



Exelixis Announces Third Quarter 2024 Financial Results and Provides Corporate Update

October 29, 2024

- Total Revenues of \$539.5 million, Cabozantinib Franchise U.S. Net Product Revenues of \$478.1 million -

- GAAP Diluted EPS of \$0.40, Non-GAAP Diluted EPS of \$0.47 -

- Increasing Total Revenues and Net Product Revenues Guidance -

- Favorable Ruling on Cabozantinib Patent Litigation Received from U.S. District Court -

- Collaboration with Merck Expands Zanzalintinib Development Program -

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

ALAMEDA, Calif.--(BUSINESS WIRE)--Oct. 29, 2024-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the third 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.

"The favorable ruling on our cabozantinib intellectual property estate and recently announced zanzalintinib development collaboration with Merck have generated important momentum to drive future growth across all components of our business," said Michael M. Morrissey, Ph.D., President and CEO, Exelixis. "We are increasing 2024 full year guidance for total and net product U.S. revenues based on the strong commercial performance of the cabozantinib franchise in the third quarter. We continue to execute on our plans for potential cabozantinib label expansions in neuroendocrine tumors and prostate cancer, with the final results from CABINET published in *The New England Journal of Medicine* in September and our partner Ipsen's regulatory submission in Europe."

Dr. Morrissey continued: "Importantly, the zanzalintinib development program, which is now the subject of six ongoing or planned phase 3 pivotal trials, including two new renal cell carcinoma studies as part of our collaboration with Merck, headlines our emerging pipeline of novel agents with the potential to improve standards of care for patients with cancer. At the same time, we are accelerating our early-stage clinical pipeline with XL309, XB010 and XL495 in phase 1 development. I want to thank everyone at Exelixis for their hard work and dedication as we continue driving value for shareholders and innovating on behalf of the patients we serve."

Third Quarter 2024 Financial Results

Total revenues for the quarter ended September 30, 2024 were \$539.5 million, as compared to \$471.9 million for the comparable period in 2023.

Total revenues for the quarter ended September 30, 2024 included net product revenues of \$478.1 million, as compared to \$426.5 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 \$61.5 million for the quarter ended September 30, 2024, as compared to \$45.4 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 September 30, 2024 were \$222.6 million, as compared to \$332.6 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.

Selling, general and administrative expenses for the quarter ended September 30, 2024 were \$111.8 million, as compared to \$138.1 million for the comparable period in 2023. The decrease in selling, general and administrative expenses was primarily related to decreases in corporate giving, stock-based compensation expenses and legal and advisory fees.

Impairment of long-lived assets for the quarter ended September 30, 2024 of \$51.7 million was related to the non-cash asset impairment charge to certain of Exelixis' leased facilities which are currently not in use and may be subleased.

Provision for income taxes for the quarter ended September 30, 2024 was \$36.8 million, as compared to \$4.8 million for the comparable period in 2023.

GAAP net income for the quarter ended September 30, 2024 was \$118.0 million, or \$0.41 per share, basic and \$0.40 per share, diluted, as compared to GAAP net income of \$1.0 million, or \$0.00 per share, basic and diluted, for the comparable period in 2023. GAAP net income per share for the quarter ended September 30, 2024 was favorably impacted by lower weighted-average common shares outstanding for the quarter ended September 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 September 30, 2024 was \$135.7 million, or \$0.47 per share, basic and diluted, as compared to non-GAAP net income of \$32.1 million, or \$0.10 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) 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⁾:

	Current Guidance (provided on October 29, 2024)	Previous Guidance (provided on August 6, 2024)			
Total revenues	\$2.150 billion - \$2.200 billion	\$1.975 billion - \$2.075 billion			
Net product revenues ⁽²⁾	\$1.775 billion - \$1.825 billion	\$1.650 billion - \$1.750 billion			
Cost of goods sold	~4.5% of net product revenues	4% - 5% of net product revenues			
Research and development expenses	\$925 million - \$950 million ⁽³⁾	\$925 million - \$975 million ⁽⁴⁾			
Selling, general and administrative expenses ⁽⁵⁾	\$475 million - \$500 million	\$450 million - \$500 million			
Effective tax rate	21% - 22%	20% - 22%			

 ^{(1) 2024} financial guidance excludes expenses related to the restructuring plan announced in January 2024 and impairment of long-lived assets announced in October 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.

⁽⁴⁾Includes \$40 million of non-cash stock-based compensation expense.

⁽⁵⁾Includes \$60 million of non-cash stock-based compensation expense.

Corporate Highlights

Favorable Ruling in Second Cabozantinib Abbreviated New Drug Application (ANDA) Litigation Against MSN Pharmaceuticals, Inc. (MSN). In October, the U.S. District Court for the District of Delaware (the District Court) ruled in Exelixis' favor, rejecting MSN's challenge to three Orange Book-listed patents related to cabozantinib (U.S. Patents No. 11,091,439 (crystalline salt forms), 11,091,440 (pharmaceutical composition) and 11,098,015 (methods of treatment)), which expire January 15, 2030. The District Court's decision follows an earlier stipulation that MSN's proposed generic cabozantinib product (ANDA No. 213878) infringes the '439, '440, and '015 patents. The District Court's ruled that Exelixis' U.S. Patent No. 11,298,349 (pharmaceutical composition) is not invalid and not infringed by MSN's proposed ANDA product. To Exelixis' knowledge, the U.S. Food and Drug Administration (FDA) has not yet granted tentative approval of MSN's proposed ANDA product. On October 23, 2024, the District Court's final judgment reflecting the opinion. Based on the District Court's final judgment, should the FDA ultimately approve MSN's ANDA, the effective date of any such approval and commercial launch in the U.S. of MSN's proposed ANDA product shall not be a date earlier than January 15, 2030, subject to Exelixis' potential additional regulatory exclusivity. The District Court's judgment is also subject to appeal by either party.

New Clinical Development Collaboration with Merck to Evaluate Zanzalintinib in Combination with KEYTRUDA[®] (pembrolizumab) in Head and Neck Cancer and with WELIREG[®] (belzutifan) in Renal Cell Carcinoma (RCC). In October, Exelixis and Merck (known as MSD outside of the U.S. and Canada) announced a clinical development collaboration to evaluate zanzalintinib in combination with KEYTRUDA in head and neck squamous cell carcinoma (HNSCC), and zanzalintinib with WELIREG in RCC. Under the terms of the collaboration, Merck will supply KEYTRUDA, its anti-PD-1 therapy, for the ongoing, Exelixis-sponsored phase 3 STELLAR-305 pivotal trial in previously untreated PD-L1 positive recurrent or metastatic HNSCC. In addition, Merck will sponsor a phase 1/2 trial and two phase 3 pivotal trials evaluating zanzalintinib in combination with WELIREG, its oral hypoxia-inducible factor-2 alpha (HIF-2α) inhibitor, in RCC. Merck will fund one of these phase 3 studies, and Exelixis will co-fund the phase 1/2 trial and the other phase 3 study, as well as supply zanzalintinib and cabozantinib. Exelixis maintains all global commercial and marketing rights to zanzalintinib.

Stock Repurchase Program. In August, Exelixis announced that the company's Board of Directors authorized the repurchase of up to \$500 million of the company's common stock through the end of 2025, the third stock repurchase program undertaken by Exelixis since March 2023. Under this program, as of September 30, 2024, Exelixis has repurchased \$12.4 million of the company's common stock, at an average price of \$25.61 per share.

Cabozantinib Highlights

Cabozantinib Franchise Net Product Revenues and Royalties. Net product revenues generated by the cabozantinib franchise in the U.S. were \$478.1 million during the third quarter of 2024, with net product revenues of \$475.7 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 September 30, 2024, Exelixis earned \$41.8 million in royalty revenues.

Exelixis' Partner Ipsen Opted into Phase 3 CABINET Pivotal Trial in Advanced Neuroendocrine Tumors (NET) and Submitted an Extension of Indication Marketing Authorization to the European Medicines Agency (EMA). 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 pancreatic NET (pNET) and extra-pancreatic NET (epNET) from regulatory authorities outside of the U.S. and Japan. As part of the agreement, Exelixis is eligible to receive reimbursement of a portion of costs related to the trial, as well as milestone payments for potential future regulatory action by the EMA. In September, Ipsen announced it submitted an extension of indication Marketing Authorization to the EMA for CABOMETYX in advanced NET. These announcements were based on detailed results from CABINET, which evaluated cabozantinib compared with placebo in patients with previously treated advanced pNET and advanced epNET. CABINET 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.

FDA Accepted Supplemental New Drug Application (sNDA) for Cabozantinib for Patients with Advanced NET. In August, Exelixis announced that the FDA accepted its sNDA for cabozantinib for patients with previously treated advanced pNET and for patients with previously treated advanced 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 sNDA was based on results from the CABINET trial.

Final Results from Phase 3 CABINET Pivotal Trial Evaluating Cabozantinib in Advanced NET Presented at the 2024 European Society for Medical Oncology (ESMO) Congress and Published in *The New England Journal of Medicine (NEJM)*. In September, detailed final results from CABINET were presented at the 2024 ESMO Congress and published in *NEJM*. The results demonstrated continued improvement with cabozantinib in the primary endpoint of progression-free survival by blinded independent central review, and additional analyses suggest benefits with cabozantinib across all clinical subgroups examined, including primary tumor site, grade and prior systemic anti-cancer therapy.

Final Overall Survival (OS) Results from Phase 3 CONTACT-02 Pivotal Trial Evaluating Cabozantinib in Combination with Atezolizumab in Metastatic Castration-Resistant Prostate Cancer (mCRPC) Presented at the 2024 ESMO Congress. In September, the final analysis of OS from the phase 3 CONTACT-02 pivotal study was presented at the 2024 ESMO Congress. The results of the final OS analysis showed a trend that favored the combination of cabozantinib and atezolizumab but was not statistically significant. The trend in OS benefit was consistently observed in key subgroups, including in patients with liver metastases, a subgroup of mCRPC patients with the poorest prognosis in need of new treatment options, which Exelixis anticipates will grow in the coming years. CONTACT-02 evaluated cabozantinib in combination with atezolizumab compared with a second novel hormonal therapy (NHT) in patients with measurable, extra-pelvic mCRPC who have progressed after treatment with one prior NHT. Exelixis intends to submit an sNDA to the FDA for cabozantinib in combination with atezolizumab for mCRPC in the fourth quarter of 2024.

⁽³⁾Includes \$30 million of non-cash stock-based compensation expense.

Pipeline Highlights

Enrollment Completion for Zanzalintinib Phase 3 STELLAR-303 Study in Metastatic Colorectal Cancer (CRC) and Announcement of STELLAR-311 Pivotal Trial Evaluating Zanzalintinib in NET. In August, Exelixis announced that enrollment was 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 CRC that is not microsatellite instability-high or mismatch repairdeficient. The primary endpoint in the study is OS in the patients without liver metastases. Exelixis anticipates preliminary results from the study in 2025. Additionally, Exelixis announced plans to initiate STELLAR-311, a new phase 3 pivotal trial evaluating zanzalintinib compared with everolimus as a first oral therapy in patients with advanced NET, regardless of site of origin, in the first half of 2025.

Initiation of Phase 1 Clinical Trial Evaluating XB010 in Patients with Advanced Solid Tumors. In August, 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 global phase 1 study is evaluating 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.

Initiation of Phase 1 Clinical Trial Evaluating XL495 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 XL495 in patients with advanced solid tumors. XL495 is a novel, potent, small molecule inhibitor of PKMYT1. The dose-escalation stage of this phase 1 study is designed to determine the maximum tolerated dose of XL495. The expansion cohorts are designed to further assess the tolerability and activity of XL495 both as monotherapy and in combination with select cytotoxic agents in tumor-specific indications.

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 September 27, 2024 and September 29, 2023, are indicated as being as of and for the periods ended September 30, 2024 and September 30, 2023.

Conference Call and Webcast

Exelixis management will discuss the company's financial results for the third 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, October 29, 2024.

To access the conference call, please register using this <u>link</u>. Upon registration, a dial-in number and unique PIN will be provided to join the call. To access the live webcast link, log onto <u>www.exelixis.com</u> and proceed to the Event Calendar page under the Investors & News heading. A webcast replay of the conference call will also be archived on <u>www.exelixis.com</u> 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 <u>www.exelixis.com</u>, follow <u>@ExelixisInc</u> on X (Twitter), like <u>Exelixis.Inc</u>, on Facebook and follow <u>Exelixis</u> on LinkedIn.

Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to: Exelixis' belief that the favorable ruling on its cabozantinib intellectual property estate and zanzalintinib development collaboration with Merck have generated important momentum to drive future growth across all components of the company's business; Exelixis' plans for cabozantinib label expansions in NET and prostate cancer; the potential for Exelixis' zanzalintinib development program (including new planned pivotal trials), along with the rest of the company's emerging pipeline, to improve standards of care for patients with cancer; Exelixis' updated 2024 financial guidance; the timing of any regulatory approval and commercial launch in the U.S. of MSN's proposed ANDA product or other proposed ANDA products, with consideration given to Exelixis' potential additional regulatory exclusivity and future appeals of the District Court's judgment by either party; Exelixis' immediate and future financial and other obligations under its clinical development collaboration with Merck; Exelixis' plans to repurchase up to an additional \$500 million of its common stock before the end of 2025; Exelixis' expectation to receive reimbursement payments from Ipsen relating to CABINET, as well as milestone payments for potential future regulatory actions by the EMA; the regulatory review process with respect to Exelixis' sNDA for cabozantinib in advanced NET, including the PDUFA target action date assigned by the FDA; Exelixis' plans to submit an sNDA for the combination of cabozantinib and atezolizumab in mCRPC to the FDA during the fourth quarter of 2024 based on the results of CONTACT-02; Exelixis' expectation for preliminary results from STELLAR-303 in 2025; Exelixis' plans to initiate STELLAR-311 in the first half 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)

	Thi	Three Months Ended September 30,			Nine Months Ended September 30,			
		2024		2023	_	2024		2023
Revenues:								
Net product revenues	\$	478,059	\$	426,497	\$	1,294,163	\$	1,199,543
License revenues		60,239		42,367		299,901		133,406
Collaboration services revenues		1,244		3,056		7,882		17,607
Total revenues		539,542		471,920		1,601,946		1,350,556
Operating expenses:								
Cost of goods sold		17,328		18,774		56,251		50,794
Research and development		222,570		332,585		661,406		799,401
Selling, general and administrative		111,801		138,144		357,800		411,264
Impairment of long-lived assets		51,672		_		51,672		_
Restructuring		96		—		33,406		_
Total operating expenses		403,467		489,503		1,160,535		1,261,459
Income (loss) from operations		136,075		(17,583)		441,411		89,097
Interest income		18,709		23,112		55,861		65,155
Other income (expense), net		(29)	_	289		(405)		230
Income before income taxes		154,755		5,818		496,867		154,482
Provision for income taxes		36,782	_	4,777		115,461	_	32,235
Net income	\$	117,973	\$	1,041	\$	381,406	\$	122,247
Net income per share:								
Basic	\$	0.41	\$	0.00	\$	1.31	\$	0.38
Diluted	\$	0.40	\$	0.00	\$	1.28	\$	0.38
Weighted-average common shares outstanding:								
Basic		285,622		315,496		291,865		321,373
Diluted		291,478		319,247		296,994		324,277

EXELIXIS, INC.

RECONCILIATION OF GAAP NET INCOME TO NON-GAAP NET INCOME

(in thousands, except per share amounts)

(unaud	ited)

	Three Months Ended September 30,			Nine Months Ended September 30,				
		2024	2023		2024		2023	
GAAP net income	\$	117,973	\$	1,041	\$	381,406	\$	122,247
Adjustments:								
Stock-based compensation - research and development expenses ⁽¹⁾		8,764		12,438		21,834		25,279
Stock-based compensation - selling, general and administrative expenses ⁽¹⁾		14,259		28,040		45,656		56,760
Income tax effect of the above adjustments		(5,335)		(9,420)		(15,624)		(19,062)
Non-GAAP net income	\$	135,661	\$	32,099	\$	433,272	\$	185,224
GAAP net income per share:								
Basic	\$	0.41	\$	0.00	\$	1.31	\$	0.38
Diluted	\$	0.40	\$	0.00	\$	1.28	\$	0.38
Non-GAAP net income per share:								
Basic	\$	0.47	\$	0.10	\$	1.48	\$	0.58
Diluted	\$	0.47	\$	0.10	\$	1.46	\$	0.57
Weighted-average common shares outstanding:								
Basic		285,622		315,496		291,865		321,373
Diluted		291,478		319,247		296,994		324,277

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

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Source: Exelixis, Inc.