

EXELIXIS, INC.

FORM 10-Q (Quarterly Report)

Filed 05/13/25 for the Period Ending 04/04/25

Address 1851 HARBOR BAY PARKWAY

ALAMEDA, CA, 94502

Telephone 6508377000

CIK 0000939767

Symbol EXEL

SIC Code 2836 - Biological Products, (No Diagnostic Substances)

Industry Biotechnology & Medical Research

Sector Healthcare

Fiscal Year 01/02



UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

	g ,		
	FORM 10-Q		
☑ QUARTERLY REPORT PU	RSUANT TO SECTION 13 OR 15(d) OF T	THE SECURITIES EXCHANGE ACT OF 19	934
	For the quarterly period ended April 4 or	4, 2025	
☐ TRANSITION REPORT PU	JRSUANT TO SECTION 13 OR 15(d) OF		934
	For the transition period from t	0	
	Commission File Number: 000-30)235 	
	EXELIXIS	•	
	EXELIXIS, INC.		
	(Exact name of registrant as specified in it	s charter)	
Delaware		04-3257	395
(State or other jurisdiction of incorporation or organization	n)	(I.R.S. Employer Identii	fication Number)
	1851 Harbor Bay Parkway Alameda, CA 94502 (650) 837-7000	,	
(Address, including zip co	de, and telephone number, including area code,	of registrant's principal executive offices)	
9	Securities registered pursuant to Section 12	2(b) of the Act:	
Title of each class	<u>Trading Symbol(s)</u>	Name of each exchange	on which registered
Common Stock, \$0.001 Par Value per Share	EXEL	The Nasdaq Stock	k Market LLC
Indicate by check mark whether the registrant (1) has f preceding 12 months (or for such shorter period that the re days). Yes \boxtimes No \square			
Indicate by check mark whether the registrant has sub- (§232.405 of this chapter) during the preceding 12 months			
Indicate by check mark whether the registrant is a large company. See the definitions of "large accelerated filer," "ac			
Large accelerated filer	×	Accelerated filer	
Non-accelerated filer		Smaller reporting company	
		Emerging growth company	
If an emerging growth company, indicate by check mar financial accounting standards provided pursuant to Section	•	e extended transition period for complyin	ng with any new or revised
Indicate by check mark whether the registrant is a shel	I company (as defined in Rule 12b-2 of the	Exchange Act). Yes No No	
As of May 5, 2025, there were 272,708,280 shares of tl	ne registrant's common stock outstanding.		

EXELIXIS, INC. QUARTERLY REPORT ON FORM 10-Q INDEX

		Page
	PART I - FINANCIAL INFORMATION	
Item 1.	<u>Financial Statements</u>	<u>3</u>
	Condensed Consolidated Balance Sheets (Unaudited)	<u>3</u>
	Condensed Consolidated Statements of Income (Unaudited)	<u>4</u>
	Condensed Consolidated Statements of Comprehensive Income (Unaudited)	<u>4</u>
	Condensed Consolidated Statements of Stockholders' Equity (Unaudited)	<u>5</u>
	Condensed Consolidated Statements of Cash Flows (Unaudited)	<u>6</u>
	Notes to Condensed Consolidated Financial Statements (Unaudited)	<u>7</u>
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	<u>21</u>
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	<u>35</u>
Item 4.	Controls and Procedures	<u>35</u>
	PART II - OTHER INFORMATION	
Item 1.	<u>Legal Proceedings</u>	<u>36</u>
Item 1A.	Risk Factors	<u>36</u>
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>40</u>
Item 3.	<u>Defaults Upon Senior Securities</u>	<u>41</u>
Item 4.	Mine Safety Disclosures	<u>41</u>
Item 5.	Other Information	<u>41</u>
Item 6.	<u>Exhibits</u>	<u>42</u>
	<u>SIGNATURES</u>	

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

EXELIXIS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (in thousands, except per share data) (unaudited)

	March 31, 2025		December 31, 2024	
ASSETS				
Current assets:				
Cash and cash equivalents	\$	183,752	\$	217,374
Marketable securities		847,564		893,902
Trade receivables, net		281,637		265,437
Inventory		24,853		22,388
Prepaid expenses and other current assets		58,696		68,478
Total current assets		1,396,502		1,467,579
Non-current marketable securities		619,441		637,291
Property and equipment, net		115,030		119,391
Deferred tax assets, net		419,045		420,027
Goodwill		63,684		63,684
Right-of-use assets and other non-current assets		223,545		239,718
Total assets	\$	2,837,247	\$	2,947,690
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	\$	42,840	\$	38,191
Accrued compensation and benefits		89,747		109,830
Accrued clinical trial liabilities		57,635		57,976
Rebates and fees due to customers		57,840		62,376
Accrued collaboration liabilities		25,489		40,384
Other current liabilities		125,551		95,012
Total current liabilities		399,102		403,769
Non-current operating lease liabilities		187,125		190,823
Other non-current liabilities		119,996		108,895
Total liabilities		706,223		703,487
Commitments and contingencies (Note 11)	<u> </u>			
Stockholders' equity:				
Preferred stock, \$0.001 par value, 10,000 shares authorized and no shares issued		_		_
Common stock, \$0.001 par value; 400,000 shares authorized; issued and outstanding: 275,033 and 281,732 at March 31, 2025, and December 31, 2024, respectively		275		282
Additional paid-in-capital		2,292,033		2,343,915
Accumulated other comprehensive income (loss)		2,010		(1,347)
Accumulated deficit		(163,294)		(98,647)
Total stockholders' equity		2,131,024		2,244,203
Total liabilities and stockholders' equity	\$	2,837,247	\$	2,947,690

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

The accompanying notes are an integral part of these Condensed Consolidated Financial Statements.

EXELIXIS, INC. CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (in thousands) (unaudited)

	Three Months Ended March 31,			
		2025		2024
Net income	\$	159,616	\$	37,317
Other comprehensive income (loss):				
Net unrealized gains (losses) on available-for-sale debt securities, net of tax impact of \$(983) and \$433, respectively		3,357		(1,454)
Comprehensive income	\$	162,973	\$	35,863

EXELIXIS, INC. CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (in thousands) (unaudited)

Three Months Ended March 31, 2025

	Inree Wonths Ended Warch 31, 2025									
	Commo		ock Amount	Addit Paid Cap	l-in	Com	cumulated Other prehensive ome (Loss)	Ac	ccumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2024	281,732	\$	282	\$ 2,34	3,915	\$	(1,347)	\$	(98,647)	\$ 2,244,203
Net income	_		_		_		_		159,616	159,616
Other comprehensive income	_		_		_		3,357		_	3,357
Issuance of common stock under the equity incentive plans	1,362		1	1	1,562		_		_	11,563
Stock transactions associated with taxes withheld on equity awards	_		_	(2	2,506)		_		_	(22,506)
Repurchases of common stock	(8,061)		(8)	(6	7,055)		_		(224,263)	(291,326)
Stock-based compensation	_		_	2	6,117		_		_	26,117
Balance at March 31, 2025	275,033	\$	275	\$ 2,29	2,033	\$	2,010	\$	(163,294)	\$ 2,131,024

	Three Months Ended March 31, 2024														
	Commor		Stock Amount		Additional Paid-in Capital		Accumulated Other Comprehensive Loss		Other Comprehensive		Other Comprehensive		occumulated Deficit	Stoc	Total kholders' Equity
Balance at December 31, 2023	302,793	\$	303	\$ 2	2,440,710	\$	(3,750)	\$	(173,351)	\$ 2,	,263,912				
Net income	_		_		_		_		37,317		37,317				
Other comprehensive loss	_		_		_		(1,454)		_		(1,454)				
Issuance of common stock under the equity incentive plans	877		1		8,437		_		_		8,438				
Stock transactions associated with taxes withheld on equity awards	_		_		(6,994)		_		_		(6,994)				
Repurchases of common stock	(8,638)		(9)		(69,618)		_		(122,914)	(192,541)				
Stock-based compensation	_		_		19,330		_		_		19,330				
Balance at March 31, 2024	295,032	\$	295	\$ 2	2,391,865	\$	(5,204)	\$	(258,948)	\$ 2,	,128,008				

EXELIXIS, INC. CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (in thousands) (unaudited)

	Three Months Ended March 31,			
		2025	2024	
Net income	\$	159,616	37,317	
Adjustments to reconcile net income to net cash provided by operating activities:				
Depreciation and amortization		7,345	6,378	
Stock-based compensation		25,930	19,113	
Non-cash lease expense		6,096	6,764	
Acquired in-process research and development technology		_	19,500	
Other, net		(4,786)	9,206	
Changes in operating assets and liabilities:				
Trade receivables, net		(16,119)	(3,170)	
Inventory		(71)	1,715	
Prepaid expenses and other assets		20,320	10,075	
Accrued collaboration liabilities		4,605	(3,829)	
Accounts payable and other liabilities		8,501	(34,247)	
Net cash provided by operating activities		211,437	68,822	
Cash flows from investing activities:				
Purchases of marketable securities		(186,701)	(138,468)	
Proceeds from maturities and sales of marketable securities		258,917	268,452	
Purchases of property, equipment and other, net		(2,952)	(9,691)	
Acquired in-process research and development technology		(19,500)	(8,500)	
Net cash provided by investing activities		49,764	111,793	
Cash flows from financing activities:				
Payments for repurchases of common stock		(283,934)	(185,375)	
Proceeds from issuance of common stock under the equity incentive plans		11,627	8,315	
Taxes paid related to net share settlement of equity awards		(22,516)	(6,988)	
Net cash used in financing activities		(294,823)	(184,048)	
Net decrease in cash and cash equivalents		(33,622)	(3,433)	
Cash and cash equivalents at beginning of period		217,374	262,994	
Cash and cash equivalents at end of period	\$	183,752	259,561	

EXELIXIS, INC. NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

NOTE 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization

Exelixis, Inc. (Exelixis, we, our or us) is an oncology company innovating next-generation medicines and combination regimens at the forefront of cancer care. We have produced four marketed pharmaceutical products, two of which are formulations of our flagship molecule, cabozantinib, and we are steadily advancing and evolving our product pipeline portfolio, including our lead asset zanzalintinib, currently the focus of an extensive phase 3 clinical development program. With a rational and disciplined approach to investment, we are leveraging our internal experience and expertise, and the strength of strategic partnerships, to identify and pursue opportunities across the landscape of scientific modalities, including small molecules, biotherapeutics and antibody-drug conjugates.

Sales related to cabozantinib account for the majority of our revenues. Cabozantinib is an inhibitor of multiple tyrosine kinases, including MET, AXL, VEGF receptors and RET and has been approved by the U.S. Food and Drug Administration (FDA) and in other countries as CABOMETYX® (cabozantinib) tablets for: advanced renal cell carcinoma (both alone and in combination with Bristol-Myers Squibb Company's nivolumab (OPDIVO®)), previously treated hepatocellular carcinoma, previously treated, radioactive iodine-refractory differentiated thyroid cancer, and previously treated, unresectable, locally advanced or metastatic, well-differentiated pancreatic neuroendocrine tumors and extra-pancreatic neuroendocrine tumors; and as COMETRIQ® (cabozantinib) capsules for progressive, metastatic medullary thyroid cancer. For physicians treating these types of cancer, cabozantinib has become or is becoming an important medicine in their selection of effective therapies.

The other two products resulting from our discovery efforts are: COTELLIC® (cobimetinib), an inhibitor of MEK approved as part of multiple combination regimens to treat specific forms of advanced melanoma and marketed under a collaboration with Genentech, Inc. (a member of the Roche Group) (Genentech); and MINNEBRO® (esaxerenone), an oral, non-steroidal, selective blocker of the mineralocorticoid receptor, approved for the treatment of hypertension in Japan and licensed to Daiichi Sankyo Company, Limited.

Basis of Presentation

The accompanying unaudited Condensed Consolidated Financial Statements include the accounts of Exelixis and those of our wholly owned subsidiaries. These entities' functional currency is the U.S. dollar. All intercompany balances and transactions have been eliminated.

We have adopted a 52- or 53-week fiscal year policy that generally ends on the Friday closest to December 31. Fiscal year 2025, which is a 52-week fiscal year, will end on January 2, 2026 and fiscal year 2024, which was a 53-week fiscal year, ended on January 3, 2025. For convenience, references in this report as of and for the fiscal periods ended April 4, 2025 and March 29, 2024, and as of and for the fiscal years ending January 2, 2026 and ended January 3, 2025, are indicated as being as of and for the periods ended March 31, 2025 and March 31, 2024, and the years ending December 31, 2025 and ended December 31, 2024, respectively.

The accompanying Condensed Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the U.S. for interim financial information and pursuant to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (SEC). Accordingly, they do not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements. In our opinion, all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation of our financial statements for the periods presented have been included. Operating results for the three months ended March 31, 2025 are not necessarily indicative of the results that may be expected for the year ending December 31, 2025 or for any future period. The accompanying Condensed Consolidated Financial Statements and Notes thereto should be read in conjunction with our Consolidated Financial Statements and Notes thereto for the fiscal year ended December 31, 2024, included in Part II, Item 8 of our Annual Report on Form 10-K, filed with the SEC on February 11, 2025 (Fiscal 2024 Form 10-K).

Use of Estimates

The preparation of the accompanying Condensed Consolidated Financial Statements conforms to accounting principles generally accepted in the U.S., which requires management to make judgments, estimates and assumptions that affect the reported amounts of assets, liabilities, equity, revenues and expenses and related disclosures. On an ongoing basis, we evaluate our significant estimates. We base our estimates on historical experience and on various other market-specific and other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ materially from those estimates.

Reclassifications

Certain prior period amounts in the accompanying Condensed Consolidated Financial Statements have been reclassified to conform to the current period presentation. Such reclassifications did not impact previously reported total revenues, income from operations, net income, total assets, total liabilities or total stockholders' equity.

Significant Accounting Policies

There have been no material changes to our significant accounting policies during the three months ended March 31, 2025, as compared to the significant accounting policies disclosed in "Note 1. Organization and Summary of Significant Accounting Policies" of the "Notes to Consolidated Financial Statements" included in Part II, Item 8 of our Fiscal 2024 Form 10-K.

Recently Adopted Accounting Pronouncements

There were no new accounting pronouncements adopted by us since our filing of the Fiscal 2024 Form 10-K, which could have a significant effect on our Condensed Consolidated Financial Statements.

Recent Accounting Pronouncements Not Yet Adopted

In December 2023, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* (ASU 2023-09), which enhances the disclosures required for income taxes in our annual consolidated financial statements. ASU 2023-09 is effective for us in our annual reporting for fiscal 2025 on a prospective basis. Early adoption and retrospective reporting are permitted. We are currently evaluating the impact of ASU 2023-09 on our Consolidated Financial Statements.

In November 2024, the FASB issued ASU 2024-03, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures* (Subtopic 220-40): Disaggregation of Income Statement Expenses (ASU 2024-03), which enhances the disclosures required for expense disaggregation in our annual and interim consolidated financial statements. In January 2025, the FASB issued ASU 2025-01, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures* (Subtopic 220-40) – Clarifying the effective Date (ASU 2025-01), which clarifies the effective date of ASU 2024-03 for companies with a non-calendar year end. ASU 2024-03 is effective for us in our annual reporting for fiscal year 2027, and in our interim periods beginning in fiscal year 2028. Early adoption and retrospective application are permitted. We are currently evaluating the impact of ASU 2024-03 on our Consolidated Financial Statements.

NOTE 2. SEGMENT REPORTING

We operate in one business segment that focuses on the discovery, development and commercialization of new medicines for difficult-to-treat cancers. Our President and Chief Executive Officer, as the chief operating decision-maker, manages and allocates resources to our operations on a total consolidated basis. Consistent with this decision-making process, our President and Chief Executive Officer uses net income to monitor budget versus actual results for purposes of evaluating performance and to make decisions about the allocation of resources.

Our significant segment expenses that are regularly provided to our President and Chief Executive Officer and included in the measure of segment net income consist of consolidated expenses for our operational departments: drug discovery, development, and selling, general and administrative and other segment items.

The segment and consolidated net income, including significant segment expenses were as follows (in thousands):

	Three Months Ended March 31,			
	 2025	2024		
Revenues	\$ 555,447 \$	425,226		
Less:				
Cost of goods sold	19,172	21,256		
Drug discovery	18,253	22,490		
Development	153,217	172,887		
Selling, general, and administrative	120,775	98,763		
Other segment items ⁽¹⁾	57,416	80,457		
Interest income	(19,076)	(19,894)		
Provision for income taxes	46,074	11,950		
Segment and consolidated net income	\$ 159,616 \$	37,317		

⁽¹⁾ Other segment items include stock-based compensation, restructuring expenses, other research and development expenses including the allocation of general corporate costs to research and development services and development cost reimbursements in connection with certain of our collaboration arrangements, and other expenses, net.

All of our long-lived assets are located in the U.S. See "Note 3. Revenues" for enterprise-wide disclosures about product sales, revenues from major customers and revenues by geographic region.

NOTE 3. REVENUES

Revenues consisted of the following (in thousands):

	Three Months Ended March 31,			
	 2025		2024	
Product revenues:				
Gross product revenues	\$ 721,711	\$	563,785	
Discounts and allowances	(208,428)		(185,262)	
Net product revenues	513,283		378,523	
Collaboration revenues:				
License revenues	42,480		44,676	
Collaboration services revenues	(316)		2,027	
Collaboration revenues	42,164		46,703	
Total revenues	\$ 555,447	\$	425,226	

The percentage of total revenues by customer who individually accounted for 10% or more of our total revenues were as follows:

	Three Months Endo	Three Months Ended March 31,			
	2025	2024			
Affiliates of Cencora, Inc.	23 %	19 %			
Affiliates of McKesson Corporation	18 %	18 %			
Affiliates of CVS Health Corporation	14 %	17 %			
Accredo Health, Incorporated	12 %	12 %			
Affiliates of Optum Specialty Pharmacy	10 %	10 %			

The percentage of trade receivables by customer who individually accounted for 10% or more of our trade receivables were as follows:

	March 31, 2025	December 31, 2024
Affiliates of Cencora, Inc.	26 %	17 %
Affiliates of McKesson Corporation	24 %	23 %
Ipsen Pharma SAS	16 %	18 %
Cardinal Health, Inc.	12 %	10 %
Affiliates of CVS Health Corporation	10 %	20 %

Total revenues by geographic region were as follows (in thousands):

		Three Months Ended March 31,						
	_	2025	2024					
U.S.	\$	517,184	\$ 381,937					
Europe		32,706	35,703					
Japan		5,557	7,586					
Total revenues	\$	555,447	\$ 425,226					

Total revenues include net product revenues attributed to geographic regions based on the ship-to location and license and collaboration services revenues attributed to geographic regions based on the location of our collaboration partners' headquarters.

Net product revenues and license revenues are recorded in accordance with Accounting Standards Codification (ASC) Topic 606, Revenue from Contracts with Customers (Topic 606). License revenues include the recognition of the portion of milestone payments allocated to the transfer of intellectual property licenses for which it had become probable in the current period that the milestone would be achieved and a significant reversal of revenues would not occur, as well as royalty revenues and our share of profits under our collaboration agreement with Genentech. Collaboration services revenues are recorded in accordance with ASC Topic 808, Collaborative Arrangements. Collaboration services revenues include the recognition of deferred revenues for the portion of upfront and milestone payments allocated to our research and development services performance obligations, development cost reimbursements earned under our collaboration agreements, product supply revenues, net of product supply costs and the royalties we paid on sales of products containing cabozantinib by our collaboration partners. License revenues and collaboration services revenues are presented in collaboration revenues in the accompanying Condensed Consolidated Statements of Income.

Net product revenues by product were as follows (in thousands):

	Three Months I	nded M	larch 31,
	 2025		2024
CABOMETYX	\$ 510,872	\$	376,417
COMETRIQ	2,411		2,106
Net product revenues	\$ 513,283	\$	378,523

Product Sales Discounts and Allowances

The activities and ending reserve balances for each significant category of discounts and allowances (which constitute variable consideration) were as follows (in thousands):

	Chargebacks, Discounts for Prompt Payment and Other			Other Customer redits/Fees and Co- pay Assistance	Rebates			Total
Balance at December 31, 2024	\$	25,267	\$	24,945	\$	37,431	\$	87,643
Provision related to sales made in:								
Current period		146,344		19,508		51,313		217,165
Prior periods		(4,271)		(2,139)		(2,327)		(8,737)
Payments and customer credits issued		(135,019)		(23,177)		(47,714)		(205,910)
Balance at March 31, 2025	\$	32,321	\$	19,137	\$	38,703	\$	90,161

The allowance for chargebacks, discounts for prompt payment and other are recorded as a reduction of trade receivables, net, and the remaining reserves are recorded as rebates and fees due to customers in the accompanying Condensed Consolidated Balance Sheets.

Contract Assets and Liabilities

We receive payments from our collaboration partners based on billing schedules established in each contract. Amounts are recorded as accounts receivable when our right to consideration is unconditional. We may also recognize revenue in advance of the contractual billing schedule and such amounts are recorded as a contract asset when recognized. We may be required to defer recognition of revenue for upfront and milestone payments until we perform our obligations under these arrangements, and such amounts are recorded as deferred revenue upon receipt or when due. For those contracts that have multiple performance obligations, contract assets and liabilities are reported on a net basis at the contract level. Contract assets are primarily related to Ipsen Pharma SAS (Ipsen) and contract liabilities are primarily related to deferred revenues from Takeda Pharmaceutical Company Limited (Takeda).

Contract assets and liabilities were as follows (in thousands):

	 March 31, 2025	December 31, 2024		
Contract assets ⁽¹⁾	\$ 326	\$	369	
Contract liabilities:				
Current portion ⁽²⁾	\$ 2,874	\$	2,739	
Non-current portion ⁽³⁾	 3,086		3,392	
Total contract liabilities	\$ 5,960	\$	6,131	

⁽¹⁾ Presented in right-of-use assets and other non-current assets in the accompanying Condensed Consolidated Balance Sheets.

During the three months ended March 31, 2025 and 2024, we recognized \$1.3 million and \$1.6 million, respectively, in revenues that were included in the beginning deferred revenues balance for those periods.

During the three months ended March 31, 2025 and 2024, we recognized \$42.5 million and \$45.9 million, respectively, in revenues for performance obligations satisfied in previous periods. Such revenues were primarily related to the recognition of license revenues for the achievement of milestones and royalty payments allocated to our license performance obligations for our collaborations with Ipsen and Takeda.

⁽²⁾ Presented in other current liabilities in the accompanying Condensed Consolidated Balance Sheets.

⁽³⁾ Presented in other non-current liabilities in the accompanying Condensed Consolidated Balance Sheets.

As of March 31, 2025, \$38.2 million of the combined transaction prices for our Ipsen and Takeda collaborations were allocated to research and development services performance obligations that had not yet been satisfied. See "Note 4. Collaboration Agreements and Business Development Activities" of the "Notes to Consolidated Financial Statements" included in Part II, Item 8 of our Fiscal 2024 Form 10-K for additional information about the expected timing to satisfy these performance obligations.

NOTE 4. COLLABORATION AGREEMENTS AND BUSINESS DEVELOPMENT ACTIVITIES

We have established multiple collaborations with leading biopharmaceutical companies for the commercialization and further development of our cabozantinib franchise. Additionally, we have made considerable progress under our existing research collaboration and in-licensing arrangements to further enhance our early-stage pipeline and expand our ability to discover, develop and commercialize novel therapies with the goal of providing new treatment options for cancer patients. Historically, we also entered into other collaborations with leading biopharmaceutical companies pursuant to which we outlicensed other compounds and programs in our portfolio.

See "Note 4. Collaboration Agreements and Business Development Activities" of the "Notes to Consolidated Financial Statements" included in Part II, Item 8 of our Fiscal 2024 Form 10-K, as further described below, for additional information on certain of our collaboration agreements and in-licensing arrangements.

Cabozantinib Commercial Collaborations

Ipsen Collaboration

In February 2016, we entered into a collaboration and license agreement with Ipsen, which was subsequently amended, for the commercialization and further development of cabozantinib. Under the collaboration agreement, as amended, Ipsen received exclusive commercialization rights for current and potential future cabozantinib indications outside of the U.S. and Japan. We have also agreed to collaborate with Ipsen on the development of cabozantinib for current and potential future indications. The parties' efforts are governed through a joint steering committee and appropriate subcommittees established to guide and oversee the collaboration's operation and strategic direction; provided, however, that we retain final decision-making authority with respect to cabozantinib's ongoing development.

Revenues under the collaboration agreement with Ipsen were as follows (in thousands):

		Three Months Ended March 31,						
	2025			2024				
License revenues	\$	33,979	\$	36,861				
Collaboration services revenues		(1,273)		(1,158)				
Total collaboration revenues	\$	32,706	\$	35,703				

Takeda Collaboration

In January 2017, we entered into a collaboration and license agreement with Takeda, which was subsequently amended, for the commercialization and further development of cabozantinib. Under the collaboration agreement, as amended, Takeda received exclusive commercialization rights for current and potential future cabozantinib indications in Japan, and the parties have agreed to collaborate on the clinical development of cabozantinib in Japan. The operation and strategic direction of the parties' collaboration is governed through a joint executive committee and appropriate subcommittees.

Revenues under the collaboration agreement with Takeda were as follows (in thousands):

	Three Months Ended March 31,						
	2025						
License revenues	\$ 2,759	\$ 2,710					
Collaboration services revenues	957	3,185					
Total collaboration revenues	\$ 3,716	\$ 5,895					

Royalty Pharma

In October 2002, we established a product development and commercialization collaboration agreement with GlaxoSmithKline (now GSK plc, or GSK), that required us to pay a 3% royalty to GSK on the worldwide net sales of any product containing cabozantinib sold by us and our collaboration partners. Effective January 1, 2021, Royalty Pharma plc (Royalty Pharma) acquired from GSK all rights, title and interest in royalties on net product sales containing cabozantinib for non-U.S. markets for the full term of the royalty and for the U.S. market through September 2026, after which time U.S. royalties will revert back to GSK. Royalty fees earned by Royalty Pharma in connection with our sales of cabozantinib are included in cost of goods sold and as a reduction of collaboration services revenues for sales by our collaboration partners. Such royalty fees earned by Royalty Pharma were \$20.4 million and \$16.7 million during the three months ended March 31, 2025 and 2024, respectively.

Research Collaborations, In-Licensing Arrangements and Other Business Development Activities

We enter into collaborative arrangements with other pharmaceutical or biotechnology companies to develop and commercialize oncology assets or other intellectual property. Our research collaborations and in-licensing arrangements are intended to enhance our early-stage pipeline and expand our ability to discover, develop and commercialize novel therapies with the goal of providing new treatment options for cancer patients. Our research collaborations, in-licensing arrangements and other strategic transactions generally include upfront payments for the purchase or in-licensing of intellectual property, development, regulatory and commercial milestone payments and royalty payments, in each case contingent upon the occurrence of certain future events linked to the success of the asset in development. Certain of our research collaborations provide us exclusive options that give us the right to license programs or acquire the intellectual property developed under the research collaborations for further discovery and development. When we decide to exercise the options, we are required to pay an exercise fee and then assume the responsibilities for all subsequent development, manufacturing and commercialization.

During the three months ended March 31, 2025 and 2024, we recognized \$5.3 million and \$22.8 million, respectively, within research and development expenses on the Condensed Consolidated Statements of Income, primarily related to development milestone payments for the costs of intellectual property that have not yet achieved technological feasibility, research and development funding and other fees.

As of March 31, 2025, in conjunction with the active collaborative in-licensing arrangements and asset purchase agreements, we are subject to potential future development milestone payments of up to \$441.5 million, regulatory milestone payments of up to \$278.0 million and commercial milestone payments of up to \$2.4 billion, each in the aggregate per product or target, as well as royalties on future net sales of products.

NOTE 5. CASH AND MARKETABLE SECURITIES

Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities consisted of the following (in thousands):

	March 31, 2025							
	Amortized Cost		G	Gross Unrealized Gross Unrealized Gains Losses				Fair Value
Debt securities available-for-sale:				_				
Commercial paper	\$	138,468	\$	_	\$	_	\$	138,468
Corporate bonds		1,054,588		3,125		(781)		1,056,932
U.S. Treasury and government-sponsored enterprises		260,693		759		(177)		261,275
Municipal bonds		2,990		23		_		3,013
Total debt securities available-for-sale		1,456,739		3,907		(958)		1,459,688
Money market funds		126,114		_		_		126,114
Certificates of deposit		64,955		_		_		64,955
Total cash, cash equivalents and marketable securities	\$	1,647,808	\$	3,907	\$	(958)	\$	1,650,757

Total

December 31, 2024 **Gross Unrealized Gross Unrealized Amortized Cost** Gains Losses **Fair Value** Debt securities available-for-sale: \$ \$ Commercial paper 172,891 \$ - \$ 172,891 Corporate bonds 1,012,035 1,498 (2,167)1,011,366 U.S. Treasury and government-sponsored enterprises 226 (959)339,126 338,393 Municipal bonds 2,990 3,001 11 Total debt securities available-for-sale 1,527,042 1,735 1,525,651 (3,126)Money market funds 145,690 145,690 Certificates of deposit 77,226 77,226 \$ 1,749,958 \$ 1.735 \$ (3,126)\$ 1.748.567 Total cash, cash equivalents and marketable securities

Interest receivable was \$12.8 million and \$14.9 million as of March 31, 2025 and December 31, 2024, respectively, and is included in prepaid expenses and other current assets in the accompanying Condensed Consolidated Balance Sheets.

Realized gains and losses on the sales of marketable securities were immaterial during the three months ended March 31, 2025 and 2024.

We manage credit risk associated with our marketable securities portfolio through our investment policy, which limits purchases to high-quality issuers and the amount of our portfolio that can be invested in a single issuer. The fair value and gross unrealized losses on debt securities available-for-sale in an unrealized loss position were as follows (in thousands):

						March 3	31, 20)25					
	In ar	In an Unrealized Loss Position Less than 12 Months				In an Unrealized Loss Position 12 Months or Greater				Total			
		Fair Value	Gro	oss Unrealized Losses		Fair Value	Gr	oss Unrealized Losses		Fair Value	Gro	ss Unrealized Losses	
Corporate bonds	\$	257,028	\$	(523)	\$	129,563	\$	(258)	\$	386,591	\$	(781)	
U.S. Treasury and government- sponsored enterprises		35,856		(109)		42,215		(68)		78,071		(177)	

171,778 \$

(326) \$

464,662

(958)

(632) \$

292,884

\$

	December 31, 2024												
	In a	In an Unrealized Loss Position Less than 12 Months				n an Unrealized Loss Position 12 Months or Greater				Total			
		Fair Value	Gre	oss Unrealized Losses		Fair Value	G	ross Unrealized Losses		Fair Value	Gr	oss Unrealized Losses	
Corporate bonds	\$	370,065	\$	(1,630)	\$	160,887	\$	(537)	\$	530,952	\$	(2,167)	
U.S. Treasury and government- sponsored enterprises		125,224		(755)		56,984		(204)		182,208		(959)	
Total	\$	495,289	\$	(2,385)	\$	217,871	\$	(741)	\$	713,160	\$	(3,126)	

There were 171 and 255 debt securities available-for-sale in an unrealized loss position as of March 31, 2025 and December 31, 2024, respectively. During the three months ended March 31, 2025, we did not record an allowance for credit losses or other impairment charges on our marketable securities. Based upon our quarterly impairment review, we determined that the unrealized losses were not attributed to credit risk but were primarily associated with changes in

interest rates and market liquidity. Based on the scheduled maturities of our marketable securities, we determined that it was more likely than not that we will hold these marketable securities for a period of time sufficient for a recovery of our cost basis.

The fair values of debt securities available-for-sale by contractual maturity were as follows (in thousands):

	M	arch 31, 2025	 December 31, 2024
Maturing in one year or less	\$	840,247	\$ 888,360
Maturing after one year through five years		619,441	637,291
Total debt securities available-for-sale	\$	1,459,688	\$ 1,525,651

NOTE 6. FAIR VALUE MEASUREMENTS

Fair value reflects the amounts that would be received upon sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value hierarchy has the following three levels:

- Level 1 quoted prices (unadjusted) in active markets for identical assets and liabilities;
- Level 2 inputs other than Level 1 that are observable either directly or indirectly, such as quoted prices in active markets for similar instruments or on industry models using data inputs, such as interest rates and prices that can be directly observed or corroborated in active markets; and
- Level 3 unobservable inputs that are supported by little or no market activity that are significant to the fair value measurement.

The classifications within the fair value hierarchy of our financial assets that were measured and recorded at fair value on a recurring basis were as follows (in thousands):

	March 31, 2025						
		Level 1		Level 2		Total	
Commercial paper	\$	_	\$	138,468	\$	138,468	
Corporate bonds		_		1,056,932		1,056,932	
U.S. Treasury and government-sponsored enterprises		_		261,275		261,275	
Municipal bonds		_		3,013		3,013	
Total debt securities available-for-sale		_		1,459,688		1,459,688	
Money market funds		126,114		_		126,114	
Certificates of deposit		_		64,955		64,955	
Total financial assets carried at fair value	\$	126,114	\$	1,524,643	\$	1,650,757	

		December 31, 2024							
	_	Level 1	Level 2		Total				
Commercial paper	\$	_	\$ 172,891	\$	172,891				
Corporate bonds		_	1,011,366		1,011,366				
U.S. Treasury and government-sponsored enterprises		_	338,393		338,393				
Municipal bonds		_	3,001		3,001				
Total debt securities available-for-sale		_	1,525,651		1,525,651				
Money market funds		145,690	_		145,690				
Certificates of deposit	_	_	77,226		77,226				
Total financial assets carried at fair value	\$	145,690	\$ 1,602,877	\$	1,748,567				

When available, we value marketable securities based on quoted prices for those financial instruments, which is a Level 1 input. Our remaining marketable securities are valued using third-party pricing sources, which use observable

market prices, interest rates and yield curves observable at commonly quoted intervals for similar assets as observable inputs for pricing, which is a Level 2 input.

The carrying amount of our remaining financial assets and liabilities, which include receivables and payables, approximate their fair values due to their short-term nature.

Forward Foreign Currency Contracts

We have entered into forward foreign currency exchange contracts that are not designated as hedges for accounting purposes to hedge certain operational exposures for the changes in foreign currency exchange rates associated with assets or liabilities denominated in foreign currencies, primarily the Euro.

As of March 31, 2025, we had one forward contract outstanding to sell €2.2 million. The forward contract with a maturity of three months is recorded at fair value and is included in other current liabilities in the accompanying Condensed Consolidated Balance Sheets. The unrealized loss on the forward contract is immaterial as of March 31, 2025. The forward contract is considered a Level 2 in the fair value hierarchy of our fair value measurements. The net realized gains (losses) we recognized on the maturity of forward contracts were immaterial for each of the three months ended March 31, 2025 and 2024 and are included in other expenses, net on our accompanying Condensed Consolidated Statements of Income.

NOTE 7. INVENTORY

Inventory consisted of the following (in thousands):

	March 31, 2025	December 31, 2024
Raw materials \$	2,529	\$ 2,784
Work in process	57,903	60,316
Finished goods	11,555	8,629
Total \$	71,987	\$ 71,729
Balance Sheet classification:		
Current portion included in inventory \$	24,853	\$ 22,388
Non-current portion included in other non-current assets	47,134	49,341
Total \$	71,987	\$ 71,729

NOTE 8. STOCKHOLDERS' EQUITY

Stock-based Compensation

We have an equity incentive plan under which we granted stock options and restricted stock units (RSUs), including market condition-based RSUs and performance-based RSUs (PSUs) to employees and directors. As of March 31, 2025, 8.3 million shares were available for grant under the Exelixis, Inc. 2017 Equity Incentive Plan (as amended and restated, the 2017 Plan). The share reserve is reduced by 1 share for each share issued pursuant to a stock option and 2 shares for full value awards, including RSUs and PSUs.

We allocated the stock-based compensation for our 2017 Plan and our 2000 Employee Stock Purchase Plan (as amended and restated, the Amended ESPP) as follows (in thousands):

	Three Months Ended March 31,			
		2025		2024
Research and development	\$	9,522	\$	3,892
Selling, general and administrative		16,408		15,221
Total stock-based compensation	\$	25,930	\$	19,113

Stock-based compensation for each type of award under our 2017 Plan and Amended ESPP were as follows (in thousands):

	Three Months Ended March 31,			
		2025		2024
Stock options	\$	1,060	\$	1,738
Restricted stock units		23,102		15,434
Performance stock units		241		727
Employee stock purchase plan		1,527		1,214
Total stock-based compensation	\$	25,930	\$	19,113

As of March 31, 2025, there were 4.0 million stock options outstanding and \$2.8 million of related unrecognized stock-based compensation.

In February 2025, we awarded to certain employees an aggregate of 1.0 million RSUs (the target number) that are subject to a total shareholder return (TSR) market condition and a time-based service condition (the 2025 TSR-based RSUs). The TSR market condition is based on our relative TSR percentile rank compared to companies in the Nasdaq Biotechnology Index during the performance period, which is January 4, 2025 through December 31, 2027. Depending on the results relative to the TSR market condition, the holders of the 2025 TSR-based RSUs may earn up to 175% of the target number of shares. Following achievement of the market condition at the end of the performance period and upon employee's continuous service through the vesting dates, 50% of the shares earned pursuant to the 2025 TSR-based RSUs will vest shortly after the end of the performance period, and the remainder will vest approximately one year later, subject to an employee's continuous service. These 2025 TSR-based RSUs will be forfeited if the market condition at or above a threshold level is not achieved, and/or the time-based service condition is not fulfilled, by the end of the performance period and through the vesting dates.

In March 2025, we awarded to employees an aggregate of 6.9 million RSUs that are subject to a stock price appreciation market condition and a time-based service condition (the 2025 stock price target-based RSUs). The market condition will be satisfied to the extent that the volume-weighted average closing price of our common stock for any consecutive 90-calendar-day period equals or exceeds \$60 per share on any day during the five-year performance period. Following achievement of the market condition, the 2025 stock price target-based RSUs will vest upon employee's continuous service through the end of the performance period on March 31, 2030 (the time-based service condition). The 2025 stock price target-based RSUs will be forfeited if the market condition at or above the target price is not achieved, and/or the time-based service condition is not fulfilled, by the end of the performance period.

We used a Monte Carlo simulation model and the following assumptions to determine the grant date fair value of \$47.58 per share for the 2025 TSR-based RSUs and \$25.10 per share for the 2025 stock price target-based RSUs:

	2025 TSI	R-based RSUs	2025 stock price target- based RSUs
Fair value of Exelixis common stock on grant date	\$	37.53	\$ 36.92
Expected volatility		32.63 %	38.31 %
Risk-free interest rate		4.0 %	3.92 %
Dividend yield		- %	- %

The Monte Carlo simulation model for our 2025 TSR-based RSUs assumed correlations of returns of the stock prices of Exelixis common stock and the common stock of a peer group of companies and historical stock price volatility of the peer group of companies. The valuation model also used terms based on the length of the performance period and compound annual growth rate goals for TSR based on the provisions of the awards. The Monte Carlo simulation model for our 2025 stock price target-based RSUs assumed historical stock price volatility and compounded risk-free rate over the length of the performance period. Stock-based compensation related to RSUs with a market condition is recognized regardless of the outcome of the market condition.

During the three months ended March 31, 2025, we granted 2.1 million service-based RSUs with a weighted- average grant date fair value of \$37.20 per share. As of March 31, 2025, there were 22.6 million RSUs outstanding, including RSUs that are subject to market conditions, and \$435.3 million of related unrecognized stock-based compensation. Service-based RSUs granted to employees during the three months ended March 31, 2025, have vesting conditions and contractual lives of a similar nature to those described in "Note 9. Stockholders' Equity" of the "Notes to Consolidated Financial Statements" included in Part II, Item 8 of our Fiscal 2024 Form 10-K.

Common Stock Repurchases

In August 2024, our Board of Directors authorized a stock repurchase program to acquire up to \$500.0 million of our outstanding common stock before December 31, 2025. In February 2025, our Board of Directors authorized the repurchase of up to an additional \$500.0 million of our outstanding common stock before December 31, 2025. Under these programs, as of March 31, 2025, we repurchased 14.2 million shares of common stock for an aggregate purchase price of \$494.5 million. As of March 31, 2025, approximately \$505.5 million remained available for future stock repurchases before December 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, Rule 10b5-1 trading plans, 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. The programs do not obligate us to acquire any amount of our common stock, and the stock repurchase programs may be modified, suspended or discontinued at any time without prior notice.

NOTE 9. PROVISION FOR INCOME TAXES

The effective tax rate for the three months ended March 31, 2025 was 22.4%, as compared to 24.3% for the corresponding period in 2024. The effective tax rate for the three months ended March 31, 2025, differed from the U.S. federal statutory tax rate of 21%, primarily due to state taxes, partially offset by excess tax benefits related to certain stock grants and the generation of federal tax credits. The effective tax rate for the three months ended March 31, 2024, differed from the U.S. federal statutory tax rate of 21%, primarily due to state taxes and interest on uncertain tax positions, offset by the generation of federal tax credits.

NOTE 10. NET INCOME PER SHARE

Net income per share — basic and diluted, were computed as follows (in thousands, except per share amounts):

		Three Months Ended March 31,			
	2025			2024	
Numerator:					
Net income	\$	159,616	\$	37,317	
Denominator:					
Weighted-average common shares outstanding — basic		278,804		300,757	
Dilutive securities		9,373		4,773	
Weighted-average common shares outstanding — diluted		288,177		305,530	
	_				
Net income per share — basic	\$	0.57	\$	0.12	
Net income per share — diluted	\$	0.55	\$	0.12	

Basic net income per share is computed using the weighted-average number of common shares outstanding during the periods. The diluted net income per share is computed using the weighted-average number of common shares outstanding and dilutive potential common shares outstanding during the periods. Dilutive common shares outstanding includes the dilutive effect of in-the-money options, unvested RSUs (including market conditions-based RSUs), unvested PSUs when the performance condition is met and ESPP contributions. The dilutive effect of such equity awards is calculated based on the average share price for each fiscal period using the treasury stock method.

Certain potential common shares were excluded from our calculation of weighted-average common shares outstanding — diluted because either they would have had an anti-dilutive effect on net income per share or they were related to shares from PSUs that were contingently issuable, and the contingency had not been satisfied at the end of the reporting period.

The weighted-average potential common shares excluded from our calculation were as follows (in thousands):

	Three Months E	nded March 31,
	2025	2024
Anti-dilutive securities and contingently issuable shares excluded	1,546	8,893

NOTE 11. COMMITMENTS AND CONTINGENCIES

Legal Proceedings

MSN ANDA Litigation

In September 2019, we received a notice letter regarding an Abbreviated New Drug Application (ANDA) submitted to the FDA by MSN Pharmaceuticals, Inc. (individually and collectively with certain of its affiliates, including MSN Laboratories Private Limited, referred to as MSN), requesting approval to market a generic version of CABOMETYX tablets. MSN's initial notice letter included a Paragraph IV certification with respect to our U.S. Patents No. 8,877,776 (salt and polymorphic forms), 9,724,342 (formulations), 10,034,873 (methods of treatment) and 10,039,757 (methods of treatment), which are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations, also referred to as the Orange Book, for CABOMETYX. MSN's initial notice letter did not provide a Paragraph IV certification against U.S. Patents No. 7,579,473 (composition of matter) or 8,497,284 (methods of treatment), each of which is listed in the Orange Book. On October 29, 2019, we filed a complaint in the United States District Court for the District of Delaware (the Delaware District Court) for patent infringement against MSN asserting infringement of U.S. Patent No. 8,877,776 arising from MSN's ANDA filing with the FDA. On November 20, 2019, MSN filed its response to the complaint, alleging that the asserted claims of U.S. Patent No. 8,877,776 are invalid and not infringed. On May 5, 2020, we received notice from MSN that it had amended its ANDA to include additional Paragraph IV certifications and to request approval to market a generic version of CABOMETYX tablets prior to expiration of the two previously unasserted CABOMETYX patents: U.S. Patents No. 7,579,473 and 8,497,284. On May 11, 2020, we filed a complaint in the Delaware District Court for patent infringement against MSN asserting infringement of U.S. Patents No. 7,579,473 and 8,497,284, and on May 22, 2020, MSN filed its response, alleging that the asserted claims of these U.S. Patents are invalid and not infringed. On March 23, 2021, MSN filed its First Amended Answer and Counterclaims (amending its prior filing from May 22, 2020), seeking, among other things, a declaratory judgment that U.S. Patent No. 9,809,549 (salt and polymorphic forms) is invalid and would not be infringed by MSN if its generic version of CABOMETYX tablets were approved by the FDA. U.S. Patent No. 9,809,549 is not listed in the Orange Book. On April 7, 2021, we filed our response to MSN's First Amended Answer and Counterclaims, denying, among other things, that U.S. Patent No. 9,809,549 is invalid or would not be infringed. The two lawsuits comprising this litigation (collectively referred to as MSN I), numbered Civil Action Nos. 19-02017 and 20-00633, were consolidated in April 2021.

A bench trial for MSN I occurred in May 2022, and on January 19, 2023, the Delaware District Court issued a ruling rejecting MSN's invalidity challenge to U.S. Patent No. 7,759,473. The Delaware District Court also ruled that MSN's proposed ANDA product does not infringe U.S. Patent No. 8,877,776. In accordance with these rulings, the Delaware District Court entered judgment that the effective date of any final FDA approval of MSN's ANDA shall not be a date earlier than August 14, 2026, the expiration date of U.S. Patent No. 7,759,473. Final judgment was entered on January 30, 2023. This ruling in MSN I did not impact our separate MSN II lawsuit (as defined below).

On January 11, 2022, we received notice from MSN that it had further amended its ANDA to assert additional Paragraph IV certifications. In particular, the January 11, 2022 amended ANDA requested approval to market a generic version of CABOMETYX tablets prior to expiration of three previously-unasserted CABOMETYX patents that are now listed in

the Orange Book: U.S. Patents No. 11,091,439 (crystalline salt forms), 11,091,440 (pharmaceutical composition) and 11,098,015 (methods of treatment). On February 23, 2022, we filed a complaint in the Delaware District Court for patent infringement against MSN asserting infringement of U.S. Patents No. 11,091,439, 11,091,440 and 11,098,015 arising from MSN's further amendment of its ANDA filing with the FDA. On February 25, 2022, MSN filed its response to the complaint, alleging that the asserted claims of U.S. Patents No. 11,091,439, 11,091,440 and 11,098,015 are invalid and not infringed. On June 7, 2022, we received notice from MSN that it had further amended its ANDA to assert an additional Paragraph IV certification. As currently amended, MSN's ANDA now requests approval to market a generic version of CABOMETYX tablets prior to expiration of a previously-unasserted CABOMETYX patent that is now listed in the Orange Book: U.S. Patent No. 11,298,349 (pharmaceutical composition). On July 18, 2022, we filed a complaint in the Delaware District Court for patent infringement against MSN asserting infringement of U.S. Patent No. 11,298,349 arising from MSN's further amendment of its ANDA filing with the FDA. On August 9, 2022, MSN filed its response to the complaint, alleging that the asserted claims of U.S. Patent No. 11,298,349 are invalid and not infringed and amended its challenges to U.S. Patents No. 11,091,439, 11,091,440 and 11,098,015 to allege that these patents are not enforceable based on equitable grounds. The two lawsuits comprising this litigation (collectively referred to as MSN II), numbered Civil Action Nos. 22-00228 and 22-00945, were consolidated in October 2022 and involve Exelixis patents that are different from those asserted in the MSN I litigation described above.

On June 21, 2022, pursuant to a stipulation between us and MSN, the Delaware District Court entered an order that (i) MSN's submission of its ANDA constitutes infringement of certain claims relating to U.S. Patents No. 11,091,439, 11,091,440 and 11,098,015, if those claims are not found to be invalid, and (ii) upon approval, MSN's commercial manufacture, use, sale or offer for sale within the U.S., and importation into the U.S., of MSN's proposed ANDA product prior to the expiration of U.S. Patents No. 11,091,439, 11,091,440 and 11,098,015 would also infringe certain claims of each patent, if those claims are not found to be invalid. In our MSN II complaints, we sought, among other relief, an order that the effective date of any FDA approval of MSN's ANDA would be a date no earlier than the expiration of all of U.S. Patents No. 11,091,439, 11,091,440, 11,098,015 and 11,298,349, the latest of which expires on February 10, 2032, and equitable relief enjoining MSN from infringing these patents. On September 28, 2023, the Delaware District Court granted the parties' stipulation of dismissal of MSN's equitable defenses and counterclaims. A bench trial occurred in October 2023, and on October 15, 2024, the Delaware District Court issued a ruling rejecting MSN's invalidity challenge to each of U.S. Patents No. 11,091,439, 11,091,440 and 11,098,015. The Delaware District Court also ruled that our U.S. Patent No. 11,298,349 is not invalid and that MSN's proposed ANDA product does not infringe this patent. In accordance with these rulings, the Delaware District Court entered final judgment on October 23, 2024, that, should the FDA ultimately approve MSN's ANDA, the effective date of any such approval of MSN's ANDA shall not be a date earlier than January 15, 2030, the expiration date of each of U.S. Patents No. 11,091,439, 11,091,440 and 11,098,015, subject to our potential additional regulatory exclusivity.

On November 22, 2024, MSN noticed an appeal to the Court of Appeals for the Federal Circuit and we noticed a cross-appeal on November 26, 2024. On April 1, 2025, MSN filed its Opening Brief arguing that the asserted claims of U.S. Patents No. 11,091,439, 11,091,440, 11,098,015, and 11,298,349 are invalid. Our response (including any cross-appeal) is currently due July 11, 2025. We are currently evaluating next steps with respect to this litigation.

In February 2025, we received another notice letter from MSN regarding its ANDA, requesting FDA approval to market a generic version of CABOMETYX tablets. MSN's notice letter included a Paragraph IV certification with respect to Orange Book-listed patent U.S. Patent No. 12,128,039 (low impurity), which expires in 2032. On March 19, 2025, we filed a complaint in the Delaware District Court for patent infringement against MSN asserting infringement of U.S. Patent No. 12,128,039 arising from MSN's further amendment of its ANDA filing with the FDA. On April 10, 2025, MSN filed its response to the complaint, alleging that the asserted claims of U.S. Patent No. 12,128,039 are invalid, unenforceable, and not infringed.

Sun ANDA Litigation

On September 17, 2024, we received a notice letter regarding an ANDA submitted to the FDA by Sun Pharmaceutical Industries Ltd. (Sun), requesting approval to market a generic version of CABOMETYX tablets. Sun's notice letter included a Paragraph IV certification with respect to our U.S. Patents No. 8,877,776 (salt and polymorphic forms), 9,724,342 (formulations), 10,034,873 (methods of treatment), 10,039,757 (methods of treatment), 11,091,439 (crystalline salt forms), 11,091,440 (pharmaceutical composition), 11,098,015 (methods of treatment) and 11,298,349 (pharmaceutical composition), which are listed in the Orange Book, for CABOMETYX. On October 30,2024 we filed a complaint in the Delaware District Court for patent infringement against Sun asserting infringement of U.S. Patent Nos. 8,877,776, 11,091,439, 11,091,440, and 11,098,015. On January 22, 2025, Sun filed its response to the complaint, alleging that the

asserted claims of U.S. Patent No. 8,877,776, 11,091,439, 11,091,440, and 11,098,015 are invalid and not infringed. Sun also filed counterclaims that, inter alia, seek a declaratory judgment that Sun's ANDA would not infringe any valid and enforceable claim of U.S. Patent Nos. 8,877,776, 11,091,439, 11,091,440, 11,098,015, 9,724,342, 10,034,873, 10,039,757, and 11,298,349.

In February 2025, we received another notice letter from Sun regarding its ANDA, requesting FDA approval to market a generic version of CABOMETYX tablets. Sun's notice letter included a Paragraph IV certification with respect to Orange Book-listed patent U.S. Patent No. 12,128,039 (low impurity), which expires in 2032. On April 4, 2025, we filed a complaint in the Delaware District Court for patent infringement against Sun asserting infringement of U.S. Patent No. 12,128,039 arising from Sun's amendment of its ANDA filing with the FDA. Trial in this matter has been scheduled for November 2, 2026.

Biocon ANDA Litigation

In March 2025, we received a notice letter regarding an ANDA submitted to the FDA by Biocon Pharma Limited (Biocon), requesting approval to market a generic version of CABOMETYX tablets. Biocon's notice letter included a Paragraph IV certification with respect to our U.S. Patents No. 8,877,776 (salt and polymorphic forms), 9,724,342 (formulations), 10,034,873 (methods of treatment), 10,039,757 (methods of treatment), 11,091,439 (crystalline salt forms), 11,091,440 (pharmaceutical composition), 11,098,015 (methods of treatment), 11,298,349 (pharmaceutical composition), 12,128,039 (low impurity) which are listed in the Orange Book, for CABOMETYX. On April 11, 2025, we filed a complaint in the Delaware District Court for patent infringement against Biocon asserting infringement of U.S. Patent Nos. 8,877,776, 11,091,439, 11,091,440, 11,098,015, and 12,128,039.

Azurity 505(b)(2) NDA Litigation

In March 2025, we received a notice letter regarding a 505(b)(2) New Drug Application (505(b)(2)) submitted to the FDA by Azurity Pharmaceuticals, Inc. (Azurity), requesting approval to market cabozantinib (S)-malate tablets. Azurity's notice letter included a Paragraph IV certification with respect to our U.S. Patents No. 8,877,776 (salt and polymorphic forms), 9,724,342 (formulations), 10,034,873 (methods of treatment), 10,039,757 (methods of treatment), 11,091,439 (crystalline salt forms), 11,091,440 (pharmaceutical composition), 11,098,015 (methods of treatment), 11,298,349 (pharmaceutical composition), 12,128,039 (low impurity) which are listed in the Orange Book, for CABOMETYX. On April 18, 2025, we filed a complaint in the Delaware District Court for patent infringement against Azurity asserting infringement of U.S. Patent Nos. 8,877,776, 11,091,439, 11,091,440, 11,098,015, 11,298,349, and 12,128,039. On April 24, 2025, we filed our First Amended Complaint alleging infringement of the same patents.

Other

On November 18, 2024, Azurity filed a petition seeking *inter partes* review of U.S. Patent No. 11,298,349 (pharmaceutical composition) at the United States Patent and Trademark Office. The proceeding was accorded a filing date of December 12, 2024. We filed our preliminary response on March 11, 2025.

On January 9, 2025, Azurity filed a petition seeking *inter partes* review of U.S. Patent No. 12,128,039 (low impurity) at the United States Patent and Trademark Office. The proceeding was accorded a filing date of March 6, 2025 and we have not yet filed our preliminary response.

The sale of any cabozantinib (S)-malate tablets besides CABOMETYX significantly earlier than CABOMETYX's patent expiration could decrease our revenues derived from the U.S. sales of CABOMETYX and thereby materially harm our business, financial condition and results of operations. It is not possible at this time to determine the likelihood of an unfavorable outcome or estimate of the amount or range of any potential loss.

We may also from time-to-time become a party or subject to various other legal proceedings and claims, either asserted or unasserted, which arise in the ordinary course of business. Some of these proceedings have involved, and may involve in the future, claims that are subject to substantial uncertainties and unascertainable damages.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

This Quarterly Report on Form 10-Q contains forward-looking statements. These statements are based on Exelixis, Inc.'s (Exelixis, we, our or us) current expectations, assumptions, estimates and projections about our business and our industry and involve known and unknown risks, uncertainties and other factors that may cause our company's or our

industry's results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied in, or contemplated by, the forward-looking statements. Our actual results and the timing of events may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such a difference include those discussed in "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, filed with the Securities and Exchange Commission (SEC) on February 11, 2025 (Fiscal 2024 Form 10-K), as supplemented by Part II, Item 1A of this Quarterly Report on Form 10-Q as well as those discussed elsewhere in this report. These and many other factors could affect our future financial and operating results. We undertake no obligation to update any forward-looking statement to reflect events after the date of this report.

This discussion and analysis should be read in conjunction with our condensed consolidated financial statements and accompanying notes included in this report and the consolidated financial statements and accompanying notes thereto included in the Fiscal 2024 Form 10-K.

Overview

We are an oncology company innovating next-generation medicines and combination regimens at the forefront of cancer care. We have produced four marketed pharmaceutical products, two of which are formulations of our flagship molecule, cabozantinib, and we are steadily advancing and evolving our product pipeline portfolio, including our lead asset zanzalintinib, currently the focus of an extensive late-stage clinical development program. With a rational and disciplined approach to investment, we are leveraging our internal experience and expertise, and the strength of strategic partnerships, to identify and pursue opportunities across the landscape of scientific modalities, including small molecules, biotherapeutics and antibody-drug conjugates (ADCs).

Sales related to cabozantinib account for the majority of our revenues. Cabozantinib is an inhibitor of multiple tyrosine kinases, including MET, AXL, VEGF receptors and RET and has been approved by the U.S. Food and Drug Administration (FDA) as CABOMETYX® (cabozantinib) tablets for: advanced renal cell carcinoma (RCC) (both alone and in combination with Bristol-Myers Squibb Company's (BMS) nivolumab (OPDIVO®)), previously treated hepatocellular carcinoma (HCC), previously treated, radioactive iodine (RAI)-refractory differentiated thyroid cancer (DTC), and previously treated, unresectable, locally advanced or metastatic, well-differentiated pancreatic neuroendocrine tumors (pNET) and extra-pancreatic neuroendocrine tumors (epNET); and as COMETRIQ® (cabozantinib) capsules for progressive, metastatic medullary thyroid cancer (MTC). Additionally, CABOMETYX is approved in 68 other countries for all or a combination of the following: advanced RCC, previously treated HCC, and/or previously treated RAI-refractory DTC; and as COMETRIQ for progressive MTC. For physicians treating these types of cancer, cabozantinib has become or is becoming an important medicine in their selection of effective therapies.

The other two products resulting from our discovery efforts are: COTELLIC® (cobimetinib), an inhibitor of MEK, approved as part of multiple combination regimens to treat specific forms of advanced melanoma and marketed under a collaboration with Genentech, Inc. (a member of the Roche Group); and MINNEBRO® (esaxerenone), an oral, non-steroidal, selective blocker of the mineralocorticoid receptor, approved for the treatment of hypertension in Japan and licensed to Daiichi Sankyo Company, Limited.

We plan to continue leveraging our operating cash flows to advance a broad array of diverse biotherapeutics and small molecule programs for the treatment of cancer, as well as to support ongoing company-sponsored and externally sponsored trials evaluating cabozantinib. Furthest along in our pipeline is zanzalintinib, a novel, potent, third-generation oral tyrosine kinase inhibitor (TKI) that targets VEGF receptors, MET and the TAM kinases (TYRO3, AXL and MER). Our zanzalintinib program includes a series of ongoing and planned pivotal trials to explore its therapeutic potential in colorectal cancer (CRC), RCC, squamous cell cancers of the head and neck (SCCHN) and NET, as well as earlier-stage trials. Our other pipeline programs in phase 1 development each have best-in-class potential and include: XL309, a small molecule inhibitor of USP1, which has emerged as a synthetic lethal target in the context of BRCA-mutated tumors; and XB010, an ADC consisting of a MMAE payload conjugated to a human mAb targeting the tumor antigen 5T4. We complement our internal drug discovery and development efforts by in-licensing investigational oncology assets or obtaining options to acquire other investigational oncology assets from third parties if those oncology assets demonstrate evidence of clinical success. Examples of this approach include XL309 and ADU-1805, a clinical-stage and potentially best-in-class human mAb that targets SIRPα.

Cabozantinib Franchise

The FDA first approved CABOMETYX in the U.S. as a monotherapy for previously treated patients with advanced RCC in April 2016, and then for previously untreated patients with advanced RCC in December 2017. In January 2021, the CABOMETYX label was expanded to include first-line advanced RCC in combination with nivolumab, which was the first CABOMETYX regimen approved for treatment in combination with an immune checkpoint inhibitor (ICI). In addition to RCC, in January 2019, the FDA approved CABOMETYX for the treatment of patients with HCC previously treated with sorafenib, and in September 2021, the FDA approved CABOMETYX for the treatment of adult and pediatric patients 12 years of age and older with locally advanced or metastatic DTC that has progressed following prior VEGF receptor-targeted therapy and who are RAI-refractory or ineligible. In March 2025, the FDA approved CABOMETYX for the treatment of adult and pediatric patients 12 years of age and older with previously treated, unresectable, locally advanced or metastatic, well-differentiated pNET and epNET.

The Inflation Reduction Act of 2022 (IRA) introduced numerous substantial changes to drug pricing, reimbursement and access support in the U.S., including enabling the Centers for Medicare & Medicaid Services (CMS) to assert control over the prices of certain single-source drugs and biotherapeutics reimbursed under Medicare Part B and Part D (the Medicare Drug Price Negotiation Program). The IRA contains a limited exception for small biotech drug manufacturers, which applies on a drug-specific basis, and provides that qualifying drugs will be exempt from selection for pricing negotiation through 2028 and eligible for a lower limit (i.e., a price floor) on the potential maximum fair price in 2029 and 2030, if the manufacturers of those drugs continue to qualify each year (small biotech exception). We have qualified for the small biotech exception with respect to our cabozantinib franchise products through 2027 and we intend to apply to CMS to maintain the small biotech exception each year through 2030. Separately, in November 2023, CMS released final guidance on another program, the Medicare Part D Manufacturer Discount Program (Part D Discount Program), which will require manufacturers to take on more of the beneficiary cost previously subsidized by the federal government through the application of increased drug discounts. We have since received notice from CMS that we qualify for the "specified small manufacturer" designation and are thereby eligible for a phase-in of the increased manufacturer discounts under the Part D Discount Program, from 2025 to 2031.

To develop and commercialize cabozantinib outside the U.S., we have entered into license agreements with Ipsen Pharma SAS (Ipsen) and Takeda Pharmaceutical Company Limited (Takeda). To Ipsen, we granted the rights to develop and commercialize cabozantinib outside of the U.S. and Japan, and to Takeda we granted such rights in Japan. Both Ipsen and Takeda also contribute financially and operationally to the further global development and commercialization of the cabozantinib franchise in other potential indications, and we work closely with them on these activities. Utilizing its regulatory expertise and established international oncology marketing network, Ipsen has continued to execute on its commercialization plans for CABOMETYX, having received regulatory approvals and launched in multiple territories outside of the U.S., including in the European Union, the United Kingdom and Canada, as a treatment for advanced RCC (both as a monotherapy and in combination with nivolumab) and for previously treated HCC and DTC indications. With respect to the Japanese market, Takeda received Manufacturing and Marketing Approvals from the Japanese Pharmaceuticals and Medical Devices Agency for monotherapy CABOMETYX as a treatment of patients with curatively unresectable or metastatic RCC and as a treatment of patients with unresectable HCC that has progressed after cancer chemotherapy, as well as for CABOMETYX in combination with nivolumab as a treatment for unresectable or metastatic RCC.

Building on preclinical and clinical observations that cabozantinib in combination with ICIs may promote a more immune-permissive tumor environment, we have initiated several pivotal studies to further explore these combination regimens, including collaborations with F. Hoffmann-La Roche Ltd. (Roche) and BMS. In August 2023, we announced positive top-line results from CONTACT-02, a phase 3 pivotal trial sponsored by us and co-funded by Roche, evaluating the combination of cabozantinib and Roche's ICI, atezolizumab, versus a second novel hormonal therapy (NHT) in patients with measurable, extrapelvic metastatic castration-resistant prostate cancer (mCRPC) who have progressed after treatment with one prior NHT. The trial met one of two primary endpoints, demonstrating a statistically significant improvement in PFS in the predefined progression-free survival (PFS) intent-to-treat population (i.e., the first 400 randomized patients), and these data were presented at the American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium in January 2024. For the second primary endpoint of overall survival (OS), the final analysis for CONTACT-02, which was presented during the GU Tumours Proffered Paper Session at the European Society for Medical Oncology Congress in September 2024, showed a trend that favored the combination of cabozantinib and atezolizumab but was not statistically significant. Of note, 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, and one we anticipate will grow in the coming years. The safety profile observed in the trial was reflective of the known safety profiles for each single agent and was consistent with the known tolerability profile of approved ICI-TKI combinations in advanced

solid tumors. Both Ipsen and Takeda opted into and are co-funding the trial. We continue to evaluate the timing of a potential regulatory submission with the FDA.

Pipeline Activities

Zanzalintinib

Zanzalintinib is a novel, potent, third-generation oral TKI that targets VEGF receptors, MET and the TAM kinases (TYRO3, AXL and MER) implicated in cancer's growth and spread, and is our first in-house compound to enter the clinic following our re-initiation of drug discovery activities in 2017. We are evaluating zanzalintinib in a growing development program that builds on our prior experience with cabozantinib and targets indications with high unmet need. We have established collaborations and will continue to explore additional opportunities for novel combinations with zanzalintinib. To date, we have initiated two large phase 1b/2 clinical trials studying zanzalintinib as a monotherapy and in combination with ICIs (STELLAR-001 and STELLAR-002). Patient enrollment into STELLAR-001 was completed in 2023 and preliminary results from a randomized expansion cohort of patients with metastatic CRC were presented at the ASCO Gastrointestinal Cancers Symposium in January 2025 (ASCO GI 2025). We anticipate initial clinical data readouts from STELLAR-002 in the first half of 2025.

We have also initiated three pivotal trials evaluating zanzalintinib in combination with ICIs. Our first such trial, STELLAR-303, was initiated in June 2022 and is evaluating zanzalintinib in combination with atezolizumab versus regorafenib in patients with metastatic, refractory non-microsatellite instability-high or non-mismatch repair-deficient CRC; we announced completion of enrollment into STELLAR-303 in August 2024, and preliminary results are expected in the second half of 2025 depending on event rates. The second pivotal trial, STELLAR-304, was initiated in December 2022 and is evaluating zanzalintinib in combination with nivolumab versus sunitinib in previously untreated patients with advanced non-clear cell RCC; we anticipate completing enrollment into STELLAR-304 by mid-2025 depending on event rates. In December 2023, we initiated STELLAR-305, a phase 2/3 pivotal trial evaluating zanzalintinib in combination with pembrolizumab (KEYTRUDA®), an anti-PD-1 ICI developed by Merck & Co., Inc., versus placebo in combination with pembrolizumab in patients with previously untreated PD-L1-positive recurrent or metastatic SCCHN; enrollment into STELLAR-305 is ongoing. We intend to initiate additional pivotal trials evaluating zanzalintinib across a broad array of future potential indications, including STELLAR-311, a phase 3 pivotal trial evaluating zanzalintinib versus everolimus as a first oral therapy in patients with advanced NET, regardless of site of origin, in the first half of 2025.

To further expand our exploration of the clinical potential of zanzalintinib, we entered into a clinical development collaboration with MSD International Business GmbH, known as Merck within the United States and Canada (Merck) to evaluate zanzalintinib in combination with WELIREG® (belzutifan), Merck's oral HIF-2α inhibitor, in RCC as well as in combination with KEYTRUDA® in SCCHN. Under the collaboration, Merck will supply KEYTRUDA for our ongoing phase 3 STELLAR-305 trial in SCCHN. In addition, Merck will sponsor a phase 1/2 trial and two phase 3 pivotal trials in RCC; Merck will fund one of these phase 3 studies, and we will co-fund the phase 1/2 study and the other phase 3 study, as well as supply zanzalintinib and cabozantinib. We maintain all global commercial and marketing rights to zanzalintinib.

Biotherapeutics

Part of our drug discovery activity focuses on discovering and advancing various biotherapeutics that have the potential to become anti-cancer therapies, such as bispecific antibodies, ADCs and other innovative treatments. ADCs in particular present a unique opportunity for new cancer treatments, given their capabilities to target the delivery of anti-cancer drug payloads to specific cells expressing the target; this increased precision should minimize collateral impact on healthy tissues that do not express the target. To facilitate the growth of our various biotherapeutics programs, we have established multiple research collaborations and in-licensing arrangements and have entered into other strategic transactions aimed at conserving capital and managing risks, collectively providing us access to antibodies, binders, payloads and conjugation technologies to generate next-generation ADCs or multispecific antibodies.

As part of our strategy to access clinical- or near-clinical-stage assets, we executed an exclusive option and license agreement and clinical development collaboration with Sairopa B.V. (Sairopa) to develop ADU-1805. ADU-1805 is currently being evaluated in a phase 1 clinical trial in patients with advanced or metastatic refractory solid tumors, and enrollment is ongoing. Plans for ADU-1805 include investigating the compound's potential in combination with approved ICIs, including pembrolizumab. In addition to the option deal with Sairopa, some of our active research collaborations for biotherapeutics programs are with:

- Adagene Inc. (Adagene), which is focused on using Adagene's SAFEbody[™] technology to develop novel masked ADCs or other innovative biotherapeutics with potential for improved therapeutic index;
- Catalent, Inc. (Catalent), which is focused on the discovery and development of multiple ADCs using Catalent's proprietary SMARTag[®] site-specific bioconjugation technology; and
- Invenra, Inc. (Invenra), which is focused on the discovery and development of novel binders and multispecific antibodies for the treatment of cancer.

We have made significant progress under our research collaborations and in-licensing arrangements and believe we will continue to do so in 2025 and in future years. For example, in March 2025, the FDA cleared our Investigational New Drug (IND) application for XB628, a first-in-class bispecific antibody that simultaneously targets PD-L1 and natural killer cell receptor group 2A (NKG2A), identified as key regulators of innate and adaptive immune cell activity, and was discovered, in part, in collaboration with Invenra. We are also advancing additional biotherapeutic candidates toward potential IND filings, and each of these candidates was discovered, in part, in connection with our research collaborations and in-licensing arrangements, including: XB371, a next-generation tissue factor (TF)-targeting ADC that consists of a topoisomerase inhibitor payload conjugated to a mAb targeting TF; XB064, a high-affinity mAb that targets ILT2; XB033, an ADC targeting the tumor antigen IL13Rα2; and XB773, an ADC targeting the tumor antigen DLL3.

Other Small Molecules

The knowledge and experience gained through our efforts to discover cabozantinib, cobimetinib and esaxerenone, each of which were approved by regulatory authorities and are commercially distributed, informs our current strategy for discovering and developing additional small molecules with the potential to treat cancer, including XL309, a potentially best-in-class small molecule inhibitor of USP1, a synthetic lethal target in the context of BRCA-mutated tumors. XL309 is currently being evaluated in a phase 1 clinical trial as monotherapy and in combination with PARP1/2 inhibition in patients with advanced solid tumors and enrollment is ongoing. XL309 has potential in patients whose tumors are no longer responsive to PARP inhibitors (PARPi), including ovarian, breast and prostate cancers, and also has potential in combination with PARPi agents to deepen and prolong the response seen to PARPi, as well as to broaden the activity beyond that observed in patients with tumors that harbor a BRCA1/2 mutation.

In October 2024, we announced the initiation of a phase 1 clinical trial evaluating XL495, an inhibitor of PKMYT1, both as a monotherapy and in combination with select cytotoxic agents, in patients with advanced solid tumors, following the FDA's acceptance of our IND application. Data analysis from the XL495 program demonstrated potential for anti-tumor activity both as monotherapy and in combination with DNA-damaging agents. However, based on early clinical data generated for XL495, we have decided to discontinue further development of this program.

Beyond these assets, we continue to make progress on multiple lead optimization programs for agents directed toward a variety of targets that we believe play significant roles in tumor biology, and we anticipate that some of these other programs could reach development candidate status in 2025 and beyond.

Future Expansion of our Pipeline

Increasing the number of novel anti-cancer agents in our pipeline is essential to our overall strategy and business goals. We are working to expand our oncology product pipeline through drug discovery efforts, which encompass our diverse biotherapeutics and small molecule programs exploring multiple modalities and mechanisms of action. This approach provides a high degree of flexibility with respect to target selection and modality of treatment and allows us to prioritize those programs that we believe have the greatest chance of delivering impactful therapeutics. As part of our strategy, our drug discovery activities have and will continue to include internal research, as well as external research, collaborations, in-licensing arrangements and other strategic transactions that collectively leverage a wide range of technology platforms and assets and increase our probability of success. As of the date of this Quarterly Report on Form 10-Q, we expect to progress up to two new development candidates into preclinical development later in 2025. We will continue to engage in pipeline expansion initiatives with the goal of discovering, acquiring and/or in-licensing promising investigational oncology assets and then further characterize and develop them utilizing our established preclinical and clinical development infrastructure.

First Quarter 2025 Business Updates and Financial Highlights

During the first quarter of 2025, we continued to execute on our business objectives, generating significant revenues from operations and enabling us to continue to seek to maximize the clinical and commercial potential of our products and expand our product pipeline. Significant business updates and financial highlights for the quarter and subsequent to quarter-end include:

Business Updates

- In January 2025, we presented preliminary results from a randomized expansion cohort of patients with metastatic CRC from STELLAR-001, and results from a subgroup analysis of patients in the epNET cohort with advanced gastrointestinal NET in CABINET, at the ASCO GI 2025.
- In February 2025, we announced final five-year follow-up results from the CheckMate -9ER trial at the ASCO Genitourinary Cancers Symposium.
- In February 2025, we announced that our Board of Directors had authorized the repurchase of up to \$500 million of our common stock before December 31, 2025. This repurchase authorization is in addition to the \$500 million repurchase authorized by our Board of Directors in August 2024. Under these programs, as of March 31, 2025, we have repurchased \$494.5 million of our common stock, at an average price of \$34.87 per share.
- In March 2025, we announced FDA Approval of CABOMETYX for patients with previously treated advanced NET.

Financial Highlights

- Net product revenues for the first quarter of 2025 were \$513.3 million, as compared to \$378.5 million for the first quarter of 2024.
- Total revenues for the first quarter of 2025 were \$555.4 million, as compared to \$425.2 million for the first quarter of 2024.
- Research and development expenses for the first quarter of 2025 were \$212.2 million, as compared to \$227.7 million for the first quarter of 2024.
- Selling, general and administrative expenses for the first quarter of 2025 were \$137.2 million, as compared to \$114.0 million for the first quarter of 2024.
- Provision for income taxes for the first quarter of 2025 was \$46.1 million, as compared to \$12.0 million for the first quarter of 2024.
- Net income for the first quarter of 2025 was \$159.6 million, or \$0.57 per share, basic and \$0.55 per share, diluted, as compared to net income of \$37.3 million, or \$0.12 per share, basic and diluted, for the first quarter of 2024.

See "Results of Operations" below for a discussion of the detailed components and analysis of the amounts above.

Outlook, Challenges and Risks

We will continue to face numerous challenges and risks that may impact our ability to execute on our business objectives. In particular, for the foreseeable future, we expect our ability to generate sufficient cash flow to fund our business operations and growth will depend upon the continued commercial success of CABOMETYX, both alone and in combination with other therapies, as a treatment for the highly competitive indications for which it is approved, and possibly for other indications for which cabozantinib is currently being evaluated in potentially label-enabling clinical trials, if warranted by the data generated from these trials. However, we cannot be certain that the clinical trials we and our collaboration partners are conducting will demonstrate adequate safety and efficacy in these additional indications to receive regulatory approval in the major commercial markets where CABOMETYX is approved.

Even if the required regulatory approvals to market CABOMETYX for additional indications are achieved, we and our collaboration partners may not be able to commercialize CABOMETYX effectively and successfully in these additional indications. In addition, CABOMETYX will only continue to be commercially successful if private third-party and government payers continue to provide coverage and reimbursement. As is the case for all innovative pharmaceutical therapies, obtaining and maintaining coverage and reimbursement for CABOMETYX is becoming increasingly difficult, both within the U.S. and in foreign markets. In addition, healthcare policymakers in the U.S. continue to express concern over healthcare costs, and corresponding legislative and policy initiatives and activities have been launched aimed at increasing the healthcare cost burdens borne by pharmaceutical manufacturers, as well as expanding access to, and restricting the prices and growth in prices of, pharmaceuticals.

Achievement of our business objectives will also depend on our ability to maintain a competitive position in the shifting landscape of therapeutic strategies for the treatment of cancer, which we may not be able to do. On an ongoing basis, we assess the constantly evolving landscape of other approved and investigational cancer therapies that could be competitive, or complementary in combination, with our products, and then we adapt our development strategies for the cabozantinib franchise and our pipeline product candidates accordingly, such as by modifying our clinical trials to include evaluation of our therapies with ICIs and other targeted agents. Even if our current and future clinical trials produce positive results sufficient to obtain marketing approval by the FDA and other global regulatory authorities, it is uncertain whether physicians will choose to prescribe regimens containing our products instead of competing products and product combinations in approved indications.

In the longer term, we may eventually face competition from potential manufacturers of generic or other versions of our marketed products, including any cabozantinib (S)-malate tablets besides CABOMETYX that are the subject of ANDAs submitted to the FDA by MSN and Sun or the 505(b)(2) submitted to the FDA by Azurity. The approval of any of these ANDAs and subsequent launch of any generic version of CABOMETYX could significantly decrease our revenues derived from the U.S. sales of CABOMETYX and thereby materially harm our business, financial condition and results of operations.

Separately, our research and development objectives may be impeded by the challenges of scaling our organization to meet the demands of expanded drug development, unanticipated delays in clinical testing and the inherent risks and uncertainties associated with drug discovery operations, especially on the global level. In connection with efforts to expand our product pipeline, we may be unsuccessful in discovering new potential cancer treatments or identifying appropriate candidates for in-licensing or acquisition.

Some of these challenges and risks are specific to our business, others are common to companies in the biopharmaceutical industry with development and commercial operations, and an additional category are macroeconomic, affecting all companies. For a more detailed discussion of challenges and risks we face, see "Risk Factors" in Part I, Item 1A of our 2024 Form 10-K, as supplemented and, to the extent inconsistent, superseded below (if applicable) in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Fiscal Year Convention

We have adopted a 52- or 53-week fiscal year policy that generally ends on the Friday closest to December 31. Fiscal year 2025, which is a 52-week fiscal year, will end on January 2, 2026 and fiscal year 2024, which was a 53-week fiscal year, ended on January 3, 2025. The 52-week fiscal year in 2025 may result in a modest year-over-year impact on revenues and expenses, as compared to 2024. For convenience, references in this report as of and for the fiscal periods ended April 4, 2025 and March 29, 2024, and as of and for the fiscal years ending January 2, 2026 and ended January 3, 2025 are indicated as being as of and for the periods ended March 31, 2025 and March 31, 2024, and the years ending December 31, 2025 and ended December 31, 2024, respectively.

Results of Operations

Revenues

Revenues by category were as follows (dollars in thousands):

	Three Months Ended March 31,				
		2025	2024	Percent Change	
Net product revenues	\$	513,283	\$ 378,523	36 %	
License revenues		42,480	44,676	-5 %	
Collaboration services revenues		(316)	2,027	n/a	
Total collaboration revenues		42,164	46,703	-10 %	
Total revenues	\$	555,447	\$ 425,226	31 %	

Net Product Revenues

Gross product revenues, discounts and allowances and net product revenues were as follows (dollars in thousands):

	Three Months Ended March 31,			
	 2025	2024	Percent Change	
Gross product revenues	\$ 721,711	\$ 563,785	28 %	
Discounts and allowances	(208,428)	(185,262)	13 %	
Net product revenues	\$ 513,283	\$ 378,523	36 %	

Net product revenues by product were as follows (dollars in thousands):

	Three Months Ended March 31,				
	 2025	2024		 Percent Change 	
CABOMETYX	\$ 510,872	\$	376,417	36 %	
COMETRIQ	2,411		2,106	14 %	
Net product revenues	\$ 513,283	\$	378,523	36 %	

The increase in net product revenues for the three months ended March 31, 2025, as compared to the corresponding prior year period, was primarily related to a 25% increase in the number of CABOMETYX units sold reflecting continuing demand for CABOMETYX in combination with nivolumab as a first-line treatment of patients with advanced RCC and, to a lesser extent, an increase of 9% in the average net selling price of CABOMETYX. The increase in sales volume is largely driven by refills, reflecting the longer duration of therapy for this combination, and an increase in related market share reflecting the continued evolution of the metastatic RCC, HCC and DTC treatment landscapes.

We project our net product revenues may increase for the remainder of 2025, as compared to the corresponding prior year period, as a result of the FDA's recent approval of CABOMETYX for patients with previously treated advanced NET, and for similar reasons noted above.

We recognize product revenues net of discounts and allowances that are described in "Note 1. Organization and Summary of Significant Accounting Policies" of the "Notes to Consolidated Financial Statements" included in Part II, Item 8 of our Fiscal 2024 Form 10-K.

Discounts and allowances have generally increased over time as the number of patients participating in government programs has increased and as the discounts given and rebates paid to government payers have also increased. The increase in the amount of discounts and allowances for the three months ended March 31, 2025, as compared to the corresponding prior year period, was primarily the result of increases in volume of units sold, and the increase in the dollar amount of chargebacks under the 340B Drug Pricing Program (the 340B Program), partially offset by lower rebates under the Part D Discount Program due to changes resulting from the IRA.

We project our discounts and allowances may increase for the remainder of 2025, as compared to the corresponding prior year period, for similar reasons noted above.

License Revenues

License revenues primarily include: (a) the recognition of the portion of milestone payments allocated to the transfer of intellectual property licenses for which it had become probable, in the related period, that a milestone would be achieved and a significant reversal of revenues would not occur in future periods; and (b) royalty revenues.

There were no milestone payments recognized in license revenues or collaboration services revenues during the three months ended March 31, 2025 and 2024. Royalty revenues for the three months ended March 31, 2025 decreased, as compared to the corresponding prior year period, primarily as a result of a decrease in Ipsen's net sales of cabozantinib outside of the U.S. and Japan, partially offset by an increase in royalty revenues from Takeda. Ipsen royalties were \$34.0 million for the three months ended March 31, 2025, as compared to \$36.9 million for the corresponding prior year period. Royalty revenues for the three months ended March 31, 2025 related to Takeda's net sales of cabozantinib were \$2.8

million, as compared to \$2.7 million for the corresponding prior year period. CABOMETYX is approved and is commercially available in 68 countries outside the U.S.

Due to uncertainties surrounding the timing and achievement of regulatory and development milestones, it is difficult to predict future milestone revenues and milestones can vary significantly from period to period.

Collaboration Services Revenues

Collaboration services revenues include: (a) the development cost reimbursements earned under our collaboration agreements and product supply revenues, net of product supply costs; (b) the recognition of deferred revenues for the portion of upfront and milestone payments that have been allocated to research and development services performance obligations; offset by (c) the royalties we pay to Royalty Pharma plc (Royalty Pharma) on sales by Ipsen and Takeda of products containing cabozantinib.

Development cost reimbursements decreased in the three months ended March 31, 2025, as compared to the corresponding prior year period, primarily attributable to decreases in spending on the CONTACT-02 and CheckMate -9ER studies.

Recognition of deferred revenues for the portion of upfront and milestone payments that have been allocated to research and development services performance obligations were not material in the three months ended March 31, 2025 and 2024, respectively.

Collaboration services revenues are reduced by the royalty payments to Royalty Pharma to account for the 3% royalty we are required to pay on the net sales by Ipsen and Takeda of any products containing cabozantinib. The royalty payments to Royalty Pharma have decreased in the three months ended March 31, 2025, as compared to the corresponding prior year period, primarily due to a reduction in the royalty generating sales of cabozantinib by Ipsen.

We project our collaboration services revenues may decrease for the remainder of 2025, as compared to the corresponding prior year period, primarily as a result of a decrease in development cost reimbursements and an increase in royalty payments to Royalty Pharma on sales by Ipsen and Takeda of products containing cabozantinib.

Cost of Goods Sold

The cost of goods sold and our gross margins were as follows (dollars in thousands):

	Three Months Ended March 31,			
	2025	2024	Percent Change	
Cost of goods sold	\$ 19,172	\$ 21,256	-10 %	
Gross margin %	96 %	94 %		

Cost of goods sold is related to our product revenues and consists of a 3% royalty payable on U.S. net sales of any product containing cabozantinib, as well as the cost of inventory sold, indirect labor costs, write-downs related to expiring, excess and obsolete inventory and other third-party logistics costs. The decrease in cost of goods sold for the three months ended March 31, 2025, as compared to the corresponding prior year period, was primarily due to a decrease in certain period costs, including a decrease in write-downs for excess inventory, partially offset by an increase in royalties as a result of increased U.S. CABOMETYX sales. We project our gross margin will not change significantly during the remainder of 2025.

Research and Development Expenses

We do not track fully burdened research and development expenses on a project-by-project basis. We group our research and development expenses into three categories: (a) development; (b) drug discovery; and (c) other research and development. Our development group leads the development and implementation of our clinical and regulatory strategies and prioritizes disease indications in which our compounds are being or may be studied in clinical trials.

Development expenses include license and other collaboration costs, primarily composed of upfront license fees, development milestones and other payments associated with our clinical-stage in-licensing collaboration programs, clinical trial costs, personnel expenses, consulting and outside services and other development costs, including manufacturing costs of our drug development candidates. Our drug discovery group utilizes a variety of technologies, including in-licensed technologies, to enable the rapid discovery, optimization and extensive characterization of lead compounds and

biotherapeutics such that we are able to select development candidates with the best potential for further evaluation and advancement into clinical development. Drug discovery expenses include license and other collaboration costs primarily composed of upfront license fees, research funding commitments, option exercise fees, development milestones and other payments associated with our in-licensing collaboration programs in preclinical development stage. Other drug discovery costs include personnel expenses, consulting and outside services and laboratory supplies. Other research and development expenses include the allocation of general corporate costs to research and development services and development cost reimbursements in connection with certain of our collaboration arrangements.

Research and development expenses by category were as follows (dollars in thousands):

Three Months Ended March 31,				
	2025	2024	Percent Change	
\$	62,741	\$ 74,718	-16 %	
	49,537	45,516	9 %	
	5,000	17,500	-71 %	
	12,703	11,126	14 %	
	23,236	24,027	-3 %	
	153,217	172,887	-11 %	
	259	5,295	-95 %	
	17,994	17,195	5 %	
	18,253	22,490	-19 %	
	9,522	3,892	145 %	
	31,241	28,420	10 %	
\$	212,233	\$ 227,689	-7 %	
	\$	\$ 62,741 49,537 5,000 12,703 23,236 153,217 259 17,994 18,253 9,522 31,241	\$ 62,741 \$ 74,718 49,537 45,516 5,000 17,500 12,703 11,126 23,236 24,027 153,217 172,887 259 5,295 17,994 17,195 18,253 22,490 9,522 3,892 31,241 28,420	

In addition, we track our external clinical trial costs by product and product candidate and by scientific modalities, which are categorized as small molecule and biotherapeutics programs. Small molecule clinical development for the reported periods was primarily composed of cabozantinib and zanzalintinib. Biotherapeutics clinical development for the reported periods was primarily composed of XB010 and XB002.

Clinical trial costs by scientific modalities, by product and by product candidate were as follows (dollars in thousands):

	Three Months Ended March 31,				- Percent	
	2025		2024	Change		
Small molecules:						
Zanzalintinib	\$	41,120	\$	40,008	3 %	
Cabozantinib		9,983		18,326	-46 %	
Other small molecules		5,516		4,089	35 %	
Total small molecules		56,619		62,423	-9 %	
Biotherapeutics		6,122		12,295	-50 %	
Total clinical trial costs	\$	62,741	\$	74,718	-16 %	

The decrease in research and development expenses for the three months ended March 31, 2025, as compared to the corresponding prior year period, 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.

Development-related license and other collaboration costs decreased for the three months ended March 31, 2025, as compared to the corresponding prior year period, primarily due to lower development milestone achievement in our clinical-stage in-licensing collaboration programs. Drug discovery-related license and other collaboration costs decreased

for the three months ended March 31, 2025, as compared to the corresponding prior year period, primarily due to lower development milestone achievement in our discovery-stage in-licensing collaboration programs and lower research funding.

Clinical trial costs decreased for the three months ended March 31, 2025, as compared to the corresponding prior year period, primarily due to lower costs associated with studies evaluating cabozantinib and XB002, partially offset by higher costs associated with XB010 and zanzalintinib studies.

In addition to reviewing the three categories of research and development expenses described above, we principally consider qualitative factors in making decisions regarding our research and development programs. These factors include enrollment in clinical trials for our product candidates, preliminary data and final results from clinical trials, the potential market indications and overall clinical and commercial potential for our product candidates, and competitive dynamics. We also make our research and development decisions in the context of our overall business strategy.

We project that clinical trial costs may increase for the remainder of 2025, as compared to the corresponding prior year period, primarily driven by higher costs associated with various studies evaluating zanzalintinib, and the XL309 and XB628 studies, partially offset by lower costs associated with various studies evaluating cabozantinib and XB002.

To continue growing our pipeline, we are prioritizing investment in new molecules that are clinically differentiated with the potential to improve the standard of care for our cancer patients, including current and planned clinical trial programs evaluating zanzalintinib, XL309, XB010 and XB628. We are working to expand our oncology product pipeline through drug discovery efforts, which encompass our diverse biotherapeutics and small molecule programs exploring multiple modalities and mechanisms of action. This approach provides a high degree of flexibility with respect to target selection and allows us to prioritize those targets that we believe have the greatest chance of yielding impactful therapeutics. As part of our strategy, our drug discovery activities have included and continue to include internal research, as well as external research collaborations, in-licensing arrangements and other strategic transactions that collectively incorporate a wide range of technology platforms and assets and increase our probability of success. As of the date of this Quarterly Report on Form 10-Q, we expect to progress up to two new development candidates into preclinical development later in 2025. We will continue to engage in pipeline expansion initiatives with the goal of acquiring and in-licensing promising investigational oncology assets and then further characterize and develop them utilizing our established preclinical and clinical development infrastructure.

We project our research and development expenses may increase for the remainder of 2025, as compared to the prior year period, primarily driven by increases in clinical trial costs, including the current and planned trials evaluating zanzalintinib, XL309, XB628, and XB010, consulting and outside services, license and other collaboration costs and stock-based compensation.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were as follows (dollars in thousands):

	Three Months Ended March 31,				Percent
		2025		2024	Change
Selling, general and administrative expenses ⁽¹⁾	\$	120,775	\$	98,763	22 %
Stock-based compensation		16,408		15,221	8 %
Total selling, general and administrative expenses	\$	137,183	\$	113,984	20 %

⁽¹⁾ Excludes stock-based compensation allocated to selling, general and administrative expenses.

Selling, general and administrative expenses consist primarily of personnel expenses, stock-based compensation, marketing costs and certain other administrative costs.

The increase in selling, general and administrative expenses for the three months ended March 31, 2025, as compared to the corresponding prior year period, was primarily due to increases in personnel expenses, corporate giving, and marketing activities in support of the anticipated commercial launch of CABOMETYX for the treatment of patients with previously treated advanced NET, and stock-based compensation.

We project our selling, general and administrative expenses may increase for the remainder of 2025, as compared to the corresponding prior year period, primarily driven by an increase in stock-based compensation.

Restructuring Expenses

There were no restructuring expenses for the three months ended March 31, 2025. Restructuring expenses for the three months ended March 31, 2024, was the result of a corporate restructuring plan announced and implemented in the first quarter of 2024 to reduce our workforce and rebalance our cost structure in alignment with our strategic priorities. Restructuring expenses consisted of severance and employee-related costs, asset impairment, and contract termination costs and were mostly incurred in the first quarter of 2024.

Restructuring expenses were as follows (dollars in thousands):

	Three Months Ended March 31,			Percent
2	025	2024		Change
\$	_		32,835	-100 %

Non-Operating Income

Non-operating income was as follows (dollars in thousands):

	Three Months Ended March 31,			Percent
		2025	2024	Change
Interest income	\$	19,076	\$ 19,8	94 -4 %
Other expenses, net		(245)	(3)	39) 175 %
Non-operating income	\$	18,831	\$ 19,8	-5 %

The decrease in non-operating income for the three months ended March 31, 2025, as compared to the corresponding prior year period, was primarily the result of a decrease in interest income due to lower average interest-bearing investment balances, and lower average interest rates.

Provision for Income Taxes

The provision for income taxes and the effective tax rates were as follows (dollars in thousands):

	Three Months Ended March 31,			
	 2025	2024	Percent Change	
Provision for income taxes	\$ 46,074 \$	11,950	286 %	
Effective tax rate	22.4 %	24.3 %		

The effective tax rate for the three months ended March 31, 2025, differed from the U.S. federal statutory rate of 21%, primarily due to state taxes, partially offset by excess tax benefits related to certain stock grants and the generation of federal tax credits. The effective tax rate for the three months ended March 31, 2024, differed from the U.S. federal statutory tax rate of 21%, primarily due to state taxes and interest on uncertain tax positions, offset by the generation of federal tax credits.

Liquidity and Capital Resources

As of March 31, 2025, we had \$1.7 billion in cash, cash equivalents and marketable securities, as compared to \$1.7 billion as of December 31, 2024. We anticipate that the aggregate of our current cash and cash equivalents, marketable securities available for operations, net product revenues and collaboration revenues will enable us to maintain our operations for at least 12 months and thereafter for the foreseeable future.

Our primary cash requirements for operating activities, which we project will increase for the remainder of 2025, as compared to the corresponding period in 2024, are employee-related expenditures; payments related to our collaboration and development programs; income tax payments; royalty payments on our net product sales; cash payments for inventory; rent payments for our leased facilities; and contract manufacturing payments.

The Tax Cuts and Jobs Act, signed into law on December 22, 2017, modified the tax treatment of research and development expenditures beginning in fiscal year 2022. Research and development expenditures are no longer currently deductible but instead must be amortized ratably over five years for domestic expenditures or 15 years for foreign expenditures. We will realize a reduction of our federal income tax liability in future years as the capitalized research and development expenditures are amortized for tax purposes.

Our primary sources of operating cash are: cash collections from customers related to net product revenues, which we project may increase for the remainder of 2025, as compared to the corresponding period in 2024; cash collections related to milestones achieved and royalties earned from our commercial collaboration arrangements with Ipsen, Takeda and others; and cash collections for cost reimbursements under certain of our development programs with Ipsen and Takeda which we project may decrease for the remainder of 2025, as compared to the corresponding period in 2024. The timing of cash generated from commercial collaborations and cash payments required for in-licensing collaborations relative to upfront license fee payments, cost reimbursements, exercise of option payments and other contingent payments such as development milestone payments may vary from period to period.

We project that we may continue to spend significant amounts of cash to fund the development of product candidates in our pipeline, including zanzalintinib, XL309, XB010, and XB628, and the development and commercialization of cabozantinib. In addition, we may continue to expand our oncology product pipeline through additional research collaborations, in-licensing arrangements and other strategic transactions that align with our oncology drug development, regulatory and commercial expertise.

In August 2024, our Board of Directors authorized a stock repurchase program to acquire up to \$500.0 million of our outstanding common stock before December 31, 2025. In February 2025, our Board of Directors authorized the repurchase of up to an additional \$500.0 million of our outstanding common stock before December 31, 2025. Under these programs, as of March 31, 2025, we repurchased 14.2 million shares of common stock for an aggregate purchase price of \$494.5 million. As of March 31, 2025, approximately \$505.5 million remained available for future stock repurchases before December 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, Rule 10b5-1 trading plans, 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.

Financing these activities could materially impact our liquidity and capital resources and may require us to incur debt or raise additional funds through the issuance of equity. Furthermore, even though we believe we have sufficient funds for our current and future operating plans, we may choose to incur debt or raise additional funds through the issuance of equity based on market conditions or strategic considerations.

Sources and Uses of Cash (dollars in thousands):

	March 31, 2025	1	December 31, 2024	Percent Change
Working capital	\$ 997,400	\$	1,063,810	-6 %
Cash, cash equivalents and marketable securities	\$ 1,650,757	\$	1,748,567	-6 %

Working Capital: The decrease in working capital as of March 31, 2025, as compared to December 31, 2024, was primarily due to repurchases of our common stock, partially offset by the favorable impact to our net current assets resulting from our increase in net product revenues. In the future, our working capital may be impacted by one of these factors or other factors, the amounts and timing of which are variable.

Cash, Cash Equivalents and Marketable Securities: Cash and cash equivalents primarily consist of deposits at major banks, money market funds, commercial paper and other securities with original maturities 90 days or less. Marketable securities primarily consist of debt securities available-for-sale and certificates of deposit. For additional information regarding our cash, cash equivalents and marketable securities, see "Note 5. Cash and Marketable Securities" of the "Notes to Condensed Consolidated Financial Statements" included in Part I, Item 1 of this Quarterly Report on Form 10-Q. The decrease in cash, cash equivalents and marketable securities as of March 31, 2025, as compared to December 31, 2024, was primarily due to cash payments to repurchase our common stock, payments to support our development and discovery programs and cash payments for employee-related expenditures, partially offset by cash inflows generated by our

operations from sales of our products and our commercial collaboration arrangements.

Cash flow activities were as follows (dollars in thousands):

	Three Months Ended March 31,			
	 2025		2024	Percent Change
Net cash provided by operating activities	\$ 211,437	\$	68,822	207 %
Net cash provided by investing activities	\$ 49,764	\$	111,793	-55 %
Net cash used in financing activities	\$ (294,823)	\$	(184,048)	60 %

Operating Activities

Cash provided by operating activities is derived by adjusting our net income for non-cash operating items such as deferred taxes, stock-based compensation, depreciation and amortization, non-cash lease expense, impairment of long-lived assets, acquired in-process research and development technology, and changes in operating assets and liabilities, which reflect timing differences between the receipt and payment of cash associated with transactions and when they are recognized in our Condensed Consolidated Statements of Income.

Net cash provided by operating activities increased for the three months ended March 31, 2025, as compared to the corresponding prior year period, primarily due to an increase in cash received on sales of our products and a decrease in cash paid for certain operating expenses.

Investing Activities

The changes in cash flows from investing activities primarily relates to the timing of marketable securities investment activity, acquisition of inprocess research and development technology and capital expenditures. Our capital expenditures primarily consist of marketable securities to expand our operations and acquire assets that further support our research and development activities.

Net cash provided by investing activities decreased for the three months ended March 31, 2025, as compared to the corresponding prior year period. The decrease in cash used in investing activities was primarily due to increases in purchases of marketable securities, purchases of in-process research and development technology related to certain in-licensing collaboration arrangements, and a decrease in cash proceeds from maturities and sales of marketable securities, partially offset by a decrease in purchases of property and equipment and other.

Financing Activities

The changes in cash flows from financing activities primarily relate to payments for repurchases of common stock, proceeds from employee stock programs and taxes paid related to net share settlement of equity awards.

Net cash used in financing activities increased for the three months ended March 31, 2025, as compared to the corresponding prior year period, primarily due to an increase in payments for repurchases of common stock.

Contractual Obligations

There were no material changes outside of the ordinary course of business in our contractual obligations as of March 31, 2025 from those disclosed in our Fiscal 2024 Form 10-K. For more information about our leases and our other contractual obligations, see "Note 12. Commitments and Contingencies" of the "Notes to Consolidated Financial Statements" included in Part II, Item 8 of our Fiscal 2024 Form 10-K.

Critical Accounting Policies and Estimates

The preparation of our Condensed Consolidated Financial Statements conforms to accounting principles generally accepted in the U.S. which requires management to make judgments, estimates and assumptions that affect the reported amounts of assets, liabilities, equity, revenues and expenses and related disclosures. An accounting policy is considered to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, and if different estimates that reasonably could have been used, or changes in the accounting estimates that are reasonably likely to occur periodically, could materially impact our Condensed Consolidated

Financial Statements. On an ongoing basis, management evaluates its estimates, including, but not limited to: those related to revenue recognition, including determining the nature and timing of satisfaction of performance obligations, and determining the standalone selling price of performance obligations, and variable consideration such as rebates, chargebacks, sales returns and sales allowances as well as milestones included in collaboration arrangements; the accrual for certain liabilities, including accrued clinical trial liabilities; and valuations of equity awards used to determine stock-based compensation, including certain awards with vesting subject to market or performance conditions; and the amounts of deferred tax assets and liabilities, including the related valuation allowance. We base our estimates on historical experience and on various other market-specific and other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our senior management has discussed the development, selection and disclosure of these estimates with the Audit Committee of our Board of Directors. Actual results could differ materially from those estimates.

We believe our critical accounting policies relating to revenue recognition, clinical trial and collaboration accruals, stock-based compensation and income taxes reflect the more significant estimates and assumptions used in the preparation of our Condensed Consolidated Financial Statements.

There have been no significant changes in our critical accounting policies and estimates during the three months ended March 31, 2025, as compared to the critical accounting policies and estimates disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in Part II, Item 7 of our Fiscal 2024 Form 10-K.

Recent Accounting Pronouncements

For a description of the expected impact of recent accounting pronouncements, see "Note 1. Organization and Summary of Significant Accounting Policies" of the "Notes to Condensed Consolidated Financial Statements" included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Our market risks, as of March 31, 2025, have not changed significantly from those described in Part II, Item 7A of our Fiscal 2024 Form 10-K.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Based on the evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) of the Securities Exchange Act of 1934, as amended (the Exchange Act)) required by Rules 13a-15(b) or 15d-15(b) of the Exchange Act, our Chief Executive Officer and Chief Financial Officer have concluded that as of the end of the period covered by this report, our disclosure controls and procedures were effective at the reasonable assurance level.

Limitations on the Effectiveness of Controls

A control system, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our principal executive officer and principal financial officer have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were effective to provide reasonable assurance that the objectives of our disclosure control system were met.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

The information required to be set forth under this Item 1 is incorporated by reference to "Note 11. Commitments and Contingencies – Legal Proceedings" of the Notes to Condensed Consolidated Financial Statements" in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Item 1A. Risk Factors.

Below we are providing, in supplemental form, changes to our risk factors from those previously disclosed in Part I, Item 1A of our Fiscal 2024 Form 10-K. Our risk factors disclosed in Part I, Item 1A of our Fiscal 2024 Form 10-K provide additional discussion regarding these supplemental risks and we encourage you to read and carefully consider all of the risk factors disclosed in Part I, Item 1A of our Fiscal 2024 Form 10-K, together with the below, for a more complete understanding of the risks and uncertainties material to our business. The risks and uncertainties described therein and below are not the only ones we face. Additional risks and uncertainties not currently known to us or that we deem immaterial also may impair our business operations.

Risks Related to the Commercialization of Our Products

Current healthcare laws, policies, and regulations in the U.S. and future legislative or regulatory reforms to the U.S. healthcare system, including those related to drug pricing, may affect our ability to commercialize our marketed products profitably. Pricing for pharmaceutical products in the U.S. has come under increasing attention and scrutiny by federal and state governments, legislative bodies and enforcement agencies. Initiatives arising from this scrutiny may result in changes that have the effect of reducing our revenue, or harming our business or reputation.

Concern over access to and affordability of pharmaceutical products continues to spur debate and action by U.S. federal and state government authorities in an effort to contain healthcare costs. Such proposals include:

- use of mandated discounts, rebates, restrictive formularies, or other reference-based price controls, such as most favored nation (MFN) or international reference pricing, as well as price transparency reporting obligations;
- efforts to reevaluate, reduce or limit the price patients pay for pharmaceutical products;
- implementation of additional data collection and transparency reporting regarding drug pricing, rebates, fees and other remuneration provided by drug manufacturers;
- tariffs on imported pharmaceuticals, or their components;
- revisions to rules associated with the calculation of average manufacturer price; best price and rebate liability (including broadening the
 circumstances under which products are subject to rebate) for the Medicaid Drug Rebate Program (MDRP), along with CMS' stated objective to
 consider potential future rulemaking that if implemented, could significantly increase manufacturer rebate liability; and
- reevaluation of safe harbors under the federal Anti-Kickback Statute.

For instance, in August 2022, former President Biden signed the IRA, which, among other things: enables CMS to assert control over the prices of certain single-source drugs and biotherapeutics reimbursed under the Medicare Drug Price Negotiation Program; subjects drug manufacturers to potential civil monetary penalties and a significant excise tax for offering a price that is not equal to or less than the government-imposed "maximum fair price" under the law; imposes Medicare rebates for certain Part B and Part D drugs where relevant pricing metrics associated with the products increase faster than inflation; and redesigns the funding and benefit structure of the Medicare Part D program, potentially increasing manufacturer liability while capping annual out-of-pocket drug expenses for Medicare beneficiaries. These provisions started taking effect incrementally in late 2022 and currently are subject to various legal challenges. As of the date of this report, for example, CMS has begun to implement aspects of the IRA and finalized regulations addressing the Medicare Part B and Medicare Part D inflation rebate provisions of the IRA. These provisions generally require manufacturers of Medicare Part B and Part D rebatable drugs to pay inflation rebates to the Medicare program if pricing metrics associated with their products increase faster than the rate of inflation. In addition, in October 2024, CMS released final guidance setting forth the requirements and procedures for implementing the Medicare Drug Price Negotiation Program for the second round of drug pricing evaluations (which commences in 2025 and will result in maximum fair prices that will become effective beginning in 2027), as well as requirements for manufacturers in effectuating maximum fair prices in 2026 and 2027. The IRA also contains the limited small biotech exception, which applies on a drug-specific basis. Qualifying drugs may be

exempt from possible pricing negotiation through 2028 and eligible for a lower limit (i.e., a price floor) on the potential maximum fair price in 2029 and 2030, if the manufacturers of those drugs continue to qualify each year. We have qualified for the Small Biotech Exception with respect to our cabozantinib franchise products through Initial Price Applicability Year (IPAY) 2027, and we plan to reapply for the Small Biotech Exception for IPAY 2028. In January 2025, CMS announced the list of 15 drugs selected for the second round of drug pricing evaluations. Separately, in November 2023, CMS released final guidance on the Part D Discount Program, which will require manufacturers to take on more of the beneficiary cost previously subsidized by the federal government through the application of increased drug discounts. As we received notice from CMS that we qualify for the "specified small manufacturer" designation, we are eligible for a phase-in of the increased manufacturer discounts under the Part D Discount Program from 2025 to 2031. In April 2025, CMS finalized regulations implementing the Medicare Prescription Payment Plan, under which Medicare Part D beneficiaries may opt to make their cost-sharing payments in capped monthly installments; CMS expects that this program will most likely benefit those beneficiaries with high cost-sharing early in their respective plan years.

Over time, the IRA could reduce the revenues we are able to collect from sales of our products or present challenges for payer negotiations and formulary access for our products, as well as increase our government discount and rebate liabilities; however, the degree of impact that the IRA will ultimately have upon our business remains unclear. In addition, we cannot know the final form or timing of any other legislative, regulatory and/or administrative measures, and some of these pending and enacted policy changes, if implemented as currently proposed, would likely have significant and farreaching impacts on the biopharmaceutical industry and therefore likely also have a material adverse impact on our business, financial condition and results of operations. Additionally, there is ongoing litigation challenging the Medicare Drug Price Negotiation Program, and we cannot predict the outcome of these cases.

If additional prescription drug price controls are implemented, the resulting changes to the pricing and reimbursement of CABOMETYX and COMETRIQ could affect our ability to continue to commercialize the products. Consolidation and integration of private payers and pharmacy benefit managers in the U.S. has also significantly impacted the market for pharmaceuticals by increasing payer leverage in negotiating manufacturer price or rebate concessions and pharmacy reimbursement rates. Such restrictive or unfavorable pricing, coverage or reimbursement determinations for CABOMETYX and COMETRIQ or our other product candidates, whether made by governments (including regulatory agencies and courts) or by private payers, may adversely impact our business.

In addition, there have been, and may in the future be, initiatives at both the federal and state level or legal challenges that could significantly modify the terms and scope of government-provided health insurance coverage, ranging from changes to or litigation opposing some or all of the provisions of the Patient Protection and Affordable Care Act of 2010, as amended, to establishing a single-payer, national health insurance system, to more limited "buyin" options to existing public health insurance programs, any of which could have a significant impact on the healthcare industry. Although such attempts to reform the U.S. healthcare system have not significantly impacted our business to date, it is possible that additional legislative, executive and judicial activities in the future could have a material adverse impact on our business, financial condition and results of operations.

In addition, the current U.S. Presidential administration has indicated that it plans to pursue additional policies aimed at lowering prescription drug costs. For example, on May 12, 2025, the current administration published an executive order that expressed support for equalizing the prices paid for drugs in the United States and other developed countries by employing an MFN approach to drug pricing. The May 12 executive order directs the Secretary of Health and Human Services, within 30 days, to communicate MFN price targets to pharmaceutical manufacturers, and if significant progress towards MFN pricing is not delivered, to propose a rulemaking plan to impose MFN pricing. It is otherwise unclear how the current administration intends to effectuate this MFN approach, although the May 12 executive order makes reference to using waivers on import restrictions under section 804(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and also to various authorities under the antitrust laws. And, previously, on April 15, 2025, the current administration published a separate executive order that, among other things, directs specified agency heads to develop and implement a Center for Medicare and Medicaid Innovation model "to improve the ability of the Medicare program to obtain better value for high-cost prescription drugs and biological products"; make it easier for States to obtain approval of proposals to import drugs from Canada; issue recommendations to accelerate the approval of generics, biosimilars, combination products, and second-in-class branded products; work with Congress on legislation that would amend the Medicare "negotiation" provisions of the IRA to align the treatment of small molecule prescription drugs with that of biological products, coupled with other reforms "to prevent any increase in overall costs to Medicare and its beneficiaries"; and provide joint recommendations to the President on "how best to ensure that manufacturers pay accurate Medicaid drug rebates..., promote innovation in Medic

States in managing drug spending." The specifics of these proposals are unclear and, as a result, there is uncertainty as to how these and other potential legal and regulatory changes may impact our business.

Furthermore, because we participate in the 340B Program to sell a portion of our marketed products, changes in the administration of the program could have a material adverse impact on our revenues. Effective July 2022, we implemented a 340B Program Integrity Initiative, pursuant to which we request all hospital covered entities (i.e., hospitals that participate in the 340B Program) to provide claims-level data for CABOMETYX and COMETRIQ dispensed by contract pharmacies. A covered entity that does not have an in-house pharmacy or an affiliated contract pharmacy capable of dispensing 340B drugs to its patients may designate a single contract pharmacy within our authorized specialty pharmacy network for delivery of 340B priced drugs. We believe this initiative will provide much-needed transparency and promote compliance with program requirements, and at the same time, should not restrict patient access to our medicines.

Some manufacturers that have implemented similar contract pharmacy integrity programs received enforcement letters from the U.S. Department of Health and Human Services (HHS) asserting that those programs violate the 340B Program statute, have been referred to the HHS Office of Inspector General for assessment of civil monetary penalties, and have been subject to administrative dispute resolution (ADR) proceedings brought on behalf of covered entities. Several manufacturers are challenging the HHS' position in litigation. Relatedly, in November 2023, we received from several covered entities a 340B Program ADR petition seeking to invoke an administrative adjudication process overseen by the HHS' Health Resources and Services Administration (HRSA). The petitioners contend that our 340B Program Integrity Initiative caused them to be overcharged for CABOMETYX and COMETRIQ. We have since received confirmation that the HRSA will assign an ADR panel to the claim and responded to the complaint in October 2024. At this time, it remains unclear what, if any, liabilities we might incur as a party to this ADR proceeding.

In addition, certain states have also enacted laws requiring manufacturers to provide the 340B Program pricing through contract pharmacy arrangements, and additional states may adopt similar laws. On March 17, 2025 and April 24, 2025, we received notice letters (Notices) from the West Virginia Board of Pharmacy (WV Board) of complaints filed against us for purported violations of laws related to distribution of drugs to 340B facilities (West Virginia Code § 60A-8-6a (WV Statute)). The WV Statute provides for civil monetary penalties, in addition to investigative demands, remedies, and other penalties for violations. We acknowledged receipt of the Notices, and there have been no further communications. Other pharmaceutical manufacturers are challenging the WV Statute in court.

We believe these laws, which are being challenged in ongoing litigation, are invalid or are otherwise inapplicable to our 340B Program Integrity Initiative, but we have carved out covered entities in certain states while litigation challenging these laws proceeds. With respect to AR Act 1103 (the Arkansas law concerning 340B Program contract pharmacy arrangements), following the federal appellate court ruling in *Pharmaceutical Research and Manufacturers of America v. McClain*, we are voluntarily complying with AR Act 1103 and certain other state laws. We also believe that our 340B Program Integrity Initiative complies with the 340B Program statute, as supported by the federal appellate court decision in *Sanofi Aventis U.S. LLC v. United States Department of Health and Human Services* and *Novartis v. Johnson*.

Depending on the outcome of the ongoing litigation or any specific proceedings involving us, however, we may be required to modify or suspend our 340B Program Integrity Initiative. Ultimately, any negative ruling in a federal court, HHS administrative proceeding, or state-level proceeding in which we are a party, or in which the compliance of our 340B Program Integrity Initiative is at issue, could have a material adverse effect on our business, financial condition and results of operations. Due to general uncertainty with respect to this litigation and in the current regulatory and healthcare policy environment, and specifically regarding positions that the U.S. Presidential administration may take with respect to these issues, we are unable to predict the impact of any future legislative, regulatory, third-party payer or policy actions, including potential cost containment and healthcare reform measures. If enacted, we and any third parties we might engage may be unable to adapt to any changes implemented because of such measures, and we could face difficulties in maintaining or increasing profitability or otherwise experience a material adverse impact on our business, financial condition and results of operations.

Other state-level price control initiatives include legislation and regulations designed to control pharmaceutical and biotherapeutic product pricing, including restrictions on pricing or reimbursement at the state government level, limitations on discounts to patients, advance notices of price increases, marketing cost disclosure and transparency measures, and, in some cases, policies to encourage importation from other countries (subject to federal approval) and bulk purchasing.

Adoption of these drug pricing transparency regulations, and our associated compliance obligations, may increase our general and administrative costs and/or diminish our revenues. Implementation of these federal and/or state cost-containment measures or other healthcare reforms may limit our ability to generate product revenue or commercialize our products, and in the case of drug pricing transparency regulations, may result in fluctuations in our results of operations.

Risks Related to Growth of Our Product Portfolio and Research and Development

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, uncertain and subject to change, and may not result in regulatory approvals for additional cabozantinib indications or for our other product candidates, such as zanzalintinib, which could have a material adverse impact on our business, financial condition and results of operations.

The activities associated with the research, development and commercialization of the cabozantinib franchise, zanzalintinib and our other product candidates are subject to extensive regulation by the FDA and other regulatory agencies in the U.S., as well as by comparable regulatory authorities in other territories. The processes of obtaining regulatory approvals in the U.S. and other foreign jurisdictions are expensive and often takes many years, if approval is obtained at all, and they can vary substantially based upon the type, complexity and novelty of the product candidates involved. For example, before an NDA or supplemental New Drug Application (sNDA) can be submitted to the FDA, or a MAA to the EMA or any application or submission to comparable regulatory authorities in other jurisdictions, the product candidate must undergo extensive clinical trials, which can take many years and require substantial expenditures.

Any clinical trial may fail to produce results satisfactory to the FDA or regulatory authorities in other jurisdictions. The FDA has substantial discretion in the approval process and may refuse to approve any NDA or sNDA or require additional preclinical, clinical, safety or other non-clinical studies. In addition, policy-based activities could delay the approval of an application for cabozantinib, zanzalintinib, or our other product candidates. For example, the FDA's OCE has many initiatives aimed at improving oncology drug development, some of which may lead to the need for additional studies, such as dose optimization. Many of these initiatives are based on guidance issued by OCE. If the FDA chooses to withdraw those guidance documents for any reason it may affect our ability to gain regulatory approval based on studies that relied on those guidance documents. The FDA also continues to develop and finalize guidance documents that further refine the development process for oncology drug products. And, as this market expands, it becomes increasingly difficult to demonstrate benefit over the standard of care, which can be a hurdle for approval. Moreover, the development of our product candidates may be delayed by other events beyond our control. For example, action by the current U.S. Presidential administration to limit federal agency budgets or personnel, may result in reductions to the FDA's budget, employees, and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates. On February 11, 2025, an executive order was issued on workforce optimization, seeking to reduce the size of the federal workforce through large-scale reductions in force and by placing limitations on the number of new employee hires. Pursuant to this executive order, on March 27, 2025, the HHS announced that it was initiating a restructuring of the department, including reducing the FDA's workforce by approximately 3,500 full-time employees, which began on April 1, 2025. The termination of these employees has been preceded and accompanied by the resignation of senior leaders within the FDA, which could result in the potential loss of certain institutional knowledge and experience. We anticipate that restructuring, terminations, and resignations at the FDA will continue. Although the full impact of these events remains unclear, we expect there will be an adverse effect on the FDA's ability to efficiently carry out its functions, including conducting inspections and timely reviewing drug product applications, and a potential impact on how it interprets and enforces its authorities. Further, ongoing deregulation efforts by the U.S. Presidential administration could create regulatory uncertainty for biopharmaceutical companies. In addition, the future of the currently applicable Prescription Drug User Fee Act construct to ensure timely FDA review of applications may be impacted due to expressed concerns about the effect on industry-FDA relations.

The FDA has also been tightening the requirements for confirmatory studies for drugs approved via accelerated approval under additional authorities the FDA received in Section 3210 of the Food and Drug Omnibus Reform Act of 2022 (incorporated in Section 3222 of the Consolidated Appropriations Act, 2023, enacted on December 29, 2022). While the standard for accelerated approval remains unchanged, the FDA may now require that confirmatory trials for drugs approved under the pathway be underway prior to approval, which was not previously a requirement. The changes to the law are intended to prevent accelerated approval of drugs without verified clinical benefit, which had previously resulted in withdrawal of approval for certain products and indications approved on an accelerated basis. While it is not clear at this time how these legislative and regulatory initiatives will affect our plans to pursue accelerated approval for one or more of

our product candidates, these developments may have a material adverse impact on our business, financial condition, and results of operations.

Even if the FDA or a comparable authority in another jurisdiction grants accelerated approval for cabozantinib in one or more new indications or for one of our other product candidates, including zanzalintinib, such accelerated approval may be limited, imposing significant restrictions on the indicated uses, conditions for use, labeling, distribution, and/or production of the product and would impose requirements for post-marketing studies, including additional research and clinical trials, all of which may result in significant expense and limit our and our collaboration partners' ability to commercialize cabozantinib, zanzalintinib or our other product candidates in any new indications. In addition, some products approved under accelerated approval have encountered challenges with CMS coverage determinations. Failure to complete post-marketing requirements could significantly increase costs or delay, limit or ultimately restrict the commercialization of cabozantinib, zanzalintinib or another product candidate in the approved indication, or result in product withdrawal. Further, current or any future laws or executive orders governing FDA or foreign regulatory approval processes that may be enacted or executed could have a material adverse impact on our business, financial condition, and results of operations.

Risks Related to Financial Matters

Risks related to recent U.S. tariff announcements

Changes in U.S. trade policy, including recently announced tariffs, related to countries where we or our suppliers operate could result in increased costs for raw materials, components, or finished goods for us, or challenges for our third-party contract manufacturers, distributors and suppliers to continue to meet demands for our products at current prices. These cost increases may reduce our margins, require us to raise prices, or make our products less competitive in the marketplace. Additionally, retaliatory tariffs imposed by other countries on U.S. exports could adversely impact demand for our products in international markets or increase the costs of conducting business. If we are unable to mitigate these risks through supply chain adjustments, pricing strategies, or other measures, our financial performance and growth prospects could be negatively affected.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

In August 2024, our Board of Directors authorized a stock repurchase program to acquire up to \$500.0 million of our outstanding common stock before December 31, 2025. In February 2025, our Board of Directors authorized the repurchase of up to an additional \$500.0 million of our outstanding common stock before December 31, 2025. Under these programs, as of March 31, 2025, we repurchased 14.2 million shares of common stock for an aggregate purchase price of \$494.5 million. As of March 31, 2025, approximately \$505.5 million remained available for future stock repurchases before December 31, 2025.

The following table summarizes the stock repurchase activity for the three months ended March 31, 2025 and the approximate dollar value of shares that may yet be purchased pursuant to our stock repurchase programs (in thousands, except per share data):

	Total Number of Shares Purchased	Av	verage Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Approximate Dollar Value of Shares That May Yet Be Purchased Under the Programs	
January 4, 2025 - January 31, 2025	2,171	\$	34.24	2,171	\$	220,011
February 1, 2025 - February 28, 2025	2,539	\$	35.25	2,539	\$	630,521
March 1, 2025 - April 4, 2025	3,351	\$	37.30	3,351	\$	505,546
Total	8,061			8,061		

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, Rule 10b5-1 trading plans, 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. The

programs do not obligate us to acquire any amount of our common stock, and the stock repurchase programs may be modified, suspended or discontinued at any time without prior notice.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Amy C. Peterson, our Executive Vice President, Product Development and Medical Affairs, and Chief Medical Officer, an officer for purposes of Section 16 of the Exchange Act, entered into a pre-arranged stock trading plan on February 13, 2025. Ms. Peterson's trading plan provides for the sale of up to 72,776 shares of our common stock (including shares obtained from the exercise of vested stock options covered by the trading plan) between May 16, 2025 and March 2, 2026. This trading plan is intended to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act and Exelixis' policies regarding transactions in Exelixis securities.

During the three months ended March 31, 2025, no other directors or Section 16 officers of Exelixis adopted, modified or terminated any "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408 of Regulation S-K.

Item 6. Exhibits.

		Incorporation by Reference							
Exhibit Number	Exhibit Description	Form	File Number	Exhibit/ Appendix Reference	Filing Date	Filed Herewith			
3.1	Restated Certificate of Incorporation of Exelixis, Inc.	10-Q	000-30235	3.1	8/5/2021				
3.2	<u>Certificate of Change of Registered Agent and/or Registered</u> <u>Office of Exelixis, Inc.</u>	10-Q	000-30235	3.2	4/30/2024				
3.3	Amended and Restated Bylaws of Exelixis, Inc.	8-K	000-30235	3.1	12/20/2023				
10.1†	Form of One-Time Performance-Based Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under the Exelixis, Inc. 2017 Equity Incentive Plan					Х			
31.1	<u>Certification of Principal Executive Officer Pursuant to Exchange</u> <u>Act Rules 13a-14(a) and Rule 15d-14(a)</u>					Х			
31.2	<u>Certification of Principal Financial Officer Pursuant to Exchange</u> <u>Act Rules 13a-14(a) and Rule 15d-14(a)</u>					Х			
32.1‡	<u>Certifications of Principal Executive Officer and Principal Financial</u> <u>Officer Pursuant to 18 U.S.C. Section 1350</u>					X			
101.INS	XBRL Instance Document	The XBRL instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.							
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					Χ			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X			
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document					Χ			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					x			
+	Management contract or compensatory plan.								
‡	This certification accompanies this Quarterly Report on Form 10-Q, reference into any filing of Exelixis, Inc. under the Securities Act of 1 (whether made before or after the date of this Quarterly Report on in such filing.	1933, as aı	mended, or the S	ecurities Exchar	ige Act of 1934, as	amended			

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

May 13, 2025

Date

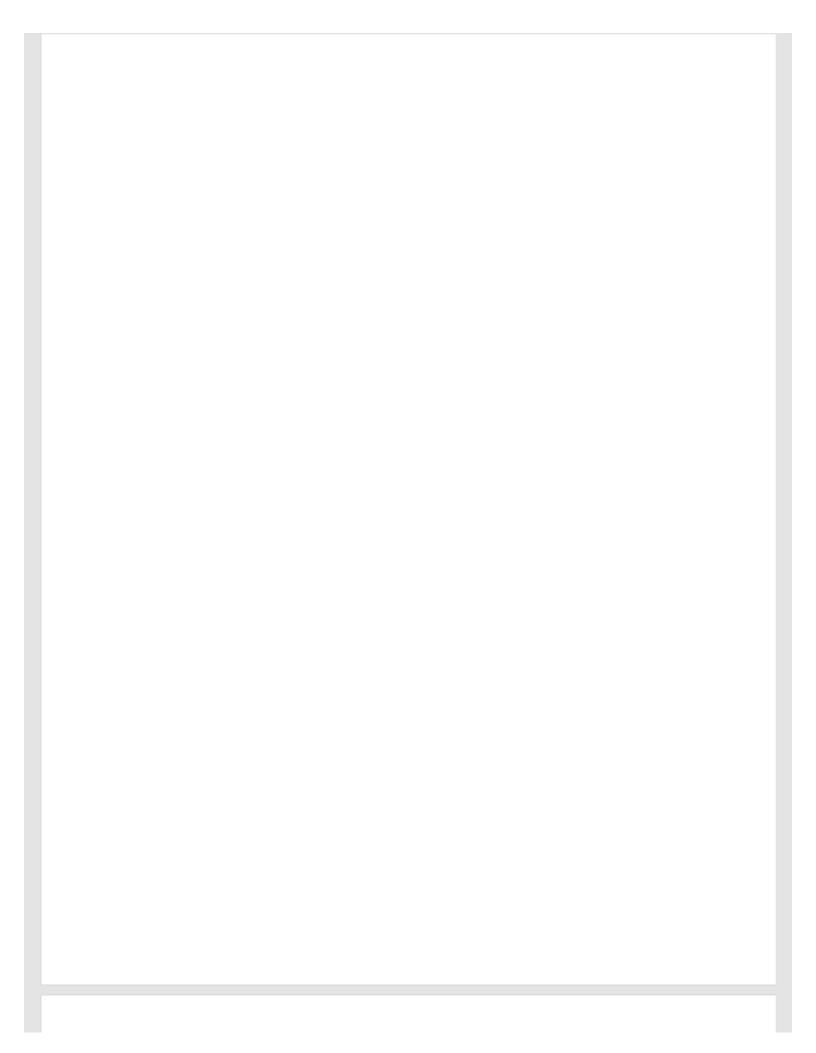
EXELIXIS, INC.

By: /s/ Christopher J. Senner

Christopher J. Senner

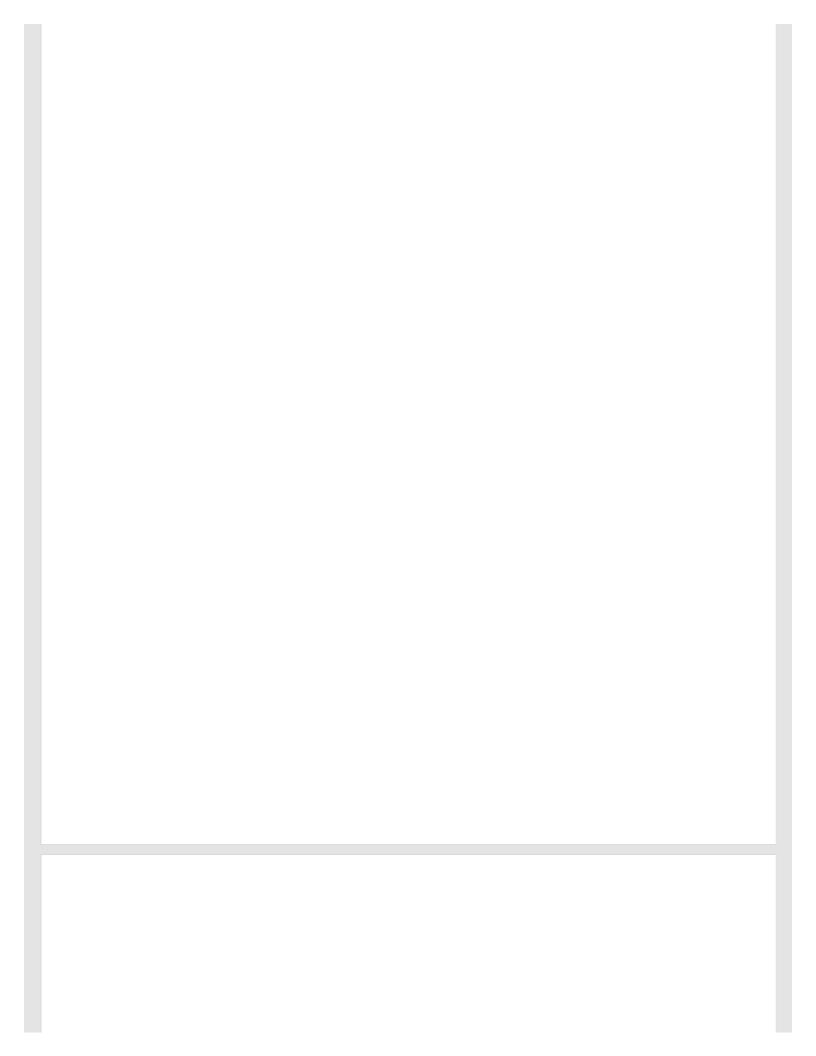
Executive Vice President and Chief Financial Officer

Executive Vice President and Chief Financial Officer (Duly Authorized Officer and Principal Financial and Accounting Officer)





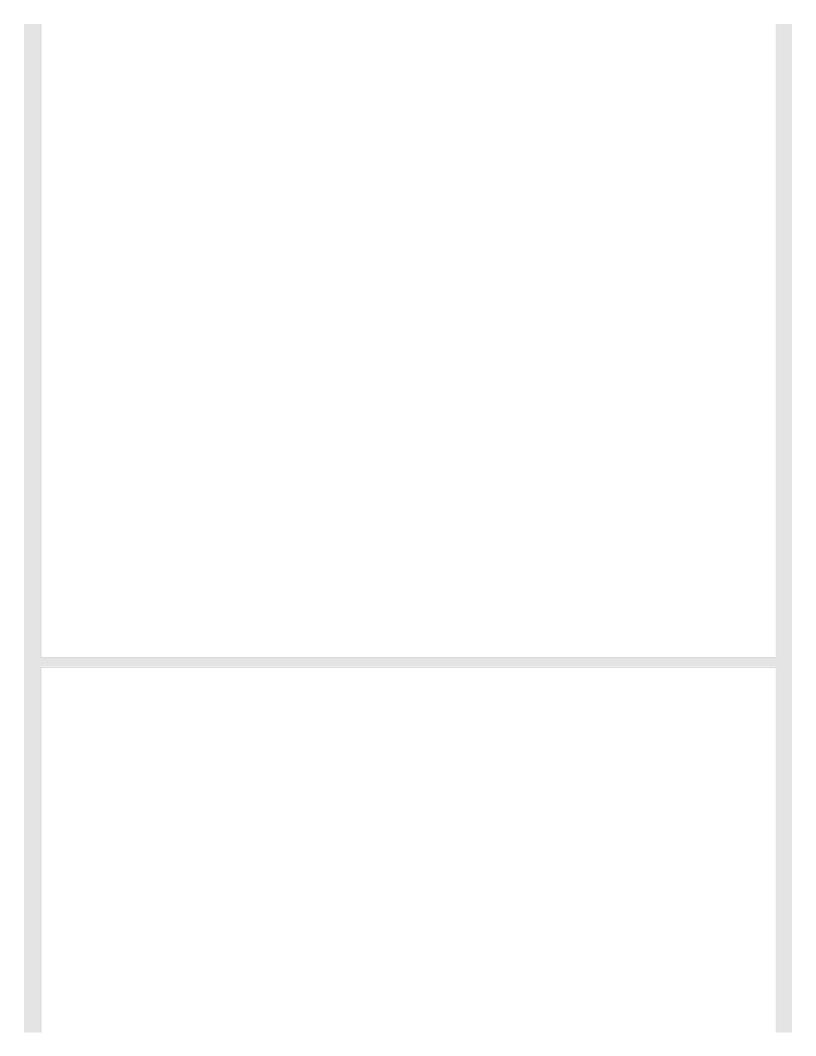


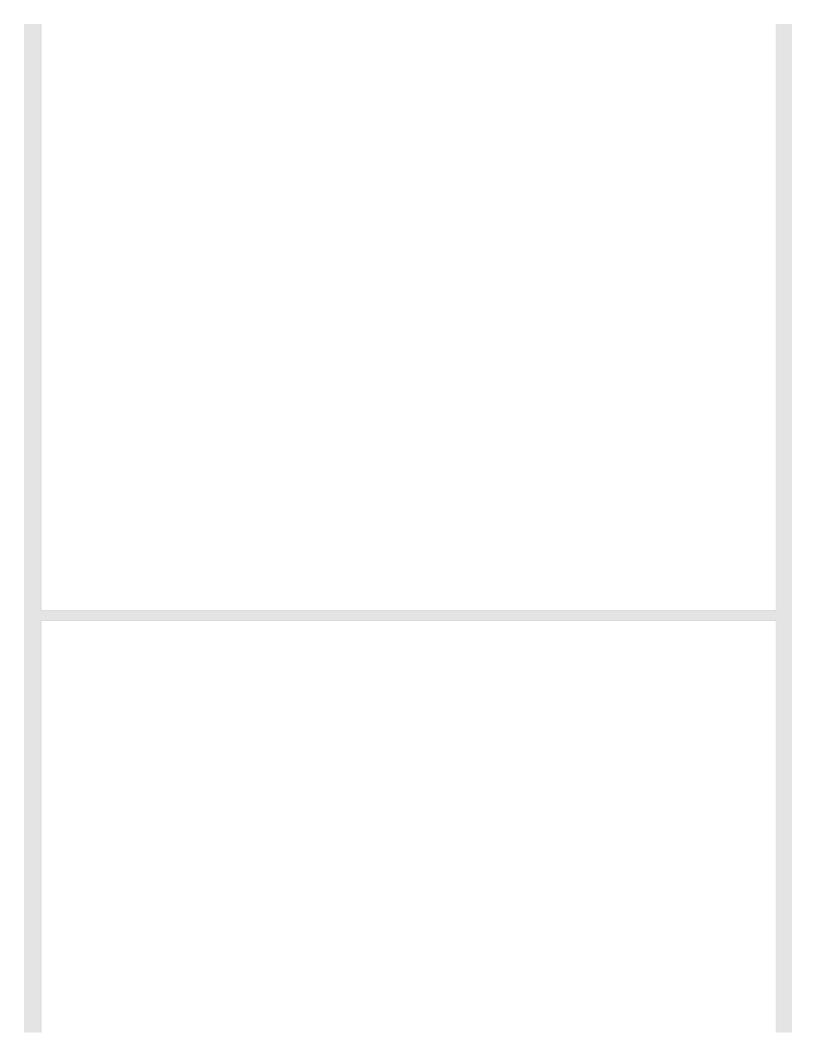


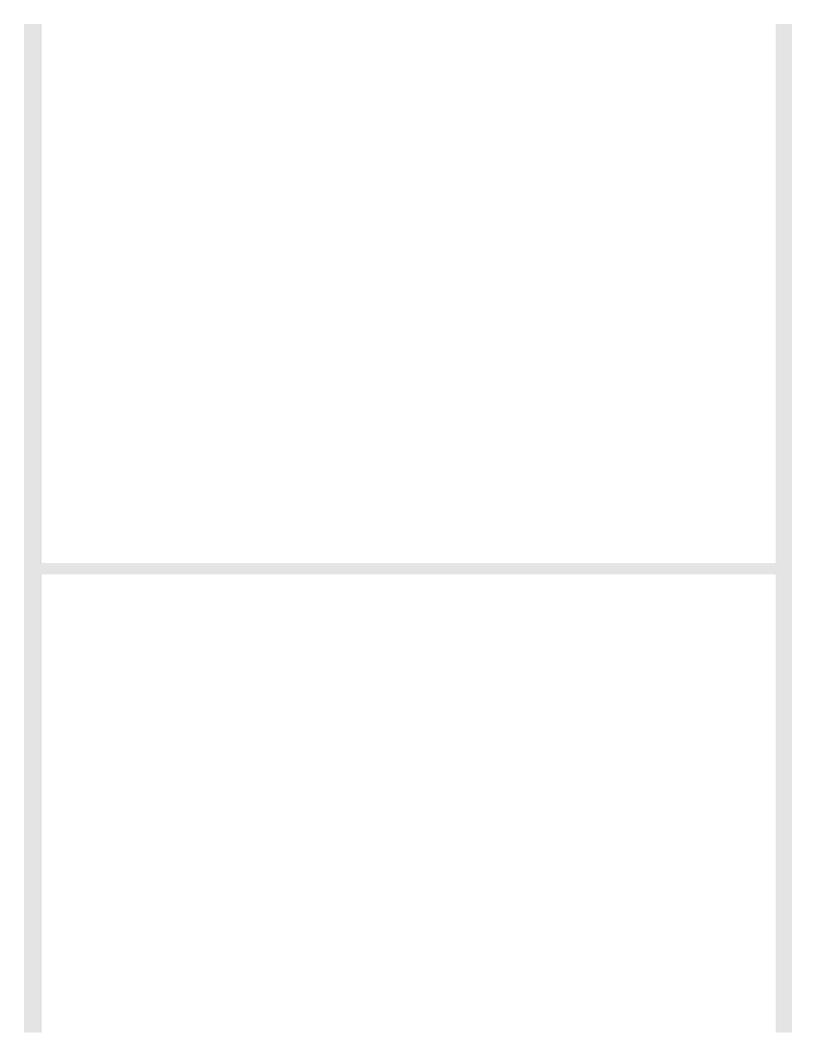


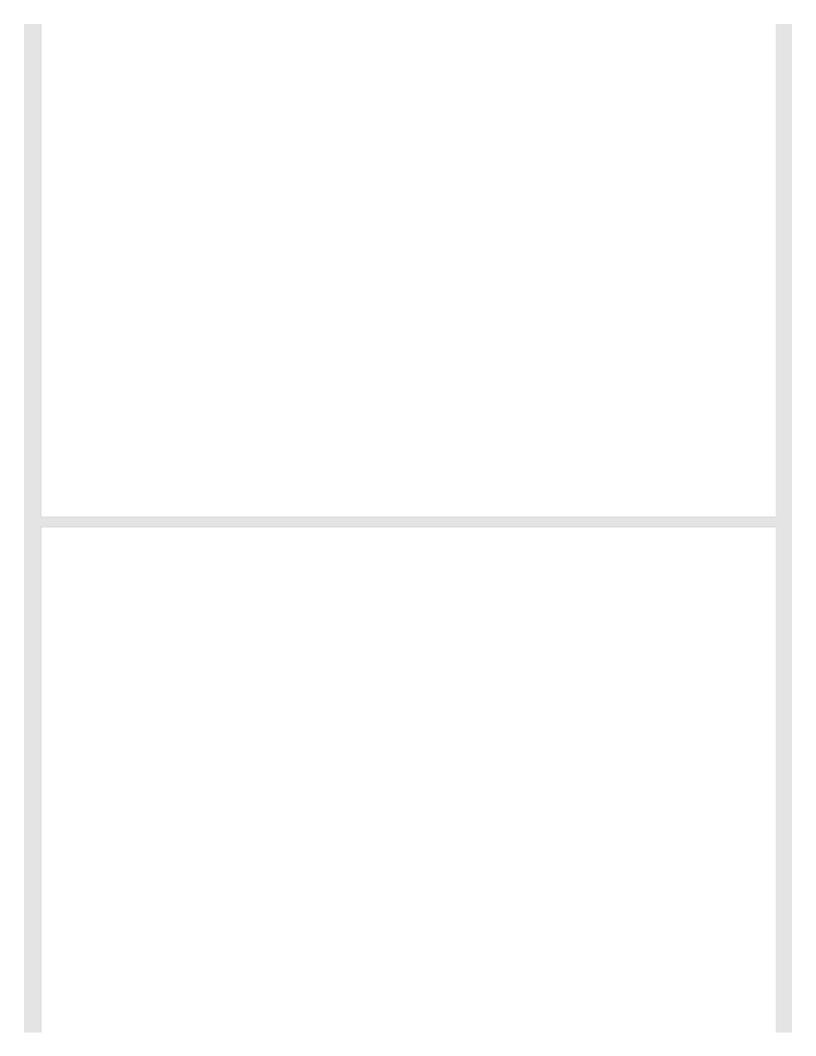


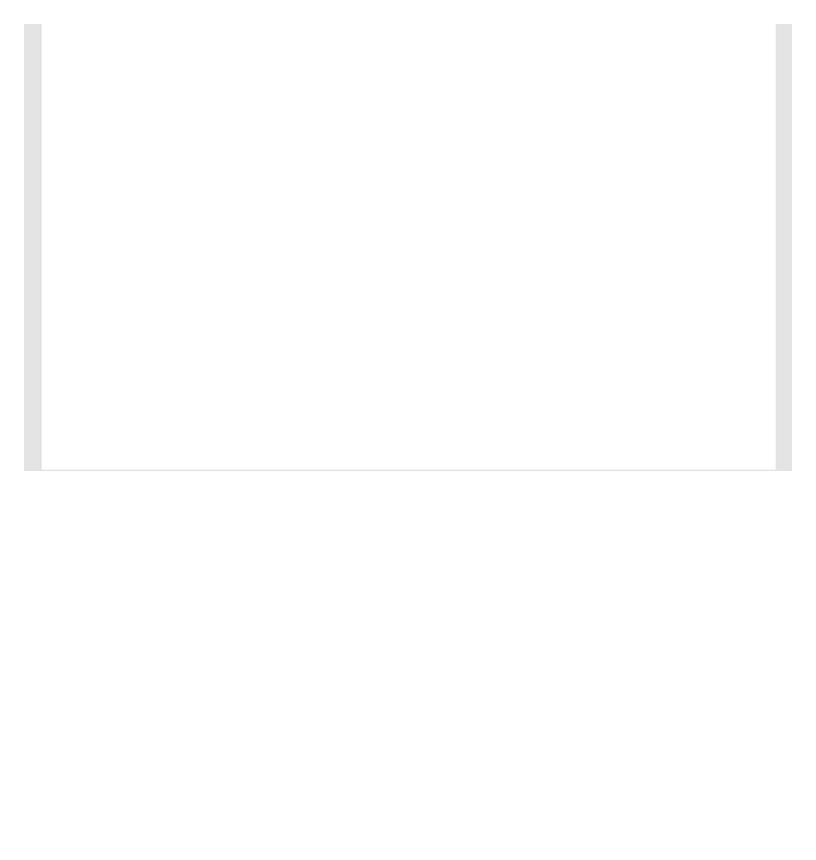












CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO EXCHANGE ACT RULES 13a-14(a) and 15d-14(a), AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael M. Morrissey, Ph.D., certify that:

- 1. I have reviewed this Form 10-Q of Exelixis, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Michael M. Morrissey

Michael M. Morrissey, Ph.D.

President and Chief Executive Officer (Principal Executive Officer)

Date: May 13, 2025

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO EXCHANGE ACT RULES 13a-14(a) and 15d-14(a), AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Christopher J. Senner, certify that:

- 1. I have reviewed this Form 10-Q of Exelixis, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Christopher J. Senner

Christopher J. Senner

Executive Vice President and Chief Financial Officer (Principal Financial Officer)

Date: May 13, 2025

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER **PURSUANT TO** 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO **SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Michael M. Morrissey, Ph.D., the President and Chief Executive Officer of Exelixis, Inc. (the "Company"), and Christopher J. Senner, the Executive Vice President and Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

- 1. The Company's Quarterly Report on Form 10-Q for the period ended April 4, 2025, to which this Certification is attached as Exhibit 32.1 (the "Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and
- 2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned have set their hands hereto as of the 13th day of May 2025.

/s/ Michael M. Morrissey /s/ Christopher J. Senner Michael M. Morrissey, Ph.D. Christopher J. Senner President and Chief Executive Officer **Executive Vice President and Chief Financial Officer**

(Principal Executive Officer)

(Principal Financial Officer)