile similar to cabozantinib with a potentially significantly improved safety profile, in advanced CRC through the STELLAR-303 global phase 3 pivotal trial expected to initiate in the second quarter of 2022.

Cabozantinib Data at the 2022 ASCO Genitourinary Cancers Symposium (ASCO GU 2022). In February 2022, cabozantinib was the subject of multiple data presentations at ASCO GU 2022. Notable presentations include two additional data sets from the phase 3 pivotal CheckMate -9ER study providing final OS analysis and organ-specific target lesion assessments with two-year follow-up, and updated health-related quality of life results.

Announcement of Final OS Results from Phase 3 COSMIC-312 Trial in Patients with Previously Untreated Advanced Hepatocellular Carcinoma (HCC). In March 2022, Exelixis announced results from the final analysis of the second primary endpoint of OS from the phase 3 COSMIC-312 trial, which evaluated cabozantinib in combination with atezolizumab versus sorafenib in patients with previously untreated advanced HCC. The final analysis showed neither improvement nor detriment in OS for cabozantinib in combination with atezolizumab versus sorafenib. Based on this outcome for OS and the rapidly evolving treatment landscape for previously untreated advanced HCC, Exelixis decided not to submit a supplemental New Drug Application to the U.S. FDA.

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 2022, 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. Both approvals were based on the positive results of the phase 3 COSMIC-311 pivotal trial.

Cabozantinib Data Presentations at the 2022 ASCO Annual Meeting. In June 2022, cabozantinib will be the subject of 13 presentations at this

year's ASCO Annual Meeting, being held from June 3-7 in Chicago. Notable presentations will include results from cohorts 7 and 20 in non-small cell lung cancer and 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.

Pipeline Highlights

Amendment of Option and License Agreement for XB002, an Antibody-Drug Conjugate (ADC) Targeting Tissue Factor (TF). In January 2022, Exelixis and Iconic Therapeutics, Inc. (Iconic) announced amended terms to their May 2019 exclusive option and license agreement for XB002, a next-generation TF-targeting ADC. Under the amended agreement, Exelixis acquired broad rights to use the anti-TF antibody incorporated into XB002 for any application, including conjugated to other payloads, as well as rights within oncology to a number of other anti-TF antibodies developed by Iconic, including for use in ADCs and multispecific biotherapeutics. Based on early clinical data supportive of a potentially differentiated and best-in-class profile, Exelixis intends to aggressively expand development of XB002, both as a monotherapy and in combination with ICIs and other targeted therapies, across a wide range of tumor types, including indications other than those currently addressed by commercially available TF-targeted therapies. Exelixis expects to provide clinical updates from the ongoing phase 1 study of XB002 in the second half of 2022.

Initiation of First-In-Human Phase 1 Trial Evaluating XL114 Monotherapy in Patients with Non-Hodgkin's Lymphoma (NHL). In April 2022, 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 ORR based on lymphoma-specific response criteria as assessed by the investigator. Exelixis in-licensed XL114 from Aurigene Discovery Technologies Limited under the companies' July 2019 collaboration, option and license agreement and assumed responsibility for the future clinical development, commercialization and global manufacturing of XL114.

Corporate Updates

Appointment of Vicki L. Goodman, M.D., as Executive Vice President, Product Development & Medical Affairs and Chief Medical Officer (CMO). In January 2022, Exelixis announced the appointment of Vicki L. Goodman, M.D., as Executive Vice President, Product Development & Medical Affairs and CMO. Dr. Goodman has more than 20 years of oncology experience as a drug development leader at global biopharmaceutical organizations, regulator and clinician. She joined from Merck & Co., where she served as Vice President, Clinical Research and Therapeutic Area Head, Late Stage Oncology. Dr. Goodman is based in the Greater Philadelphia area. As part of her role overseeing the company's product development operations, she is leading the buildout of a new Exelixis team that will expand the company's development activities on the East Coast. Exelixis' East Coast presence will complement the company's growing West Coast development team and enable the company to lay additional groundwork for potential future growth outside the U.S.

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 April 1, 2022, and April 2, 2021, are indicated as being as of and for the periods ended March 31, 2022, and March 31, 2021, respectively.

Conference Call and Webcast

Exelixis management will discuss the company's financial results for the first 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, May 10, 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 855-793-2457 (domestic) or 631-485-4921 (international) and provide the conference call passcode 6282616 to join by phone.

A telephone replay will be available until 8:00 p.m. ET on Thursday, May 12, 2022. Access numbers for the telephone replay are: 855-859-2056 (domestic) and 404-537-3406 (international); the passcode is 6282616. 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' expectations and anticipated timelines for top-line results from the COSMIC-313, CONTACT-01 and CONTACT-03 pivotal phase 3 clinical trials during 2022; Exelixis' plans to initiate the pivotal trial series for XL092 beginning in the second quarter of 2022 with STELLAR-303, as well as to advance the ongoing phase 1

studies of XL092, XB002 and XL102, and to present initial data from these trials later in 2022; Exelixis' 2022 financial guidance; Exelixis' planned cabozantinib presentations at the 2022 ASCO Annual Meeting; the potentially differentiated and best-in-class profile of XB002 and Exelixis' intention to aggressively expand development of XB002, both as a monotherapy and in combination with ICIs and other targeted therapies, into indications other than those currently addressed by commercially available TF-targeted therapies; Exelixis' clinical development plans for XL114; Exelixis' plans to expand its development activities on the East Coast and for potential future growth outside the U.S.; 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' Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on February 18, 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 May 10, 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 March 31,	
	2022	**2021**
Revenues:		
Net product revenues	$ 310,298	$ 227,212
License revenues	32,067	27,528
Collaboration services revenues	13,615	15,490
Total revenues	355,980	270,230
Operating expenses:		
Cost of goods sold	13,203	13,198
Research and development	156,671	159,288
Selling, general and administrative	102,863	102,351
Total operating expenses	272,737	274,837
Income (loss) from operations	83,243	(4,607)
Interest income	1,822	2,682
Other income (expense), net	164	(90)
Income (loss) before income taxes	85,229	(2,015)
Provision for (benefit from) income taxes	16,656	(3,616)
Net income	$ 68,573	$ 1,601
Net income per share:		
Basic	$ 0.21	$ 0.01
Diluted	$ 0.21	$ 0.00
Weighted-average common shares outstanding:		
Basic	319,582	312,473
Diluted	323,289	321,287

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

	Three Months Ended March 31,	
	2022	**2021**
GAAP net income	$ 68,573	$ 1,601
Adjustments:		
Stock-based compensation - research and development expenses [1]	8,899	12,396
Stock-based compensation - selling, general and administrative expenses [1]	10,860	22,257
Income tax effect of the above adjustments	(4,439)	(7,789)
Non-GAAP net income	$ 83,893	$ 28,465
GAAP net income per share:		
Basic	$ 0.21	$ 0.01
Diluted	$ 0.21	$ 0.00
Non-GAAP net income per share:		
Basic	$ 0.26	$ 0.09
Diluted	$ 0.26	$ 0.09
Weighted-average common shares outstanding:		
Basic	319,582	312,473
Diluted	323,289	321,287

[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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