Exelixis Announces First Quarter 2025 Financial Results and Provides Corporate Update

May 13, 2025

- Total Revenues of $555.4 million, Cabozantinib Franchise U.S. Net Product Revenues of $513.3 million -

- GAAP Diluted EPS of $0.55, Non-GAAP Diluted EPS of $0.62 -

- Increasing 2025 Full Year Net Product Revenues and Total Revenues Guidance by $100 million -

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

ALAMEDA, Calif.--(BUSINESS WIRE)--May 13, 2025-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the first quarter of 2025, provided an update on progress toward achieving key corporate objectives, and outlined its commercial, clinical and pipeline development milestones.

“Exelixis delivered outstanding financial performance in the first quarter of 2025, driven by accelerating growth in CABOMETYX ® demand, new patient starts and revenues,” said Michael M. Morrissey, Ph.D., President and Chief Executive Officer, Exelixis. “Based on the strong first quarter dynamics of CABOMETYX, we’re increasing our 2025 full year financial guidance for net product revenues and total revenues by $100 million. The Exelixis commercial team rapidly mobilized for the launch of CABOMETYX in advanced neuroendocrine tumors (NET) within hours of receiving U.S. regulatory approval in late March. We are very pleased with the initial reception and plan to provide further updates to our 2025 financial guidance as we build momentum on the NET launch and gain further clarity on additional revenue opportunities for 2025.”

Dr. Morrissey continued: “As we work toward our goal of becoming a multi-franchise oncology company, we look forward to important potential milestones for zanzalintinib in the second half of 2025, based on anticipated event rates. These include pivotal trial readouts from STELLAR-303 in colorectal cancer and STELLAR-304 in non-clear cell renal cell carcinoma, as well as data to drive a decision to move into the phase 3 portion of the STELLAR-305 trial in head and neck cancer. We also look forward to the initiation of the STELLAR-311 pivotal study in neuroendocrine tumors in the first half of the year, and Merck’s anticipated initiation of two pivotal studies evaluating zanzalintinib and belzutifan in renal cell carcinoma. Furthermore, we continue to provide insights on our earlier-stage pipeline, with preclinical data presented on multiple programs at the AACR Annual Meeting in April. I’m proud of the entire Exelixis team for our progress so far in 2025 and look forward to sharing additional updates throughout the year.”

First Quarter 2025 Financial Results

Total revenues for the quarter ended March 31, 2025 were $555.4 million, as compared to $425.2 million for the comparable period in 2024.

Total revenues for the quarter ended March 31, 2025 included net product revenues of $513.3 million, as compared to $378.5 million for the comparable period in 2024. 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 $42.2 million for the quarter ended March 31, 2025, as compared to $46.7 million for the comparable period in 2024. The decrease in collaboration revenues was primarily related to lower 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, and lower development cost reimbursements earned.

Research and development expenses for the quarter ended March 31, 2025 were $212.2 million, as compared to $227.7 million for the comparable period in 2024. The decrease in research and development expenses was primarily related to decreases in license and other collaboration costs and clinical trial costs, partially offset by increases in stock-based compensation and personnel expenses.

Selling, general and administrative expenses for the quarter ended March 31, 2025 were $137.2 million, as compared to $114.0 million for the comparable period in 2024. The increase in selling, general and administrative expenses was primarily related to increases in personnel expenses, corporate giving, and marketing expenses.

Provision for income taxes for the quarter ended March 31, 2025 was $46.1 million, as compared to $12.0 million for the comparable period in 2024.

GAAP net income for the quarter ended March 31, 2025 was $159.6 million, or $0.57 per share, basic and $0.55 per share, diluted, as compared to GAAP net income of $37.3 million, or $0.12 per share, basic and diluted, for the comparable period in 2024. GAAP net income per share for the quarter ended March 31, 2025 was favorably impacted by lower weighted-average common shares outstanding for the quarter ended March 31, 2025, as compared to the comparable period in 2024, as a result of the stock repurchase programs.

Non-GAAP net income for the quarter ended March 31, 2025 was $179.6 million, or $0.64 per share, basic and $0.62 per share, diluted, as compared to non-GAAP net income of $52.0 million, or $0.17 per share, basic and diluted, for the comparable period in 2024.

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, 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, 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.

2025 Financial Guidance

Exelixis is providing the following updated financial guidance for fiscal year 2025:

	Current Guidance (provided on May 13, 2025)	**Previous Guidance** (provided on January 12, 2025)
Total revenues	$2.25 billion - $2.35 billion	$2.15 billion - $2.25 billion
Net product revenues	$2.05 billion - $2.15 billion(1)	$1.95 billion - $2.05 billion(1)
Cost of goods sold	4% - 5% of net product revenues	4% - 5% of net product revenues
Research and development expenses	$925 million - $975 million(2)	$925 million - $975 million(4)
Selling, general and administrative expenses	$475 million - $525 million(3)	$475 million - $525 million(5)
Effective tax rate	21% - 23%	21% - 23%

(1) Exelixis' 2025 net product revenues guidance range includes the impact of a U.S. wholesale acquisition cost increase of 2.8% for CABOMETYX effective Jan. 1, 2025.

(2) Includes $50.0 million of non-cash stock-based compensation.

(3) Includes $80.0 million of non-cash stock-based compensation.

(4) Includes $40.0 million of non-cash stock-based compensation.

(5) Includes $60.0 million of non-cash stock-based compensation.

Cabozantinib and Pipeline Highlights

Cabozantinib Franchise Net Product Revenues and Royalties. Net product revenues generated by the cabozantinib franchise in the U.S. were $513.3 million during the first quarter of 2025, with net product revenues of $510.9 million from CABOMETYX (cabozantinib) and $2.4 million from COMETRIQ® (cabozantinib). Based upon cabozantinib-related net product revenues generated by Exelixis' collaboration partners during the quarter ended March 31, 2025, Exelixis earned $36.7 million in royalty revenues.

Received U.S. Food and Drug Administration (FDA) Approval of CABOMETYX for Patients with Previously Treated Advanced NET. In March, Exelixis announced that the U.S. FDA approved CABOMETYX for the treatment of 1) adult and pediatric patients 12 years of age and older with previously treated, unresectable, locally advanced or metastatic, well-differentiated pancreatic NET (pNET); and 2) adult and pediatric patients 12 years of age and older with previously treated, unresectable, locally advanced or metastatic, well-differentiated extra-pancreatic NET (epNET). These latest FDA approvals — adding to five previous approvals for CABOMETYX — are based on results from CABINET, a phase 3 pivotal trial evaluating CABOMETYX compared with placebo in two cohorts of patients with previously treated NET: advanced pNET and advanced epNET. CABOMETYX is now the first and only systemic treatment that is FDA approved for previously treated NET regardless of primary tumor site, grade, somatostatin receptor expression and functional status. NET are heterogeneous tumors that arise from the neuroendocrine cells of the digestive tract and other organs, such as the lung and pancreas.

Announced Final Five-Year Follow-up Results from CheckMate -9ER Trial Evaluating CABOMETYX in Combination with Nivolumab (Opdivo®) in Patients with Advanced Kidney Cancer at the American Society of Clinical Oncology 2025 Genitourinary Cancers Symposium (ASCO GU 2025). In February, final results from the phase 3 CheckMate -9ER pivotal trial evaluating CABOMETYX in combination with nivolumab versus sunitinib for patients with previously untreated advanced renal cell carcinoma (RCC) were presented at ASCO GU 2025. After more than five years of follow-up, the findings demonstrated that efficacy benefits with CABOMETYX in combination with nivolumab were sustained long term. Safety and tolerability with long-term follow-up were manageable and consistent with previous analyses. No new safety signals were reported.

Detailed Results from Subgroup Analysis of Phase 3 CABINET Pivotal Study Evaluating Cabozantinib in Advanced Gastrointestinal (GI) NET Presented at the American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO GI 2025). In January, results from a subgroup analysis of the CABINET study of patients with epNET arising in the GI tract were featured in a poster session at ASCO GI 2025. The analysis showed cabozantinib was associated with an improvement in progression-free survival (PFS) compared with placebo in patients with advanced GI NET, which was a subgroup of the epNET cohort. Earlier in January, the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology for Neuroendocrine and Adrenal Tumors were updated to include cabozantinib as category 1 preferred regimen for the majority of well-differentiated advanced NET following specific treatments, and as a category 2A preferred regimen for other forms of advanced NET, depending on tumor grade and different requirements for prior therapy.

Encouraging Results from Phase 1b/2 STELLAR-001 Trial Evaluating Zanzalintinib Alone or in Combination with Atezolizumab (Tecentriq®) in Metastatic Colorectal Cancer (CRC) Presented at ASCO GI 2025. In January, results from a randomized expansion cohort of the phase 1b/2 STELLAR-001 trial evaluating zanzalintinib versus the combination of zanzalintinib and atezolizumab in patients with previously treated metastatic CRC were presented during a poster session at ASCO GI 2025. Results from the study demonstrated that all efficacy parameters, including objective

response rate, PFS and overall survival favored the combination of zanzalintinib plus atezolizumab over zanzalintinib monotherapy in the overall population, as well as in a subgroup of patients without liver metastases. These data provide insights into the contribution of components and support zanzalintinib's ongoing pivotal development in metastatic CRC.

Presentation of Preclinical Data from Four Pipeline Programs in Advanced Cancers at the American Association for Cancer Research Annual Meeting (AACR 2025). In April, Exelixis presented preclinical data from four pipeline molecules at AACR 2025. Presentations included data for XL309 and XL495, small molecules that have demonstrated synthetic lethality in the context of certain genetic anomalies found in varying frequencies across a broad array of tumor types. The XL309 findings demonstrated activity of XL309 as monotherapy or in combination with PARP or topoisomerase inhibitors. Data analysis from the XL495 program demonstrated the potential for anti-tumor activity both as a monotherapy and in combination with DNA-damaging agents. However, based on early clinical data generated for XL495, Exelixis has discontinued further development of this program. Preclinical data were also presented for the PD-L1 + NKG2A-targeting bispecific antibody XB628 and for the tissue factor-targeting antibody-drug conjugate XB371. Data analysis from the XB628 program demonstrated the molecule's tumor cell killing activity both *in vitro* and *in vivo*, supporting advancement of this molecule into clinical development. Earlier in March, the U.S. FDA cleared Exelixis' Investigational New Drug (IND) application for XB628, and the company initiated the phase 1 study in April. Findings from XB371 non-clinical experiments demonstrated potent anti-tumor activity *in vivo* across a range of human tumor xenograft models including colorectal, lung, and pancreatic cancers, supporting the molecule's advancement into phase 1 clinical development. Exelixis is on track to submit an IND application for XB371 to the FDA in 2025.

Cabozantinib and Zanzalintinib Data Presentations at the 2025 American Society of Clinical Oncology Annual Meeting (ASCO 2025). Cabozantinib and zanzalintinib will be the subject of 17 presentations at ASCO 2025, which is being held from May 30 through June 3 in Chicago. Notably, presentations will include health-related quality of life findings from the phase 3 CABINET pivotal trial for cabozantinib, as well as results from two dose-escalation cohorts in advanced solid tumors and a clear cell RCC expansion cohort of the phase 1b/2 STELLAR-002 trial evaluating zanzalintinib in combination with immune checkpoint inhibitors in advanced solid tumors.

Corporate Highlights

Stock Repurchase Program. In August 2024, Exelixis' Board of Directors authorized a stock repurchase program to acquire up to $500 million of the company's common stock before December 31, 2025. In February 2025, the Board of Directors authorized the repurchase of up to an additional $500 million of the company's common stock before December 31, 2025. Under these programs, as of March 31, 2025, Exelixis has repurchased $494.5 million of the company's common stock, at an average price of $34.87 per share. Since the approval of the first stock repurchase program in March 2023, the weighted-average diluted common shares outstanding has decreased from 326.3 million shares to 288.2 million shares as of March 31, 2025. Stock repurchases under these programs 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 stock repurchases under the stock repurchase programs 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 our common stock and general market conditions.

Basis of Presentation

Exelixis has adopted a 52- or 53-week fiscal year that generally ends on the Friday closest to December 31. For convenience, references in this press release as of and for the fiscal periods ended April 4, 2025 and March 29, 2024, are indicated as being as of and for the periods ended March 31, 2025 and March 31, 2024**.**

Conference Call and Webcast

Exelixis management will discuss the company's financial results for the first quarter 2025 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 13, 2025.

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. 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 drug 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 X (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' updated 2025 financial guidance and any plans to provide further updates; Exelixis' goal of becoming a multi-franchise oncology company; anticipated zanzalintinib pivotal data milestones with respect to the STELLAR-303, STELLAR-304 and STELLAR-305 trials; Exelixis' anticipated timing to initiate the STELLAR-311 pivotal study in neuroendocrine tumors in the first half of 2025; Exelixis' expectations with respect to its clinical development collaboration with Merck; Exelixis' plans to submit an IND application for XB371 to the FDA in 2025; Exelixis' plans to present data at ASCO 2025; 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, zanzalintinib 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, including as a result of changing trade policies and tariffs and the related uncertainty thereof; and other factors detailed from time to time under the caption "Risk Factors" in Exelixis' most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q, and in Exelixis' other future filings with the Securities and Exchange Commission. 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,	
	2025	**2024**
Revenues:		
Net product revenues	$ 513,283	$ 378,523
Collaboration revenues	42,164	46,703
Total revenues	555,447	425,226
Operating expenses:		
Cost of goods sold	19,172	21,256
Research and development	212,233	227,689
Selling, general and administrative	137,183	113,984
Restructuring	—	32,835
Total operating expenses	368,588	395,764
Income from operations	186,859	29,462
Interest income	19,076	19,894
Other expenses, net	(245)	(89)
Income before income taxes	205,690	49,267
Provision for income taxes	46,074	11,950
Net income	$ 159,616	$ 37,317
Net income per share:		
Basic	$ 0.57	$ 0.12
Diluted	$ 0.55	$ 0.12
Weighted-average common shares outstanding:		
Basic	278,804	300,757
Diluted	288,177	305,530

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

	Three Months Ended March 31,	
	2025	**2024**
GAAP net income	$ 159,616	$ 37,317
Adjustments:		

Stock-based compensation - research and development[1]	9,522	3,892
Stock-based compensation - selling, general and administrative[1]	16,408	15,221
Income tax effect of the above adjustments	(5,993)	(4,448)
Non-GAAP net income	$ 179,553	$ 51,982
GAAP net income per share:		
Basic	$ 0.57	$ 0.12
Diluted	$ 0.55	$ 0.12
Non-GAAP net income per share:		
Basic	$ 0.64	$ 0.17
Diluted	$ 0.62	$ 0.17
Weighted-average common shares outstanding:		
Basic	278,804	300,757
Diluted	288,177	305,530

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

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