Exelixis Announces Second Quarter 2024 Financial Results and Provides Corporate Update

August 6, 2024

- Total Revenues of $637.2 million, Cabozantinib Franchise U.S. Net Product Revenues of $437.6 million -
- GAAP Diluted EPS of $0.77, Non-GAAP Diluted EPS of $0.84 -
- U.S. Food and Drug Administration (FDA) Accepts Supplemental New Drug Application (sNDA) for Cabozantinib in Advanced Neuroendocrine Tumors (NET) -
- Earned $150 million Cabozantinib Sales-Based Milestone from Ipsen -
- Completed $450 million Stock Repurchase Program for 2024 -
- Announced Additional Stock Repurchase Program for up to $500 million through the End of 2025 -
- Conference Call and Webcast Today at 5:00 PM Eastern Time -

ALAMEDA, Calif.--(BUSINESS WIRE)--Aug. 6, 2024-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the second quarter of 2024, provided an update on progress toward achieving key corporate objectives, and detailed its recent and anticipated commercial, clinical and pipeline development milestones.

“Exelixis is well positioned for an impactful second half of 2024 as we continue to grow the cabozantinib franchise, execute on our regulatory and development objectives, and advance our next-generation pipeline,” said Michael M. Morrissey, Ph.D., President and CEO, Exelixis. “Cabozantinib’s second quarter commercial performance was strong both in the U.S. and globally, with Ipsen’s success prompting a $150 million milestone payment to Exelixis based on sales over the past four quarters. On the regulatory front, the FDA accepted the sNDA for cabozantinib in advanced NET, granted standard review and assigned a target action date of April 3, 2025. We’re actively preparing for launch and excited at the prospect of bringing this new treatment option to previously treated advanced NET patients with high unmet medical need. At the same time, we are prioritizing our clinical pipeline with plans to initiate a new phase 3 pivotal trial for zanzalintinib in NET, advance phase 1 efforts for XL309 and XB010, and discontinue development of XB002. I’d like to thank the entire Exelixis team for their hard work and contributions toward achieving these important milestones for cabozantinib and advancing our broad, differentiated pipeline of oncology therapeutics to help the patients we serve.”

Second Quarter 2024 Financial Results

Total revenues for the quarter ended June 30, 2024 were $637.2 million, as compared to $469.8 million for the comparable period in 2023.

Total revenues for the quarter ended June 30, 2024 included net product revenues of $437.6 million, as compared to $409.6 million for the comparable period in 2023. The increase in net product revenues was primarily due to an increase in sales volume and average net selling price.

Collaboration revenues, composed of license revenues and collaboration services revenues, were $199.6 million for the quarter ended June 30, 2024, as compared to $60.2 million for the comparable period in 2023. The increase in collaboration revenues was primarily related to an increase in milestone-related revenues recognized in the quarter 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, partially offset by a decrease in development cost reimbursements earned.

Research and development expenses for the quarter ended June 30, 2024 were $211.1 million, as compared to $232.6 million for the comparable period in 2023. 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 an increase in manufacturing costs to support our development candidates.

Selling, general and administrative expenses for the quarter ended June 30, 2024 were $132.0 million, as compared to $141.7 million for the comparable period in 2023. The decrease in selling, general and administrative expenses was primarily related to a decrease in legal and advisory fees related to the proxy contest in the prior year.

Provision for income taxes for the quarter ended June 30, 2024 was $66.7 million, as compared to $19.2 million for the comparable period in 2023.

GAAP net income for the quarter ended June 30, 2024 was $226.1 million, or $0.78 per share, basic and $0.77 per share, diluted, as compared to GAAP net income of $81.2 million, or $0.25 per share, basic and diluted, for the comparable period in 2023. GAAP net income per share for the quarter ended June 30, 2024 was favorably impacted by lower weighted-average common shares outstanding for the quarter ended June 30, 2024, as compared to the comparable period in 2023, as a result of the stock repurchase programs.

Non-GAAP net income for the quarter ended June 30, 2024 was $245.6 million, or $0.85 per share, basic and $0.84 per share, diluted, as compared to non-GAAP net income of $100.3 million, or $0.31 per share, basic and diluted, for the comparable period in 2023.

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.

2024 Financial Guidance

Exelixis is providing the following updated financial guidance for fiscal year 2024 [(1)]:

Total revenues	$1.975 billion - $2.075 billion
Net product revenues [2]	$1.650 billion - $1.750 billion
Cost of goods sold	4% - 5% of net product revenues
Research and development expenses [3]	$925 million - $975 million
Selling, general and administrative expenses [4]	$450 million - $500 million
Effective tax rate	20% - 22%

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[1] 2024 financial guidance excludes expenses related to the restructuring plan announced in January 2024.

[2] Exelixis' 2024 net product revenues guidance range includes the impact of a U.S. wholesale acquisition cost increase of 2.2% for both CABOMETYX and COMETRIQ effective on January 1, 2024.

[3] Includes $40 million of non-cash stock-based compensation expense.

[4] Includes $60 million of non-cash stock-based compensation expense.

Cabozantinib and Pipeline Highlights

Cabozantinib Franchise Net Product Revenues and Royalties. Net product revenues generated by the cabozantinib franchise in the U.S. were $437.6 million during the second quarter of 2024, with net product revenues of $433.3 million from CABOMETYX® (cabozantinib) and $4.2 million from COMETRIQ® (cabozantinib). Based upon cabozantinib-related net product revenues generated by Exelixis' collaboration partners during the quarter ended June 30, 2024, Exelixis earned $41.2 million in royalty revenues.

Achievement of Cabozantinib Sales-Based Milestone from Ipsen. Today, Exelixis announced it earned and recognized in license revenues a $150 million commercial milestone from Ipsen during the second quarter of 2024 based on Ipsen achieving $600 million in cumulative net sales of cabozantinib in its related license territory over four consecutive quarters. Exelixis expects to receive the milestone payment during the third quarter of 2024.

FDA Accepts for Standard Review the sNDA for Cabozantinib for Patients with Advanced NET; Updated Results from Phase 3 CABINET Study to be Presented during an Oral Presentation at the European Society for Medical Oncology (ESMO) Congress 2024. Today, Exelixis announced that the FDA accepted its sNDA for cabozantinib for patients with previously treated advanced pancreatic NET (pNET), and for patients with previously treated advanced extra-pancreatic NET (epNET). The FDA assigned a standard review with a Prescription Drug User Fee Act (PDUFA) target action date of April 3, 2025. The FDA also granted orphan drug designation to cabozantinib for the treatment of pNET. The application was based on results from the phase 3 CABINET trial, which evaluated cabozantinib compared with placebo in patients with previously treated pNET and epNET. The CABINET study is sponsored by the National Cancer Institute (NCI), part of the National Institutes of Health, and led by the NCI-funded Alliance for Clinical Trials in Oncology. Updated results from CABINET, including final results on the primary efficacy endpoint of progression-free survival by Blinded Independent Central Review, will be presented during the ESMO Congress 2024 in September.

Exelixis Partner Ipsen Opts into Phase 3 CABINET Pivotal Trial in Advanced NET. In July, Ipsen announced it opted into the phase 3 CABINET pivotal trial, expanding the existing collaboration and license agreement with Exelixis and permitting Ipsen to seek potential marketing authorizations for CABOMETYX in advanced pNET and epNET from regulatory authorities outside of the U.S. and Japan. As part of the agreement, Exelixis is eligible to receive a reimbursement of a portion of costs related to the trial, as well as milestone payments for potential future regulatory action by the European Medicines Agency. The decision to expand the existing agreement was based on detailed results from the CABINET trial, which were first presented at the ESMO Congress 2023.

Phase 3 CONTACT-02 Metastatic Castration-Resistant Prostate Cancer (mCRPC) Study Update and Intention to Submit sNDA in 2024. Today, Exelixis announced that the final overall survival (OS) analysis for the phase 3 CONTACT-02 trial has been completed. This study is evaluating cabozantinib in combination with atezolizumab compared with a second novel hormonal therapy (NHT) in patients with mCRPC and measurable soft-tissue disease who have progressed after treatment with one prior NHT. As previously reported, the CONTACT-02 study met one of its two primary endpoints, demonstrating a statistically significant benefit in progression-free survival (PFS) (hazard ratio: 0.65; 95% confidence interval: 0.50–0.84; p=0.0007) in the predefined PFS intent-to-treat population (i.e., the first 400 randomized patients). While final OS continued to favor the combination of cabozantinib and atezolizumab, it did not achieve statistical significance. The safety profile of the combination regimen was reflective of the known safety profiles for each single agent and was consistent with the known tolerability profile of approved immune checkpoint inhibitor-tyrosine kinase inhibitor combinations in advanced solid tumors. Exelixis intends to submit an sNDA to the FDA this year and to present these final data at a future medical meeting.

Enrollment Completion for Zanzalintinib Phase 3 STELLAR-303 Study and Announcement of New Pivotal Trial for Zanzalintinib in Neuroendocrine Tumors. Today, Exelixis announced that enrollment has been completed in the STELLAR-303 phase 3 pivotal study. STELLAR-303 is evaluating zanzalintinib in combination with atezolizumab compared with regorafenib in patients with metastatic refractory colorectal cancer that is not microsatellite instability-high or mismatch repair-deficient. The primary endpoint in the study is OS in the patients without liver metastases. Exelixis anticipates preliminary results from the study to readout in 2025. Additionally, Exelixis intends to initiate a new phase 3 pivotal trial, STELLAR-311, evaluating zanzalintinib compared with everolimus as a first oral therapy in patients with pNET and epNET, in the first half of 2025.

Initiation of Phase 1 Clinical Trial Evaluating XB010 in Patients with Advanced Solid Tumors. Today, Exelixis announced the initiation of the dose-escalation stage of the first-in-human phase 1 clinical trial of XB010 in patients with locally advanced or metastatic solid tumors. XB010, an antibody-drug conjugate (ADC) consisting of a monomethyl auristatin E payload conjugated to a monoclonal antibody targeting the tumor antigen 5T4, is the first custom ADC generated through Exelixis' biotherapeutics collaboration network. The dose-escalation stage of this phase 1, global, open-label study will evaluate XB010 as a single agent and in combination with pembrolizumab to inform the cohort-expansion stage. The expansion cohorts are designed to further assess the tolerability and activity of monotherapy and of the combination in specific indications.

Portfolio Prioritization Update. Today, Exelixis announced it will discontinue the development of XB002, the company's tissue factor (TF)-targeting ADC, as part of its portfolio prioritization efforts. Based on available data, the compound is unlikely to improve upon tisotumab vedotin or other competitor TF-targeting ADCs currently in development. The company plans to disclose data from the phase 1 JEWEL-101 study, evaluating XB002 in advanced solid tumors, at a later date. Preclinical development of XB371, its ADC consisting of a topoisomerase payload conjugated to a TF-targeting monoclonal antibody, is ongoing. Exelixis plans to reallocate resources to new pivotal trials with zanzalintinib, advancing XL309 and its growing pipeline.

Corporate Highlights

Settlement of CABOMETYX Patent Litigation with Cipla Limited and Cipla USA. In May, Exelixis entered into a Settlement and License Agreement (Agreement) with Cipla Ltd. and Cipla USA, Inc. (individually and collectively referred to as Cipla) resolving two patent litigations brought by Exelixis in response to Cipla's Abbreviated New Drug Application (ANDA) seeking approval to market generic versions of CABOMETYX tablets (20 mg / 40 mg / 60 mg) prior to the expiration of the applicable patents. Pursuant to the terms of the Agreement, Exelixis will grant Cipla a license to market generic versions of CABOMETYX in the United States beginning on January 1, 2031, if approved by the FDA and subject to conditions and exceptions common to agreements of this type. The U.S. District Court for the District of Delaware dismissed the case without prejudice in July 2024 per the parties' joint request, effectively terminating all ongoing Hatch-Waxman litigation between Exelixis and Cipla regarding CABOMETYX patents

Completion of the $450 million 2024 Stock Repurchase Program. As of June 30, 2024, Exelixis completed the repurchase of 20.3 million shares of the company's common stock for a total of $450 million, fulfilling its commitment under the stock repurchase program announced in January 2024. With the completion of this 2024 stock repurchase program, the company has returned $1 billion to shareholders since the initial $550 million stock repurchase program was authorized in March 2023.

Announcement of Additional Stock Repurchase Program for up to $500 million through the End of 2025. Today, Exelixis announced that the company's Board of Directors has authorized the repurchase of up to an additional $500 million of the company's common stock through the end of 2025. The newly authorized stock repurchase program is the third such program undertaken by Exelixis since March 2023. Stock repurchases under the newly authorized program may be made from time to time through a variety of methods, which may include open market purchases, in block trades, accelerated share repurchase transactions, exchange transactions, or any combination of such methods. The timing and amount of any stock repurchases under the stock repurchase program will be based on a variety of factors, including ongoing assessments of the

capital needs of the business, alternative investment opportunities, the market price of Exelixis' common stock and general market conditions.

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 June 28, 2024 are indicated as being as of and for the periods ended June 30, 2024.

Conference Call and Webcast

Exelixis management will discuss the company's financial results for the second quarter of 2024 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 6, 2024.

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' belief that it is well-positioned for an impactful second half of 2024; the regulatory review process with respect to Exelixis' sNDA for cabozantinib in advanced NET, including the PDUFA target action date assigned by the FDA, and the potential to bring cabozantinib as a new treatment option for these patients with high unmet medical need; Exelixis' plans to reallocate resources to new pivotal trials in zanzalintinib and to advancing phase 1 efforts for XL309 and XB010, as well as to the rest of the company's growing pipeline; Exelixis' updated 2024 financial guidance; the anticipated timing for receipt of a $150 million milestone payment from Ipsen; Exelixis' plans to present updated results from CABINET, including final results for the primary efficacy endpoint of PFS, at the ESMO Congress 2024 in September; Exelixis' expectation to receive reimbursement payments from Ipsen relating to CABINET, as well as milestone payments for potential future regulatory actions by the European Medicines Agency; Exelixis' plans to submit an sNDA for the combination of cabozantinib and atezolizumab in mCRPC to the FDA this year based on the results of CONTACT-02, and to present final data from CONTACT-02 at a future medical meeting; Exelixis' expectation that preliminary results from STELLAR-303 will readout in 2025; Exelixis' plans to initiate STELLAR-311 in the first half of 2025; Exelixis' plans to disclose data from JEWEL-101 at a later date; Exelixis' future obligations under the Agreement settling the company's patent litigation with Cipla; Exelixis' plans to repurchase up to an additional $500 million of its common stock before the end of 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 and other Exelixis product candidates; Exelixis' dependence on third-party vendors for the development, manufacture and supply of its products and product candidates; Exelixis' ability to protect its intellectual property rights; market competition, including the potential for competitors to obtain approval for generic versions of Exelixis' marketed products; changes in economic and business conditions; and other factors 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.

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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,	
	2024	2023	2024	2023
Revenues:				
Net product revenues	$ 437,581	$ 409,646	$ 816,104	$ 773,046
License revenues	194,986	52,747	239,662	91,039
Collaboration services revenues	4,611	7,455	6,638	14,551
Total revenues	637,178	469,848	1,062,404	878,636
Operating expenses:				
Cost of goods sold	17,667	17,705	38,923	32,020
Research and development	211,147	232,570	438,836	466,816
Selling, general and administrative	132,015	141,723	245,999	273,120
Restructuring	475	—	33,310	—
Total operating expenses	361,304	391,998	757,068	771,956
Income from operations	275,874	77,850	305,336	106,680
Interest income	17,258	22,541	37,152	42,043

Other expense, net	(287)	(5)	(376)	(59)
Income before income taxes	292,845	100,386	342,112	148,664
Provision for income taxes	66,729	19,208	78,679	27,458
Net income	$ 226,116	$ 81,178	$ 263,433	$ 121,206
Net income per share:				
Basic	$ 0.78	$ 0.25	$ 0.89	$ 0.37
Diluted	$ 0.77	$ 0.25	$ 0.88	$ 0.37
Weighted-average common shares outstanding:				
Basic	289,216	324,205	294,986	324,312
Diluted	293,974	327,305	299,752	326,792

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,	
	2024	2023	2024	2023
GAAP net income	$ 226,116	$ 81,178	$ 263,433	$ 121,206
Adjustments:				
Stock-based compensation - research and development expenses [1]	9,178	9,589	13,070	12,841
Stock-based compensation - selling, general and administrative expenses [1]	16,176	15,311	31,397	28,720
Income tax effect of the above adjustments	(5,841)	(5,781)	(10,289)	(9,642)
Non-GAAP net income	$ 245,629	$ 100,297	$ 297,611	$ 153,125
GAAP net income per share:				
Basic	$ 0.78	$ 0.25	$ 0.89	$ 0.37
Diluted	$ 0.77	$ 0.25	$ 0.88	$ 0.37
Non-GAAP net income per share:				
Basic	$ 0.85	$ 0.31	$ 1.01	$ 0.47
Diluted	$ 0.84	$ 0.31	$ 0.99	$ 0.47
Weighted-average common shares outstanding:				
Basic	289,216	324,205	294,986	324,312
Diluted	293,974	327,305	299,752	326,792

[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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