# **UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

Fo	IT TO SECTION 13 OR 15(d) OF THE SECUR IT the quarterly period ended September 27, 202 or  NT TO SECTION 13 OR 15(d) OF THE SECUR For the transition period from to  Commission File Number: 000-30235  EXELIXIS, INC.  Exact name of registrant as specified in its charter)	4	
☐ TRANSITION REPORT PURSUA	For the transition period from to  Commission File Number: 000-30235  EXELIXIS, INC.	RITIES EXCHANGE ACT OF 1934	
	EXELIXIS° EXELIXIS, INC.		
	EXELIXIS, INC.		
	Exact name of registrant as specified in its charter)		
<b>Delaware</b> (State or other jurisdiction of incorporation or organization)		<b>04-3257395</b> (I.R.S. Employer Identification	on Number)
	1851 Harbor Bay Parkway Alameda, CA 94502 (650) 837-7000		
(Address, including zip code, and	telephone number, including area code, of registra	nnt's principal executive offices)	
Securit	ies registered pursuant to Section 12(b) of the	e Act:	
<u>Title of each class</u> Common Stock, \$0.001 Par Value per Share	<u>Trading Symbol(s)</u> <b>EXEL</b>	Name of each exchange on w The Nasdaq Stock Ma	
Indicate by check mark whether the registrant (1) has filed preceding 12 months (or for such shorter period that the registr days). Yes $\boxtimes$ No $\square$			
Indicate by check mark whether the registrant has submitt (§232.405 of this chapter) during the preceding 12 months (or f	· · · · · ·	-	-
Indicate by check mark whether the registrant is a large ac growth company. See the definitions of "large accelerated filer," Exchange Act.			
Large accelerated filer Non-accelerated filer	☐ Smalle	erated filer er reporting company ging growth company	
If an emerging growth company, indicate by check mark if the financial accounting standards provided pursuant to Section 13(	=	nded transition period for complyin	g with any new or revised
Indicate by check mark whether the registrant is a shell cor	npany (as defined in Rule 12b-2 of the Exchan	nge Act). Yes □ No ⊠	
As of October 21, 2024, there were 285,579,020 shares of	the registrant's common stock outstanding.		

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

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# PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	September 30, 2024			December 31, 2023		
ASSETS			_			
Current assets:						
Cash and cash equivalents	\$	258,346	\$	262,994		
Marketable securities		930,815		732,308		
Trade receivables, net		269,706		237,407		
Inventory		21,013		17,323		
Prepaid expenses and other current assets		69,838		67,926		
Total current assets		1,549,718		1,317,958		
Non-current marketable securities		523,421		728,717		
Property and equipment, net		124,414		128,731		
Deferred tax assets, net		358,869		361,145		
Goodwill		63,684		63,684		
Right-of-use assets and other non-current assets		340,170		342,122		
Total assets	\$	2,960,276	\$	2,942,357		
LIABILITIES AND STOCKHOLDERS' EQUITY			_			
Current liabilities:						
Accounts payable	\$	59,309	\$	33,768		
Accrued compensation and benefits		90,605		93,325		
Accrued clinical trial liabilities		56,184		71,615		
Rebates and fees due to customers		62,495		59,619		
Accrued collaboration liabilities		30,030		27,533		
Other current liabilities		95,723		108,417		
Total current liabilities		394,346		394,277		
Non-current portion of operating lease liabilities		194,445		189,944		
Other non-current liabilities		96,066		94,224		
Total liabilities		684,857		678,445		
Commitments and contingencies (Note 10)						
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: 285,780 and 302,793 at September 30, 2024, and December 31, 2023, respectively		286		303		
Additional paid-in capital		2,361,470		2,440,710		
Accumulated other comprehensive income (loss)		3,956		(3,750)		
Accumulated deficit		(90,293)		(173,351)		
Total stockholders' equity		2,275,419		2,263,912		
Total liabilities and stockholders' equity	\$	2,960,276	\$	2,942,357		

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

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

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

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 September 30,					Nine Months Ended September 30,					
		2024		2023		2024		2023			
Net income	\$	117,973	\$	1,041	\$	381,406	\$	122,247			
Other comprehensive income:											
Net unrealized gains on available-for-sale debt securities, net of tax impact of \$(2,692), \$(126), \$(2,276) and \$(121), respectively		9,105		425		7,706		509			
Comprehensive income	\$	127,078	\$	1,466	\$	389,112	\$	122,756			

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

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

# Three Months Ended September 30, 2024

	Common Stock				Additional						Total
	Shares	Shares Amount			Paid-in Capital		mprehensive come (Loss)	Accumulated Deficit		Stockholders' Equity	
Balance at June 30, 2024	285,222	\$	285	\$	2,324,570	\$	(5,149)	\$	(199,972)	\$	2,119,734
Net income	_		_		_		_		117,973		117,973
Other comprehensive income	_		_		_		9,105		_		9,105
Issuance of common stock under the equity incentive plan	1,041		2		19,787		_		_		19,789
Stock transactions associated with taxes withheld on equity awards	_		_		(2,166)		_		_		(2,166)
Repurchases of common stock	(483)		(1)		(3,939)		_		(8,294)		(12,234)
Stock-based compensation	_		_		23,218		_		_		23,218
Balance at September 30, 2024	285,780	\$	286	\$	2,361,470	\$	3,956	\$	(90,293)	\$	2,275,419

# Three Months Ended September 30, 2023

	Common Stock				Additional		cumulated Other	Retained Earnings			Total
	Shares	ļ	Amount		Paid-in Capital		nprehensive Loss	•	mulated ficit)	St	tockholders' Equity
Balance at June 30, 2023	320,253	\$	320	\$	2,530,869	\$	(14,437)	\$	11,186	\$	2,527,938
Net income	_		_		_		_		1,041		1,041
Other comprehensive income	_		_		_		425		_		425
Issuance of common stock under the equity incentive plan	1,052		1		7,089		_		_		7,090
Stock transactions associated with taxes withheld on equity awards	_		_		(9,751)		_		_		(9,751)
Repurchases of common stock	(10,335)		(10)		(81,666)		_	(1	38,276)		(219,952)
Stock-based compensation	_		_		40,829		_		_		40,829
Balance at September 30, 2023	310,970	\$	311	\$	2,487,370	\$	(14,012)	\$ (1	26,049)	\$	2,347,620

Continued on next page

Balance at September 30, 2023

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

Nine Months Ended September 30, 2024

	and the state of t										
	Commo		ock		Additional Paid-in Capital	Со	ccumulated Other mprehensive come (Loss)	A	ccumulated Deficit	Total Stockholder Equity	rs'
Balance at December 31, 2023	302,793	\$	303	\$	2,440,710	\$	(3,750)	\$	(173,351)	\$ 2,263,912	.2
Net income	_		_		_		_		381,406	381,40	16
Other comprehensive income	_		_		_		7,706		_	7,70	16
Issuance of common stock under the equity incentive plan and stock purchase plan	3,770		4		42,882		_		_	42,88	6
Stock transactions associated with taxes withheld on equity awards	-		_		(22,175)		_		_	(22,175	5)
Repurchases of common stock	(20,783)		(21)		(168,090)		_		(298,348)	(466,459	9)
Stock-based compensation	_		_		68,143		_		_	68,14	3
Balance at September 30, 2024	285,780	\$	286	\$	2,361,470	\$	3,956	\$	(90,293)	\$ 2,275,419	.9
=		_		_				_			=

Nine Months Ended September 30, 2023 Accumulated **Common Stock Additional** Other Total Paid-in Comprehensive Accumulated Stockholders' **Shares** Capital Loss Deficit Equity Amount Balance at December 31, 2022 323,951 \$ \$ 2,536,849 (34,225) \$ 2,488,427 324 (14,521)Net income 122,247 122,247 Other comprehensive income 509 509 Issuance of common stock under the equity incentive plan and stock purchase plan 3,962 4 24,413 24,417 Stock transactions associated with taxes withheld on equity awards (23,096)(23,096)Repurchases of common stock (16,943)(17)(133,678)(214,071)(347,766)Stock-based compensation 82,882 82,882

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

311

2,487,370

(14,012)

(126,049)

2,347,620

310,970

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

	Nine Months Ended September 30,				
		2024		2023	
Net income	\$	381,406	\$	122,247	
Adjustments to reconcile net income to net cash provided by operating activities:					
Depreciation		21,161		19,191	
Impairment of long-lived assets		64,238		_	
Stock-based compensation		67,490		82,039	
Non-cash lease expense		21,111		21,475	
Acquired in-process research and development technology		31,250		128,500	
Other, net		(9,247)		(12,372)	
Changes in operating assets and liabilities:					
Trade receivables, net		(32,192)		(33,804)	
Inventory		2,691		(14,503)	
Prepaid expenses and other assets		(63,068)		2,430	
Accrued collaboration liabilities		(1,003)		1,081	
Accounts payable and other liabilities		(24,129)		6,469	
Net cash provided by operating activities		459,708		322,753	
Cash flows from investing activities:					
Purchases of marketable securities		(622,522)		(823,847)	
Proceeds from maturities and sales of marketable securities		651,148		884,989	
Purchases of property, equipment and other, net		(24,458)		(27,334)	
Acquired in-process research and development technology		(27,750)		(122,500)	
Net cash used in investing activities		(23,582)		(88,692)	
Cash flows from financing activities:					
Payments for repurchases of common stock		(461,621)		(341,082)	
Proceeds from issuance of common stock under the equity incentive plan and stock purchase plan		43,027		24,339	
Taxes paid related to net share settlement of equity awards		(22,180)		(23,136)	
Net cash used in financing activities		(440,774)		(339,879)	
Net decrease in cash and cash equivalents		(4,648)		(105,818)	
Cash and cash equivalents at beginning of period		262,994		502,677	
Cash and cash equivalents at end of period	\$	258,346	\$	396,859	
Supplemental cash flow disclosures:					
Non-cash operating activities:					
Right-of-use assets obtained in exchange for lease obligations	\$	15,313	\$	13,612	

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

# 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 (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) and in other countries: as CABOMETYX® (cabozantinib) tablets for advanced renal cell carcinoma (RCC) (both alone and in combination with Bristol-Myers Squibb Company's (BMS) nivolumab), for previously treated hepatocellular carcinoma (HCC) and for previously treated, radioactive iodine (RAI)-refractory differentiated thyroid cancer (DTC); 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 (Daiichi Sankyo).

#### **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 2024, which is a 53-week fiscal year, will end on January 3, 2025 and fiscal year 2023, which was a 52-week fiscal year, ended on December 29, 2023. For convenience, references in this report as of and for the fiscal periods ended September 27, 2024, June 28, 2024, and September 29, 2023, and as of and for the fiscal years ending January 3, 2025 and ended December 29, 2023 and December 30, 2022 are indicated as being as of and for the periods ended September 30, 2024, June 30, 2024, and September 30, 2023, and the years ending December 31, 2024 and ended December 31, 2023, and December 31, 2022, 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 nine months ended September 30, 2024 are not necessarily indicative of the results that may be expected for the year ending December 31, 2024 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, 2023, included in Part II, Item 8 of our Annual Report on Form 10-K, filed with the SEC on February 6, 2024 (Fiscal 2023 Form 10-K).

#### **Segment Information**

We operate in one business segment that focuses on the discovery, development and commercialization of new medicines for difficult-to-treat cancers. Our 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 Chief Executive Officer uses consolidated, single-segment financial information for purposes of evaluating performance, forecasting future period financial results, allocating resources and setting incentive targets.

All of our long-lived assets are located in the U.S. See "Note 2. Revenues" for enterprise-wide disclosures about product sales, revenues from major customers and revenues by geographic region.

#### 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 nine months ended September 30, 2024, 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 2023 Form 10-K.

#### **Recently Adopted Accounting Pronouncements**

There were no new accounting pronouncements adopted by us since our filing of the Fiscal 2023 Form 10-K, which could have a significant effect on our Condensed Consolidated Financial Statements.

#### **Recent Accounting Pronouncements Not Yet Adopted**

In November 2023, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures (ASU 2023-07), which requires all public entities, including public entities with a single reportable segment, to provide in our annual and interim consolidated financial statements, one or more measures of segment profit or loss used by the chief operating decision maker to allocate resources and assess performance. Additionally, the standard requires disclosures of significant segment expenses and other segment items as well as incremental qualitative disclosures. ASU 2023-07 is effective for us in our annual reporting for fiscal 2024 and for interim period reporting beginning in fiscal 2025 on a retrospective basis. Early adoption is permitted. We are currently evaluating the impact of ASU 2023-07 on our Consolidated Financial Statements.

In December 2023, the FASB issued 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.

# **NOTE 2. REVENUES**

Revenues consisted of the following (in thousands):

	Three Months Ended September 30,				Nine Months Ended September 30,					
	 2024		2023		2024		2023			
Product revenues:										
Gross product revenues	\$ 646,419	\$	590,442	\$	1,814,495	\$	1,674,937			
Discounts and allowances	(168,360)		(163,945)		(520,332)		(475,394)			
Net product revenues	478,059		426,497		1,294,163		1,199,543			
Collaboration revenues:										
License revenues	60,239		42,367		299,901		133,406			
Collaboration services revenues	1,244		3,056		7,882		17,607			
Total collaboration revenues	61,483		45,423		307,783		151,013			
Total revenues	\$ 539,542	\$	471,920	\$	1,601,946	\$	1,350,556			

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

	Three Months Ended S	eptember 30,	Nine Months Ended September 30,			
	2024	2023	2024	2023		
Affiliates of Cencora, Inc. (formerly AmerisourceBergen Corporation)	20 %	18 %	17 %	17 %		
Affiliates of McKesson Corporation	18 %	18 %	16 %	17 %		
Affiliates of CVS Health Corporation	17 %	17 %	16 %	17 %		
Accredo Health, Incorporated	11 %	12 %	10 %	12 %		
Affiliates of Optum Specialty Pharmacy	10 %	10 %	9 %	10 %		

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

	September 30, 2024	December 31, 2023
Ipsen Pharma SAS	23 %	19 %
Affiliates of Cencora, Inc. (formerly AmerisourceBergen Corporation)	22 %	17 %
Affiliates of McKesson Corporation	21 %	21 %
Affiliates of CVS Health Corporation	14 %	20 %
Cardinal Health, Inc.	9 %	11 %

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

	•	Three Months En	ded Se	ptember 30,	Nine Months Ended September 30,						
	2024			2023		2024	2023				
U.S.	\$	481,461	\$	429,605	\$	1,303,874	\$	1,213,089			
Europe		51,081		36,021		277,343		106,286			
Japan		7,000		6,294		20,729		31,181			
Total revenues	\$	539,542	\$	471,920	\$	1,601,946	\$	1,350,556			

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.

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

	Three Months End	ded S	eptember 30,	Nine Months End	led S	September 30,
	 2024		2023	2024		2023
CABOMETYX	\$ 475,665	\$	422,155	\$ 1,285,423	\$	1,187,220
COMETRIQ	2,394		4,342	8,740		12,323
Net product revenues	\$ 478,059	\$	426,497	\$ 1,294,163	\$	1,199,543

#### **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):

	backs, Discounts mpt Payment and Other	Cre	Other Customer edits/Fees and Co-pay Assistance	Rebates	Total
Balance at December 31, 2023	\$ 25,221	\$	19,721	\$ 39,898	\$ 84,840
Provision related to sales made in:					
Current period	343,999		45,277	134,806	524,082
Prior periods	(891)		(2,043)	(816)	(3,750)
Payments and customer credits issued	(338,676)		(43,324)	(131,024)	(513,024)
Balance at September 30, 2024	\$ 29,653	\$	19,631	\$ 42,864	\$ 92,148

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):

	Septemb	er 30, 2024	Decem	ber 31, 2023
Contract assets <sup>(1)</sup>	\$	275	\$	1,321
Contract liabilities:				
Current portion <sup>(2)</sup>	\$	3,251	\$	5,406
Non-current portion <sup>(3)</sup>		3,951		5,524
Total contract liabilities	\$	7,202	\$	10,930

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

During the nine months ended September 30, 2024 and 2023, we recognized \$4.3 million and \$4.9 million, respectively, in revenues that were included in the beginning deferred revenues balance for those periods.

During the three and nine months ended September 30, 2024 and 2023, we recognized \$60.7 million and \$302.0 million, respectively, in revenues for performance obligations satisfied in previous periods, as compared to \$41.1 million and \$133.0 million, respectively, for the corresponding prior year periods. Such revenues were primarily related to the recognition of license revenues for the achievement of milestones during the second and third quarters of 2024 and royalty payments allocated to our license performance obligations for our collaborations with Ipsen, Takeda, Daiichi Sankyo and Genentech.

As of September 30, 2024, \$45.9 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 3. Collaboration Agreements and Business Development Activities" of the "Notes to Consolidated Financial Statements" included in Part II, Item 8 of our Fiscal 2023 Form 10-K for additional information about the expected timing to satisfy these performance obligations.

#### NOTE 3. 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 and their physicians. Historically, we also entered into other collaborations with leading biopharmaceutical companies pursuant to which we out-licensed other compounds and programs in our portfolio.

See "Note 3. Collaboration Agreements and Business Development Activities" of the "Notes to Consolidated Financial Statements" included in Part II, Item 8 of our Fiscal 2023 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.

<sup>&</sup>lt;sup>(2)</sup> Presented in other current liabilities in the accompanying Condensed Consolidated Balance Sheets.

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

During the second quarter of 2024, Ipsen opted into and is now co-funding the development costs for CABINET, a phase 3 pivotal study that evaluated cabozantinib versus placebo in patients with either advanced pancreatic neuroendocrine tumors (pNET) or advanced extra-pancreatic neuroendocrine tumors (epNET) who experienced progression after prior systemic therapy. Under the terms of the agreement, Ipsen is now obligated to reimburse us for its share of the CABINET global development costs. We determined that Ipsen's decision to opt into and co-fund the development costs for CABINET represented a contract modification for additional distinct services at its standalone selling price and therefore was treated as a separate contract under Topic 606. Accordingly, collaboration services revenues for the nine months ended September 30, 2024 includes a cumulative catch-up for Ipsen's share of global development costs incurred since the beginning of the study and through the opt-in date.

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

	Three Months End	ded Se	ptember 30,	Nine Months Ended September 30,						
	 2024		2023		2024		2023			
License revenues	\$ 51,275	\$	34,777	\$	276,062	\$	98,607			
Collaboration services revenues	(194)		1,244		1,281		7,679			
Total collaboration revenues	\$ 51,081	\$	36,021	\$	277,343	\$	106,286			

During the three and nine months ended September 30, 2024, we recognized \$10.8 million in license revenues and \$0.5 million in collaboration services revenues, in connection with a \$12.5 million regulatory milestone upon submission of a variation application to the European Medicines Agency for evaluating cabozantinib versus placebo in patients with either advanced pNET or advanced epNET who experienced progression after prior systemic therapy. In addition, we recognized \$2.2 million in license revenues for a commercial milestone from Ipsen upon its achievement of CAD\$30.0 million in cumulative net sales of cabozantinib over four consecutive quarters in Canada. License revenues for the nine months ended September 30, 2024 also included \$150.0 million related to a commercial milestone from Ipsen upon its achievement of \$600.0 million in cumulative net sales of cabozantinib over four consecutive quarters in its related Ipsen license territory.

As of September 30, 2024, \$27.4 million of the transaction price for this collaboration agreement, as amended, was allocated to our research and development services performance obligation that has not yet been satisfied.

#### 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 En	ded Sep	otember 30,		eptember 30,		
	 2024		2023		2024		2023
License revenues	\$ 3,524	\$	2,974	\$	9,528	\$	17,185
Collaboration services revenues	1,438		1,812		6,601		9,928
Total collaboration revenues	\$ 4,962	\$	4,786	\$	16,129	\$	27,113

As of September 30, 2024, \$18.5 million of the transaction price for this collaboration agreement, as amended, was allocated to our research and development services performance obligations that have not yet been satisfied.

#### **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 \$19.7 million and \$54.8 million during the three and nine months ended September 30, 2024, respectively, as compared to \$17.5 million and \$50.2 million, respectively, for the corresponding prior year periods.

#### 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 and their physicians. 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 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.

As part of the 2024 Restructuring Plan (as defined below), we have terminated certain of our in-licensing collaboration arrangements, including Aurigene Oncology, Ltd., BioInvent International AB, Cybrexa Therapeutics LLC, NBE-Therapeutics AG and STORM Therapeutics LTD. The termination of these agreements was effective in April 2024. See "Note 11. Restructuring" for additional information.

During the three and nine months ended September 30, 2024, we recognized \$18.7 million and \$47.2 million, respectively, within research and development expenses on the Condensed Consolidated Statements of Income, primarily related to development milestone payments and option exercise fees for the costs of intellectual property that have not yet achieved technological feasibility, research and development funding and other fees.

As of September 30, 2024, 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 \$509.6 million, regulatory milestone payments of up to \$365.3 million and commercial milestone payments of up to \$2.5 billion, each in the aggregate per product or target, as well as royalties on future net sales of products.

#### **NOTE 4. CASH AND MARKETABLE SECURITIES**

### Cash, Cash Equivalents and Marketable Securities

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

				Septembe	r 30,	2024	
	Am	ortized Cost	Gr	oss Unrealized Gains	Gr	oss Unrealized Losses	Fair Value
Debt securities available-for-sale:							
Commercial paper	\$	201,849	\$	_	\$	(2)	\$ 201,847
Corporate bonds		975,118		5,667		(717)	980,068
U.S. Treasury and government-sponsored enterprises		304,139		916		(430)	304,625
Municipal bonds		2,990		48		_	3,038
Total debt securities available-for-sale		1,484,096		6,631		(1,149)	1,489,578
Money market funds		179,467		_		_	179,467
Certificates of deposit		43,537		_		_	43,537
Total cash, cash equivalents and marketable securities	\$	1,707,100	\$	6,631	\$	(1,149)	\$ 1,712,582

December 31, 2023

	Amo	ortized Cost	Gr	oss Unrealized Gains	Gro	oss Unrealized Losses		Fair Value
Debt securities available-for-sale:								
Commercial paper	\$	214,016	\$	_	\$	_	\$	214,016
Corporate bonds		870,870		1,652		(4,277)		868,245
U.S. Treasury and government-sponsored enterprises		409,157		414		(2,250)		407,321
Municipal bonds		7,880		10		(49)		7,841
Total debt securities available-for-sale		1,501,923		2,076		(6,576)		1,497,423
Money market funds		154,287		_		_		154,287
Certificates of deposit		72,309		_		_		72,309
Total cash, cash equivalents and marketable securities	\$	1,728,519	\$	2,076	\$	(6,576)	\$	1,724,019

Interest receivable was \$13.0 million and \$13.1 million as of September 30, 2024 and December 31, 2023, 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 and nine months ended September 30, 2024 and 2023.

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):

In an Unrealized Loss Position Less than

Unrealized Loss Position 12	
Months or Greater	

	12 M	onth	S	Months or Greater					Total			
	 Fair Value	Gr	oss Unrealized Losses		Fair Value	Gı	ross Unrealized Losses		Fair Value	Gr	oss Unrealized Losses	
Commercial paper	\$ 13,735	\$	(2)	\$	_	\$	_	\$	13,735	\$	(2)	
Corporate bonds	37,447		(10)		214,727		(707)		252,174		(717)	
U.S. Treasury and government- sponsored enterprises	40,743		(30)		101,284		(400)		142,027		(430)	
Total	\$ 91,925	\$	(42)	\$	316,011	\$	(1,107)	\$	407,936	\$	(1,149)	

# December 31, 2023

September 30, 2024

	In a		oss Position Less than Months			In an Unrealized Months			Total				
		Fair Value	Gr	oss Unrealized Losses		Fair Value	G	ross Unrealized Losses		Fair Value	Gr	oss Unrealized Losses	
Corporate bonds	\$	255,958	\$	(847)	\$	281,837	\$	(3,430)	\$	537,795	\$	(4,277)	
U.S. Treasury and government- sponsored enterprises		163,339		(406)		155,452		(1,844)		318,791		(2,250)	
Municipal bonds		_		_		5,951		(49)		5,951		(49)	
Total	\$	419,297	\$	(1,253)	\$	443,240	\$	(5,323)	\$	862,537	\$	(6,576)	

There were 108 and 230 debt securities available-for-sale in an unrealized loss position as of September 30, 2024 and December 31, 2023, respectively. During the nine months ended September 30, 2024, 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):

	Septemb	er 30, 2024	December 31, 2023
Maturing in one year or less	\$	966,157	\$ 768,706
Maturing after one year through five years		523,421	728,717
Total debt securities available-for-sale	\$	1,489,578	\$ 1,497,423

#### **NOTE 5. 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

September 30, 2024

· 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):

Ċ					
Ş	_	\$	201,847	\$	201,847
	_		980,068		980,068
	_		304,625		304,625
	_		3,038		3,038
	_		1,489,578		1,489,578
	179,467		_		179,467
	_		43,537		43,537
\$	179,467	\$	1,533,115	\$	1,712,582
		Dec	ember 31, 2023		
	Level 1		Level 2		Total
\$		\$	214,016	\$	214,016
	_		868,245		868,245
	_		407,321		407,321
	_		7,841		7,841
	_		1,497,423		1,497,423
	154,287		_		154,287
	_		72,309		72,309
\$	154,287	\$	1,569,732	\$	1,724,019
	\$ \$	\$ 179,467   Level 1   \$	\$ 179,467 \$ Decorate	—       980,068         —       304,625         —       3,038         —       1,489,578         179,467       —         —       43,537         \$ 1,533,115         December 31, 2023         Level 1       Level 2         \$       214,016         —       868,245         —       407,321         —       7,841         —       1,497,423         154,287       —         —       72,309	—       980,068         —       304,625         —       3,038         —       1,489,578         179,467       —         —       43,537         \$       1,533,115       \$         December 31, 2023         Level 1       Level 2         \$       —       \$ 214,016       \$         —       868,245         —       407,321       —         —       7,841       —         —       1,497,423       —         —       72,309       —

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.

#### Impairment of Long-Lived Assets

When necessary, we record impairments of long-lived assets for the amount by which the fair value is less than the carrying value of these assets. When an impairment indicator exists, we calculate the undiscounted value of the projected cash flows for the asset, or asset group, and compare this estimated amount to the carrying amount. If the carrying amount is greater, we record an impairment loss for the excess of carrying value over fair value. In addition, in all cases of an impairment review, we reevaluate the remaining useful lives of the assets and modify them, as appropriate. In connection with the 2024 Restructuring Plan, we determined certain long-lived assets were impaired. The fair value was determined using an income approach where certain Level 3 inputs were used, including estimates and assumptions on the timing and amount of discounted cash flows. See "Note 11. Restructuring" for additional information.

During the third quarter of fiscal 2024, we evaluated our plans for the Alameda leased facilities and listed certain buildings for sublease. As a result, we determined the related right-of-use assets and leasehold improvements should be evaluated for impairment as separate asset groups. We concluded that the asset groups were not recoverable as of September 30, 2024 and recognized a \$51.7 million non-cash impairment charge. The estimated fair value was determined using an income approach comprised of projected discounted cash flows that included certain Level 3 inputs, such as sublease income and discount rates. The assumptions associated with sublease income and discount rates are subject to risks and uncertainties and could materially differ from our estimates. The impairment charge is presented in impairment of long-lived assets in the accompanying Condensed Consolidated Statements of Income.

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 September 30, 2024, we had one forward contract outstanding to sell €3.5 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 September 30, 2024. The forward contract is considered a Level 2 in the fair value hierarchy of our fair value measurements. The net realized and unrealized gains (losses) we recognized on the maturity of forward contracts were immaterial for each of the three and nine months ended September 30, 2024 and 2023 and are included in other income (expense), net in the accompanying Condensed Consolidated Statements of Income.

# **NOTE 6. INVENTORY**

Inventory consisted of the following (in thousands):

	5	September 30, 2024	December 31, 2023
Raw materials	\$	2,631	\$ 7,313
Work in process		60,422	59,422
Finished goods		11,225	9,581
Total	\$	74,278	\$ 76,316
Balance Sheet classification:			
Current portion included in inventory	\$	21,013	\$ 17,323
Non-current portion included in other non-current assets		53,265	58,993
Total	\$	74,278	\$ 76,316

### **NOTE 7. STOCKHOLDERS' EQUITY**

#### **Stock-based Compensation**

We have an equity incentive plan under which we granted stock options and restricted stock units (RSUs), including performance-based restricted stock units (PSUs), to employees and directors. As of September 30, 2024, 24.7 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.

On May 30, 2024, at the 2024 Annual Meeting of Stockholders, our stockholders approved the amendment and restatement of the Exelixis, Inc. 2000 Employee Stock Purchase Plan (as amended and restated, the Amended ESPP). The amendment and restatement increased the share reserve under the Amended ESPP by 6.0 million shares. As of September 30, 2024, 7.2 million shares were available for grant under the Amended ESPP.

We allocated the stock-based compensation expense for our equity incentive plan and our Amended ESPP as follows (in thousands):

		Three Months En	ded Se	ptember 30,	Nine Months Ended September 30,						
	2024			2023		2024	2023				
Research and development	\$	8,764	\$	12,438	\$	21,834	\$	25,279			
Selling, general and administrative		14,259		28,040		45,656		56,760			
Total stock-based compensation expense	\$	23,023	\$ 40,478		\$ 67,490			82,039			

Stock-based compensation expense for each type of award under our equity incentive plan and Amended ESPP were as follows (in thousands):

		Three Months End	ded S	eptember 30,	Nine Months Ended September 30,						
	2024			2023		2024	2023				
Stock options	\$	1,397	\$	1,882	\$	4,659	\$	5,966			
Restricted stock units				18,440		58,224		50,804			
Performance stock units		370		19,463		2,194		22,129			
Employee stock purchase plan		630		693		2,413		3,140			
Total stock-based compensation expense	\$	23,023	\$	40,478	\$	67,490	\$	82,039			

During the nine months ended September 30, 2024, we granted 0.1 million stock options with a weighted-average exercise price of \$22.46 per share and a weighted-average grant date fair value of \$9.79 per share. Stock options granted during the nine months ended September 30, 2024 have vesting conditions and contractual lives of a similar nature to those described in "Note 8. Stockholders' Equity" of the "Notes to Consolidated Financial Statements" included in Part II, Item 8 of our Fiscal 2023 Form 10-K. As of September 30, 2024, there were 6.2 million stock options outstanding and \$5.3 million of related unrecognized compensation expense.

In February 2024, we awarded to certain employees an aggregate of 1.3 million RSUs (the target number) that are subject to a total shareholder return (TSR) market condition (the 2024 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 December 30, 2023 through January 1, 2027. Depending on the results relative to the TSR market condition, the holders of the 2024 TSR-based RSUs may earn up to 175% of the target number of shares. 50% of the shares earned pursuant to the 2024 TSR-based RSU awards 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 2024 TSR-based RSUs will be forfeited if the market condition at or above a threshold level is not achieved at the end of the performance period on January 1, 2027.

We used a Monte Carlo simulation model and the following weighted-average assumptions to determine the weighted-average grant date fair value of \$20.19 per share for the 2024 TSR-based RSUs:

Fair value of Exelixis common stock on grant date	\$ 21.71
Expected volatility	36.68 %
Risk-free interest rate	4.42 %
Dividend yield	<b>-</b> %

The Monte Carlo simulation model 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.

During the nine months ended September 30, 2024, we granted 3.4 million service-based RSUs with a weighted- average grant date fair value of \$22.00 per share. As of September 30, 2024, there were 13.5 million RSUs outstanding, including RSUs that are subject to a TSR market condition, and \$178.7 million of related unrecognized compensation expense. Service-based RSUs granted to employees during the nine months ended September 30, 2024 have vesting conditions and contractual lives of a similar nature to those described in "Note 8. Stockholders' Equity" of the "Notes to Consolidated Financial Statements" included in Part II, Item 8 of our Fiscal 2023 Form 10-K.

As of September 30, 2024, there were 2.4 million PSUs outstanding, of which 0.8 million PSUs relate to awards for which we either achieved the performance goal or determined that attainment of the performance goal was probable. Expense recognition for PSUs commences when it is determined that attainment of the performance goal is probable. As of September 30, 2024, the remaining unrecognized stock-based compensation expense for the PSUs that were either achieved or deemed probable of achievement was \$1.2 million. The total unrecognized compensation expense for the PSUs for which we have not yet determined that attainment of the performance goal is probable was \$35.9 million. For more information about our PSUs, see "Note 8. Stockholders' Equity" of the "Notes to Consolidated Financial Statements" included in Part II, Item 8 of our Fiscal 2023 Form 10-K.

#### **Common Stock Repurchases**

In January 2024, our Board of Directors authorized a stock repurchase program to acquire up to \$450.0 million of our outstanding common stock before the end of 2024. As of June 30, 2024, we completed the repurchase of 20.3 million shares of common stock for an aggregate purchase price of \$450.0 million pursuant to our stock repurchase program. 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 the end of 2025. Under this program, during the third quarter of 2024, we repurchased 0.5 million shares of common stock for an aggregate purchase price of \$12.4 million. As of September 30, 2024, approximately \$487.6 million remained available for future stock repurchases before the end of 2025.

Stock repurchases under this program 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 program will be based on a variety of factors, including ongoing assessments of the capital needs of the business, alternative investment opportunities, the market price of our common stock and general market conditions. The program does not obligate us to acquire any particular amount of our common stock, and the stock repurchase program may be modified, suspended or discontinued at any time without prior notice.

#### NOTE 8. PROVISION FOR INCOME TAXES

The effective tax rates for the three and nine months ended September 30, 2024, were 23.8% and 23.2%, respectively, as compared to 82.1% and 20.9%, respectively, for the corresponding periods in 2023. The effective tax rates for the three and nine months ended September 30, 2024, differed from the U.S. federal statutory tax rate of 21% primarily due to state taxes, partially offset by the generation of federal tax credits. The effective tax rates for the three months ended September 30, 2023, differed from the U.S. federal statutory tax rate of 21%, primarily due to non-deductible executive compensation and the branded prescription drug fee, partially offset by the generation of federal tax credits. The effective tax rate for the nine months ended September 30, 2023, differed from the U.S. federal statutory tax rate of 21% primarily due to the generation of federal tax credits, partially offset by non-deductible executive compensation and state taxes.

### **NOTE 9. NET INCOME PER SHARE**

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

		Three Months End	ded s	September 30,	Nine Months Ended September 30,					
	2024			2023	2024			2023		
Numerator:										
Net income	\$	117,973	\$	1,041	\$	381,406	\$	122,247		
Denominator:	-		_							
Weighted-average common shares outstanding — basic		285,622		315,496		291,865		321,373		
Dilutive securities		5,856		3,751		5,129		2,904		
Weighted-average common shares outstanding — diluted		291,478		319,247		296,994		324,277		
Net income per share — basic	\$	0.41	\$	0.00	\$	1.31	\$	0.38		
Net income per share — diluted		0.40	\$	0.00	\$	1.28	\$	0.38		

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 TSR-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 Ended	l September 30,	Nine Months Ended September 30,				
-	2024	2023	2024	2023			
Anti-dilutive securities and contingently issuable shares excluded	4,040	10,144	7,241	13,164			

#### **NOTE 10. COMMITMENTS AND CONTINGENCIES**

# **Legal Proceedings**

# **MSN I 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. In particular, the May 5, 2020 amended ANDA requested approval to

market a generic version of CABOMETYX tablets prior to expiration of 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 arising from MSN's amended ANDA filing with the FDA. Neither of our complaints have alleged infringement of U.S. Patents No. 9,724,342, 10,034,873 and 10,039,757. On May 22, 2020, MSN filed its response to the complaint, alleging that the asserted claims of U.S. Patents No. 7,579,473 and 8,497,284 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.

On October 1, 2021, 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. 7,579,473 and 8,497,284, 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. 7,579,473 and 8,497,284 would also infringe certain claims of each patent, if those claims are not found to be invalid. Then, on October 12, 2021, pursuant to a separate stipulation between us and MSN, the Delaware District Court entered an order dismissing MSN's counterclaims with respect to U.S. Patent No. 9,809,549. In our MSN I complaints, we sought, among other relief, an order that the effective date of any FDA approval of MSN's ANDA be a date no earlier than the expiration of all of U.S. Patents No. 7,579,473, 8,497,284 and 8,877,776, the latest of which expires on October 8, 2030, and equitable relief enjoining MSN from infringing these patents. In an effort to streamline the case, the parties narrowed their assertions. On April 8, 2022, MSN withdrew its validity challenge to U.S. Patent No. 8,877,776. On April 14, 2022, we agreed not to assert U.S. Patent No. 8,497,284 at trial and MSN, correspondingly, agreed to withdraw its validity challenges to U.S. Patent No. 8,497,284, as well as claims 1-4 and 6-7 of U.S. Patent No. 7,579,473. As a result of this narrowing, the trial addressed two issues: (1) infringement of claim 1 of the U.S. Patent No. 8,877,776; and (2) validity of claim 5 of the U.S. Patent No. 7,579,473. 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).

#### MSN II ANDA Litigation

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

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. The Delaware District Court's judgment is also subject to appeal by either party. We are currently evaluating next steps with respect to this litigation.

# Teva ANDA Litigation

In May 2021, we received notice letters regarding an ANDA submitted to the FDA by Teva Pharmaceutical Industries Limited, Teva Pharmaceuticals Development, Inc. and Teva Pharmaceuticals USA, Inc. (individually and collectively referred to as Teva), requesting approval to market a generic version of CABOMETYX tablets. Teva's notice letters included a Paragraph IV certification with respect to our U.S. Patents No. 9,724,342 (formulations), 10,034,873 (methods of treatment) and 10,039,757 (methods of treatment), which are listed in the Orange Book. Teva's notice letters did not provide a Paragraph IV certification against any additional CABOMETYX patents. On June 17, 2021, we filed a complaint in the Delaware District Court for patent infringement against Teva asserting infringement of U.S. Patents No. 9,724,342, 10,034,873 and 10,039,757 arising from Teva's ANDA filing with the FDA. On August 27, 2021, Teva filed its answer and counterclaims to the complaint, alleging that the asserted claims of U.S. Patents No. 9,724,342, 10,034,873 and 10,039,757 are invalid and not infringed. On September 17, 2021, we filed an answer to Teva's counterclaims. On July 29, 2022, we received notice from Teva that it had amended its ANDA to assert an additional Paragraph IV certification. As amended, Teva'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 September 2, 2022, we filed a complaint in the Delaware District Court for patent infringement against Teva, asserting infringement of U.S. Patent No. 11,298,349 arising from Teva's amended ANDA filing with the FDA. We sought, among other relief, an order that the effective date of any FDA approval of Teva's ANDA be a date no earlier than the expiration of all of U.S. Patents No. 9,724,342, 10,034,873, 10,039,757 and 11,298,349, the latest of which expires on July 9, 2033, and equitable relief enjoining Teva from infringing these patents. On September 30, 2022, the parties filed a stipulation to consolidate the two lawsuits, numbered Civil Action Nos. 21-00871 and 22-01168, and to stay all proceedings, which was granted by the Delaware District Court on October 3, 2022. Following a similar order granted by the Delaware District Court on February 9, 2022 to stay all proceedings with respect to Civil Action No. 21-00871, this case remained administratively closed, and Civil Action No. 22-01168 was administratively closed on October 3, 2022. In July 2023, we entered into a settlement and license agreement with Teva (the Teva Settlement Agreement) to end these litigations. Pursuant to the terms of the Teva Settlement Agreement, we will grant Teva a license to market its generic version of CABOMETYX in the U.S. beginning on January 1, 2031, if approved by the FDA and subject to conditions and exceptions common to agreements of this type. On September 15, 2023, the parties filed a joint stipulation of dismissal with the Delaware District Court, and on September 19, 2023, the Delaware District Court granted the parties' stipulation and dismissed the case without prejudice.

#### Cipla ANDA Litigation

On February 6, 2023, we received a notice letter regarding an ANDA submitted to the FDA by Cipla, Ltd. and Cipla USA, Inc. (individually and collectively referred to as Cipla), including a Paragraph IV certification with respect to our U.S. Patents No. 8,877,776 (salt and polymorphic forms), 9,724,342 (formulations), 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). Cipla's notice letter did not provide a Paragraph IV certification against any additional CABOMETYX patents. On March 16, 2023, we filed a complaint in the Delaware District Court for patent infringement against Cipla asserting infringement of U.S. Patents No. 8,877,776, 11,091,439, 11,091,440, 11,098,015 and 11,298,349 arising from Cipla's ANDA filing with the FDA. Cipla's ANDA requests approval to market a generic version of

CABOMETYX tablets prior to the expiration of the aforementioned patents. We sought, among other relief, an order that the effective date of any FDA approval of Cipla's ANDA would be a date no earlier than the expiration of all of U.S. Patents No. 8,877,776, 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 Cipla from infringing these patents. On May 4, 2023, we filed, under seal, a stipulation and proposed order to stay all proceedings, and the Delaware District Court, in a sealed order on the same day, granted the proposed order and administratively closed the case. On May 5, 2023, the Delaware District Court issued a redacted version of the May 4, 2023 stipulation and proposed order. On March 27, 2024, we received notice from Cipla that it had amended its ANDA to assert additional Paragraph IV certifications. The ANDA now requests approval to market generic versions of CABOMETYX tablets with 20 mg and 40 mg dosage strengths (in addition to the 60 mg dosage strength contemplated by Cipla's original ANDA) prior to expiration of U.S. Patents No. 8,877,776, 9,724,342, 10,039,757, 11,091,439, 11,091,440, 11,098,015 and 11,298,349. In May 2024, we entered into a settlement and license agreement (the Cipla Settlement Agreement) with Cipla to end these litigations. Pursuant to the terms of the Cipla Settlement Agreement, we granted Cipla a license to market its generic version of CABOMETYX in the U.S. beginning on January 1, 2031, if approved by the FDA and subject to conditions and exceptions common to agreements of this type. On July 8, 2024, the parties filed a joint stipulation of dismissal with the Delaware District Court, and on July 9, 2024, the Delaware District Court granted the parties' stipulation and dismissed the case without prejudice.

#### Other

On September 17, 2024, we received a notice letter regarding an ANDA submitted to the FDA by Sun Pharmaceutical Industries Ltd. (Sun), including 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), the latest of which expires on February 10, 2032. Sun's ANDA requests approval to market a generic version of CABOMETYX tablets prior to the expiration of the aforementioned patents. We have not yet responded to this Paragraph IV certification notice but are evaluating it.

The sale of any generic version of CABOMETYX earlier than its patent expiration 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. 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.

### **NOTE 11. RESTRUCTURING**

Our Board of Directors authorized, and we implemented, a corporate restructuring plan (the 2024 Restructuring Plan) to reduce our workforce and rebalance our cost structure in alignment with our strategic priorities. Restructuring expenses expected to be incurred under the 2024 Restructuring Plan include: severance and employee-related costs; asset impairment; and contract termination and other exit costs. The total estimated restructuring costs associated with the 2024 Restructuring Plan are approximately \$33.5 million and will be recorded to the restructuring expense line item within our Condensed Consolidated Statements of Income as they are incurred through the end of the plan. During the three and nine months ended September 30, 2024, we recognized \$0.1 million and \$33.4 million, respectively, in expenses associated with the 2024 Restructuring Plan, which are presented in restructuring in the accompanying Condensed Consolidated Statements of Income.

In connection with the 2024 Restructuring Plan, we exited two leases in the Greater Philadelphia area and the right-of-use assets, related leasehold improvements and certain other long-lived assets were remeasured and recorded at fair value, see "Note 5. Fair Value Measurements" for additional information.

We incurred the majority of the charges related to the 2024 Restructuring Plan during the first quarter of 2024 and substantially completed the 2024 Restructuring Plan as of the end of the second quarter of 2024. The expected pre-tax charges are estimates and are subject to a number of assumptions and actual results may vary from the estimates provided.

The restructuring activities and balances as of and for the nine months ended September 30, 2024 were as follows (in thousands):

		Nine Months Ended September 30, 2024														
	D	Accrued at ecember 3 2023		Ini	tial Costs		Adj. to Costs <sup>(2)</sup>		Non-cash charges		Cash Payments		Accrued at September 30, 2024 <sup>(3)</sup>	otal Costs ncurred to Date	Ex	Total pected Plan Costs
Severance and employee- related costs	\$		_	\$	15,656	\$	69	\$		\$	(15,469)	\$	256	\$ 15,725	\$	15,725
Contract termination and other exit $costs^{(1)}$			_		5,119		(4)		_		(5,115)		_	5,115		5,201
Asset impairment			_		12,318		248		(12,566)		_		_	12,566		12,566
Total restructuring	\$		_	\$	33,093	\$	313	\$	(12,566)	\$	(20,584)	\$	256	\$ 33,406	\$	33,492

<sup>(1)</sup> Contract termination costs consist of accruals for costs to be incurred without future economic benefit, and other exit costs expensed as incurred.

#### 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, 2023, filed with the Securities and Exchange Commission (SEC) on February 6, 2024 (Fiscal 2023 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 2023 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 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 (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) and in 68 other countries: as CABOMETYX® (cabozantinib) tablets for advanced renal cell carcinoma (RCC) (both alone and in combination with Bristol-Myers Squibb Company's (BMS) nivolumab (OPDIVO®)), for previously treated hepatocellular carcinoma (HCC) and for previously treated, radioactive iodine (RAI)-refractory differentiated thyroid cancer (DTC); 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.

<sup>(2)</sup> Adjustments to costs consist of changes in estimates whereby increases and decreases in costs were recorded to operating expenses in the period of adjustments.

<sup>(3)</sup> As of September 30, 2024, all restructuring liabilities have been recorded in accrued compensation and benefits in the accompanying Condensed Consolidated Balance Sheets.

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.

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 neuroendocrine tumors (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; XB010, an ADC consisting of a monomethyl auristatin E (MMAE) payload conjugated to a human monoclonal antibody (mAb) targeting the tumor antigen 5T4; and XL495, a small molecule inhibitor of PKMYT1. 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 then 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.

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 qualifying drugs will 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 (small biotech exception). As of the date of this Quarterly Report on Form 10-Q, CMS has informed us that we have qualified for the small biotech exception with respect to our cabozantinib franchise products through 2026 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. We expect the increase in manufacturer discount will be 1% in 2025 and will further increase according to a schedule set by CMS until we are required to pay the full 20% discount paid by other manufacturers in 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 (EU), 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 Ministry of Health, Labour and Welfare (MHLW) 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.

We are also pursuing other indications for cabozantinib that have the potential to increase the number of cancer patients who could potentially benefit from this medicine. In August 2023, we announced positive results from CABINET, a phase 3 pivotal study that evaluated cabozantinib versus placebo in patients with NET who experienced progression after prior systemic therapy in two independently powered cohorts: one for patients with advanced pancreatic NET (pNET) and another for patients with advanced extra-pancreatic NET (epNET). The trial was unblinded and stopped early due to the dramatic improvement in efficacy with respect to the primary endpoint of progression-free survival (PFS) observed at interim analysis. Data from CABINET demonstrated that cabozantinib substantially prolonged PFS as assessed by blinded independent central review in both pNET and epNET cohorts, and that the safety profile of cabozantinib observed in the trial was consistent with its known safety profile. In August 2024, we announced that the FDA had accepted our supplemental New Drug Application (sNDA) seeking approval for cabozantinib to treat adult patients with previously treated, locally advanced/unresectable or metastatic, well- or moderately differentiated pNET or epNET, granted standard review in the U.S., and assigned a Prescription Drug User Fee Act (PDUFA) target action date of April 3, 2025. The FDA also granted orphan drug designation to cabozantinib for the treatment of pNET. Detailed final results from CABINET were presented during the NETs and Endocrine Tumours Proffered Paper Session at the European Society for Medical Oncology Congress in September 2024 (ESMO 2024) and were concurrently published in *The New England Journal of Medicine* (NEJM). CABINET was conducted by the Alliance for Clinical Trials in Oncology through our Cooperative Research and Development Agreement with the National Cancer Institute's Cancer Therapy Evaluation Program, which along with our investigator-sponsored trial program, provides an avenue

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 PFS intent-to-treat population (i.e., the first 400 randomized patients), and these data were presented at the American Society of Clinical Oncology 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 ESMO 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. We intend to submit an sNDA to the FDA during the fourth quarter of 2024.

In August 2024, we announced the final analysis for the secondary endpoint of OS for COSMIC-313, a phase 3 pivotal trial evaluating the combination of cabozantinib, nivolumab and ipilimumab versus the combination of nivolumab and ipilimumab in patients with previously untreated advanced intermediate- or poor-risk RCC. At the final analysis, the experimental arm did not demonstrate an OS benefit over the control arm. Based on these results and the evolution of the first-line RCC treatment landscape since this study was initiated in May 2019, Exelixis will not pursue a regulatory path for COSMIC-313. Detailed final results will be presented at a future medical meeting.

# **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 enrollment into STELLAR-002 is ongoing. In addition, in December 2023, we initiated a targeted phase 1b/2 trial (STELLAR-009) studying zanzalintinib in combination with AB521, an inhibitor of hypoxia-inducible factor-2 alpha (HIF-2 $\alpha$ ) developed by Arcus Biosciences, Inc. (Arcus); however, enrollment into STELLAR-009 was halted as of September 2024 following the joint decision between us and Arcus to wind down the study and end our clinical collaboration given the two companies' differing strategies with respect to potential TKI-HIF combination regimens to treat RCC.

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 2025. 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. In December 2023, we initiated STELLAR-305, a phase 2/3 pivotal trial evaluating zanzalintinib in combination with pembrolizumab, an anti-PD-1 ICI developed by Merck & Co., Inc. (collectively with its affiliates and subsidiaries, Merck), versus monotherapy 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 in STELLAR-311, a planned phase 3 pivotal trial evaluating zanzalintinib versus everolimus as a first oral therapy in patients with advanced NET, regardless of site of origin, which we anticipate initiating 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 Merck to evaluate zanzalintinib in combination with KEYTRUDA® (pembrolizumab) in SCCHN and in combination with WELIREG® (belzutifan), Merck's oral HIF-2α inhibitor, in RCC. Under the collaboration, Merck US 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**

Much 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. This approach has been validated by multiple regulatory approvals of ADCs in the past several years. 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. Future 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<sup>™</sup> 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 during the remainder of 2024 and in future years. For example, in August 2024, we announced the initiation of a phase 1 clinical trial evaluating XB010, both as a monotherapy and in combination with pembrolizumab, in

patients with advanced solid tumors, following the FDA's acceptance of our Investigational New Drug (IND) application, and enrollment is ongoing. XB010 is our first ADC advanced internally and consists of an MMAE payload conjugated to a mAb targeting the tumor antigen 5T4. XB010 was constructed using Catalent's SMARTag site-specific bioconjugation platform, and its 5T4-targeting mAb was discovered in collaboration with Invenra. Over the next two years, we also intend to advance four 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: XB628, a bispecific antibody that targets both PD-L1 and NKG2A; 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; and XB033, an ADC targeting the tumor antigen IL13Rα2.

In August 2024, we announced that we will discontinue the development of XB002, our TF-targeting ADC, as part of our portfolio prioritization efforts. Based on available data, the compound is unlikely to improve upon tisotumab vedotin or other competitor TF-targeting ADCs currently in development. We plan to disclose data from the phase 1 JEWEL-101 study, evaluating XB002 in advance solid tumors, at a later date. We plan to reallocate resources to new pivotal trials with zanzalintinib, advancing XL309 and our growing pipeline.

#### 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:

- XL309 is a potentially best-in-class small molecule inhibitor of USP1, a synthetic lethal target in the context of BRCA-mutated tumors. It 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; enrollment is ongoing. XL309 has potential in patients whose tumors are no longer responsive to PARP inhibitors (PARPi), including ovarian, breast and prostate cancers. XL309 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.
- XL495 is an inhibitor of PKMYT1 with best-in-class potential to treat solid tumors due to its improved selectivity and pharmacokinetic profiles. In October 2024, we announced the initiation of a phase 1 clinical trial evaluating XL495, 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.

Beyond these assets, we continue to make progress on multiple lead optimization programs for inhibitors of a variety of targets that we believe play significant roles in tumor growth, and we anticipate that some of these other programs could reach development candidate status before the end of 2024 or 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 targets that we believe have the greatest chance of becoming 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 2024. 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.

#### Third Quarter 2024 Business Updates and Financial Highlights

During the third quarter of 2024, 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 July 2024, Ipsen announced the expansion of our collaboration for the commercialization of cabozantinib to include pNET and epNET indications. Accordingly, Ipsen has sought marketing authorizations for CABOMETYX in these indications in certain territories outside of the U.S. and Japan, and in addition, Ipsen has opted into and is now co-funding the development costs for CABINET.
- In August 2024, we announced that the FDA had accepted our sNDA for CABOMETYX as a treatment for adult patients with previously treated, locally advanced/unresectable or metastatic, well- or moderately differentiated pNET and epNET, granted standard review and assigned a PDUFA target action date of April 3, 2025.
- In August 2024, we announced the initiation of a phase 1 clinical trial evaluating XB010, our first ADC advanced internally, following the FDA's earlier acceptance of our IND filing.
- In August 2024, we announced the achievement of a \$150.0 million commercial milestone, recognized as license revenues from Ipsen during the second quarter of 2024, following Ipsen's achievement of \$600.0 million in cumulative net sales of cabozantinib in its related license territory over four consecutive quarters. We received the milestone payment during the third quarter of 2024.
- In August 2024, our Board of Directors authorized the repurchase of up to \$500 million of our common stock before the end of 2025. As of September 30, 2024, we have repurchased \$12.4 million of our common stock under this program.
- In September 2024, final data from CABINET were presented during the NETs and Endocrine Tumours Proffered Paper Session at ESMO 2024 and concurrently published in NEJM. In addition, we presented detailed final OS results from CONTACT-02 during the GU Tumours Proffered Paper Session at ESMO 2024.
- In September 2024, we received a notice letter regarding an Abbreviated New Drug Application (ANDA) submitted to the FDA by Sun Pharmaceutical Industries Ltd. (Sun), including a Paragraph IV certification with respect to our U.S. Patent Nos. 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), the latest of which expires on February 10, 2032. Sun's ANDA requests approval to market a generic version of CABOMETYX tablets prior to the expiration of the aforementioned patents. We have not yet responded to this Paragraph IV certification notice but are evaluating it consistent with our intention to vigorously defend our intellectual property rights.
- In October 2024, we announced a clinical development collaboration with Merck US to support the evaluation of the combination of zanzalintinib and KEYTRUDA in SCCHN through our ongoing STELLAR-305 phase 3 pivotal trial, as well as future evaluations of the combination of zanzalintinib and WELIREG in RCC, including a phase 1/2 trial and two phase 3 pivotal trials to be sponsored by Merck US.
- In October 2024, the United States District Court for the District of Delaware (the Delaware District Court) issued a ruling in our two consolidated patent lawsuits against MSN Pharmaceuticals, Inc. (individually and collectively with certain of its affiliates, including MSN Laboratories Private Limited, referred to as MSN, and such lawsuits collectively referred to as MSN II), rejecting MSN's invalidity challenge to each of U.S. Patents No. 11,091,439, 11,091,440 and 11,098,015, which expire January 15, 2030. The Delaware District Court had previously entered a stipulation that MSN's proposed ANDA product infringes these patents. 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, which expires February 10, 2032. 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 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. The Delaware District Court judgment is also subject to appeal by either party. For a more detailed discussion of the MSN II litigation matter, see "Legal Proceedings" in Part II, Item 1 of this Quarterly Report on Form 10-Q.
- In October 2024, we announced the initiation of a phase 1 clinical trial evaluating XL495, our small molecule inhibitor of PKMYT1, following the FDA's earlier acceptance of our IND filing.

#### **Financial Highlights**

- Net product revenues for the third quarter of 2024 were \$478.1 million, as compared to \$426.5 million for the third quarter of 2023.
- Total revenues for the third quarter of 2024 were \$539.5 million, as compared to \$471.9 million for the third quarter of 2023.
- Research and development expenses for the third quarter of 2024 were \$222.6 million, as compared to \$332.6 million for the third quarter of 2023.
- Selling, general and administrative expenses for the third quarter of 2024 were \$111.8 million, as compared to \$138.1 million for the third quarter of 2023.
- Provision for income taxes for the third quarter of 2024 was \$36.8 million, as compared to \$4.8 million for the third quarter of 2023.
- Net income for the third quarter of 2024 was \$118.0 million, or \$0.41 per share, basic and \$0.40 per share, diluted, as compared to net income of \$1.0 million, or \$0.00 per share, basic and diluted, for the third quarter of 2023.

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 versions of our marketed products, including the proposed generic versions of CABOMETYX tablets that are the subject of ANDAs submitted to the FDA by MSN, Teva (as defined below), Cipla (as defined below) and Sun. 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 2023 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 2024, which is a 53-week fiscal year, will end on January 3, 2025 and fiscal year 2023, which was a 52-week fiscal year, ended on December 29, 2023. For convenience, references in this report as of and for the fiscal periods ended September 27, 2024 and September 29, 2023, and as of and for the fiscal years ending January 3, 2025 and ended December 29, 2023 are indicated as being as of and for the periods ended September 30, 2024 and September 30, 2023, and the years ending December 31, 2024 and ended December 31, 2023, respectively.

#### **Results of Operations**

#### Revenues

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

	Thr	ee Months En	ded S	September 30,	Percent	N	line Months End	Percent			
	2024		2023		Change		2024		2023	Change	
Net product revenues	\$	478,059	\$	426,497	12 %	\$	1,294,163	\$	1,199,543	8 %	
License revenues		60,239		42,367	42 %		299,901		133,406	125 %	
Collaboration services revenues		1,244		3,056	-59 %		7,882		17,607	-55 %	
Total revenues	\$	539,542	\$	471,920	14 %	\$	1,601,946	\$	1,350,556	19 %	

#### **Net Product Revenues**

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

	Th	ree Months End	ded S	September 30,	Percent	Ni	ne Months End	Percent		
		2024		2023	Change		2024	2023		Change
Gross product revenues	\$	646,419	\$	590,442	9 %	\$	1,814,495	\$	1,674,937	8 %
Discounts and allowances		(168,360)		(163,945)	3 %		(520,332)		(475,394)	9 %
Net product revenues	\$	478,059	\$	426,497	12 %	\$	1,294,163	\$	1,199,543	8 %

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

	Thr	ee Months End	ded	September 30,	Percent	Percent					
		2024		2023	Change	2024		2023		Change	
CABOMETYX	\$	475,665	\$	422,155	13 %	\$	1,285,423	\$	1,187,220	8 %	
COMETRIQ		2,394		4,342	-45 %		8,740		12,323	-29 %	
Net product revenues	\$	478,059	\$	426,497	12 %	\$	1,294,163	\$	1,199,543	8 %	

The increases in net product revenues for the three and nine months ended September 30, 2024, as compared to the corresponding prior year periods, were primarily related to increases of 7% and 6%, respectively, for each period in the

number of CABOMETYX units sold as a result of the FDA's approval of CABOMETYX in combination with nivolumab as a first-line treatment of patients with advanced RCC and, to a lesser extent, increases of 5% and 2%, respectively, 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 2024, as compared to the corresponding prior year period, 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 2023 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 increases in the amount of discounts and allowances for the three and nine months ended September 30, 2024, as compared to the corresponding prior year periods, were primarily the result of increases in volume of units sold, and the increase in utilization and dollar amount of chargebacks under the 340B Drug Pricing Program and the Federal Supply Schedule program.

We project our discounts and allowances may increase for the remainder of 2024, as compared to the corresponding prior year period, for similar reasons noted above.

#### License Revenues

License revenues 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; (b) royalty revenues; and (c) the profit on the U.S. commercialization of COTELLIC from Genentech.

Milestone revenues, which are allocated between license revenues and collaboration services revenues, were \$14.6 million and \$167.7 million for the three and nine months ended September 30, 2024, respectively, as compared to \$0.9 million and \$13.1 million, respectively, for the corresponding prior year periods. Milestone revenues by period included the following:

- For the three and nine months ended September 30, 2024, \$11.3 million in revenues was recognized in connection with a \$12.5 million regulatory milestone from Ipsen upon submission of a variation application to the European Medicines Agency for evaluating cabozantinib versus placebo in patients with either advanced pNET or advanced epNET who experienced progression after prior systemic therapy. The three and nine months ended September 30, 2024 also includes \$2.2 million in license revenues recognized in connection with a commercial milestone from Ipsen upon its achievement of CAD\$30.0 million in cumulative net sales of cabozantinib over four consecutive quarters in Canada.
- For the nine months ended September 30, 2024, \$150.0 million in license revenues was recognized in connection with a commercial milestone from Ipsen upon its achievement of \$600.0 million in cumulative net sales of cabozantinib over four consecutive quarters in its related Ipsen license territory.
- For the nine months ended September 30, 2023, \$9.9 million in revenues was recognized in connection with a commercial milestone of \$11.0 million from Takeda upon its achievement of \$150.0 million of cumulative net sales of cabozantinib in Japan.

Royalty revenues increased primarily as a result of an increase in Ipsen's net sales of cabozantinib outside of the U.S. and Japan. Ipsen royalties were \$38.3 million and \$113.0 million for the three and nine months ended September 30, 2024, respectively, as compared to \$34.8 million and \$98.6 million, respectively, for the corresponding prior year periods. Ipsen's net sales of cabozantinib have continued to grow since the first commercial sale of CABOMETYX in the Ipsen territories in 2016, primarily due to regulatory approvals in new territories, including regulatory approval in the EU for the combination therapy of CABOMETYX and nivolumab received in March 2021. Royalty revenues for the three and nine months ended September 30, 2024 also included \$3.5 million and \$9.5 million, respectively, related to Takeda's net sales of cabozantinib, as compared to \$3.0 million and \$9.2 million, respectively, for the corresponding prior year periods.

Takeda's net sales of cabozantinib have continued to grow since Takeda's first commercial sale of CABOMETYX in Japan in 2020; however, royalty revenues during the nine months ended September 30, 2024 were unfavorably impacted by foreign currency rate fluctuations, as compared to the corresponding prior year period. CABOMETYX is approved and is commercially available in 68 countries outside the U.S.

Our share of profits on the U.S. commercialization of COTELLIC under our collaboration agreement with Genentech were \$2.7 million and \$7.4 million for the three and nine months ended September 30, 2024, respectively, as compared to \$2.1 million and \$10.5 million, respectively, for the corresponding prior year periods. We also earned royalties on ex-U.S. net sales of COTELLIC by Genentech of \$0.7 million and \$2.3 million for the three and nine months ended September 30, 2024, respectively, as compared to \$1.0 million and \$3.0 million, respectively, for the corresponding prior year periods.

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 the recognition of deferred revenues for the portion of upfront and milestone payments that have been allocated to research and development services performance obligations, development cost reimbursements earned under our collaboration agreements and product supply revenues, which are net of product supply costs and the royalties we pay to Royalty Pharma on sales by Ipsen and Takeda of products containing cabozantinib.

Development cost reimbursements were \$5.2 million and \$20.1 million for the three and nine months ended September 30, 2024, respectively, as compared to \$7.3 million and \$27.5 million, respectively, for the corresponding prior year periods. The decreases in development cost reimbursements during the three and nine months ended September 30, 2024 were primarily attributable to decreases in spending on the CONTACT-02, CheckMate -9ER and COSMIC-021 studies, partially offset by Ipsen's decision to opt-in and co-fund CABINET development costs in the second quarter of 2024, which includes a cumulative catch-up for Ipsen's share of global development costs incurred since the beginning of the study and through the opt-in date.

Collaboration services revenues were reduced by \$5.3 million and \$16.0 million for the three and nine months ended September 30, 2024, respectively, as compared to \$4.8 million and \$14.2 million, respectively, for the corresponding prior year periods, to account for the 3% royalty we are required to pay on the net sales by Ipsen and Takeda of any product containing cabozantinib. As royalty generating sales of cabozantinib by Ipsen have increased as described above, our royalty payments have also increased.

We project our collaboration services revenues may decrease for the remainder of 2024, as compared to the corresponding prior year period, primarily as a result of a decrease in development cost reimbursement revenues and uncertainties regarding the timing and achievement of milestone revenues.

## Cost of Goods Sold

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

	Three	Months En	ded S	September 30,	Percent	N	ine Months En	Percent		
	 2024			2023	Change	2024			2023	Change
Cost of goods sold	\$ 5	17,328	\$	18,774	-8 %	\$	56,251	\$	50,794	11 %
Gross margin %		96 %		96 %			96 %		96 %	

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 September 30, 2024, as compared to the corresponding prior year period, was primarily due to a decrease in certain period costs, partially offset by the increase in royalties as a result of increased U.S. CABOMETYX sales. The increase in cost of goods sold for the nine months ended September 30, 2024, as compared to the corresponding prior year period, was primarily due to the increase in royalties as a result of increased U.S. CABOMETYX sales, and an increase in certain period costs. We project our gross margin will not change significantly during the remainder of 2024.

#### **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: (1) development; (2) drug discovery; and (3) 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 September 30,				Percent	Nine	Months End	Percent		
	2024		2023		Change		2024		2023	Change
Development:										
Clinical trial costs	\$	73,599	\$	76,845	-4 %	\$	207,532	\$	197,647	5 %
Personnel expenses		43,105		43,786	-2 %		135,915		127,846	6 %
License and other collaboration costs		10,000		80,013	-88 %		27,500		80,022	-66 %
Consulting and outside services		10,621		9,835	8 %		34,654		30,803	13 %
Other development costs		21,040		24,286	-13 %		71,885		65,150	10 %
Total development		158,365		234,765	-33 %		477,486		501,468	-5 %
Drug discovery:										
License and other collaboration costs		8,662		23,437	-63 %		19,725		85,014	-77 %
Other drug discovery costs		16,559		31,265	-47 %		53,082		93,333	-43 %
Total drug discovery		25,221		54,702	-54 %		72,807		178,347	-59 %
Stock-based compensation		8,764		12,438	-30 %		21,834		25,279	-14 %
Other research and development		30,220		30,680	-1 %		89,279		94,307	-5 %
Total research and development expenses	\$	222,570	\$	332,585	-33 %	\$	661,406	\$	799,401	-17 %

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 XB002.

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

	Three Months Ended September 30,				Percent	ı	Nine Months End	Percent		
		2024		2023	Change		2024		2023	Change
Small molecules:									,	
Zanzalintinib	\$	33,107	\$	40,898	-19 %	\$	104,208	\$	90,327	15 %
Cabozantinib		16,245		25,179	-35 %		50,970		82,368	-38 %
Other small molecules		6,082		2,281	167 %		13,661		7,574	80 %
Total small molecules		55,434		68,358	-19 %		168,839		180,269	-6 %
Biotherapeutics		18,165		8,487	114 %		38,693		17,378	123 %
Total clinical trial costs	\$	73,599	\$	76,845	-4 %	\$	207,532	\$	197,647	5 %

The decreases in research and development expenses for the three and nine months ended September 30, 2024, as compared to the corresponding prior year periods, were primarily related to decreases in license and other collaboration costs and other drug discovery costs. For the nine months ended September 30, 2024, the decrease in license and other collaboration costs was partially offset by an increase in other development costs, primarily related to manufacturing costs to support Exelixis' development candidates and clinical trial costs.

Development-related license and other collaboration costs decreased for the three and nine months ended September 30, 2024, as compared to the corresponding prior year periods, primarily due to an \$80.0 million upfront payment made upon the execution of the exclusive license agreement with Insilico in September 2023 and lower development milestone achievement in our clinical-stage in-licensing collaboration programs. Drug discovery-related license and other collaboration costs decreased for the three and nine months ended September 30, 2024, as compared to the corresponding prior year periods, primarily due to lower upfront fees and lower research funding. Other drug discovery costs decreased for the three and nine months ended September 30, 2024, as compared to the corresponding prior year periods, primarily due to decreases in personnel expenses, laboratory supplies and consulting and outside services.

Clinical trial costs, which include services performed by third-party contract research organizations and other vendors who support our clinical trials, decreased for the three months ended September 30, 2024, as compared to the corresponding prior year period, primarily due to lower costs associated with cabozantinib and zanzalintinib studies, partially offset by higher costs associated with studies evaluating XB010, XB002, and XL309. Clinical trial costs increased for the nine months ended September 30, 2024, as compared to the corresponding prior year period, primarily due to higher costs associated with studies evaluating zanzalintinib, XB002, XL309 and XB010, partially offset by lower costs associated with cabozantinib 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 decrease for the remainder of 2024, as compared to the corresponding prior year period, primarily driven by lower costs associated with various studies evaluating zanzalintinib, cabozantinib and XB002, partially offset by higher costs associated with XL309 and XB010.

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 XL495. 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 at least two new development candidates into preclinical

development later in 2024. 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 decrease for fiscal year 2024, as compared to the prior year, primarily driven by decreases in license and collaboration expenses, partially offset by higher manufacturing costs to support development candidates and clinical trial costs, including the current and planned trials evaluating zanzalintinib, XL309, XB010 and XL495.

# Selling, General and Administrative Expenses

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

	Three Months Ended September 30,				Percent	Percent Nine Months Enc			eptember 30,	Percent
	2024			2023	Change 2024		2023		Change	
Selling, general and administrative expenses <sup>(1)</sup>	\$	97,542	\$	110,104	-11 %	\$	312,144	\$	354,504	-12 %
Stock-based compensation		14,259		28,040	-49 %		45,656		56,760	-20 %
Total selling, general and administrative expenses	\$	111,801	\$	138,144	-19 %	\$	357,800	\$	411,264	-13 %

<sup>(1)</sup> 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 decreases in selling, general and administrative expenses for the three and nine months ended September 30, 2024, as compared to the corresponding prior year periods, were primarily due to decreases in corporate giving, legal and advisory fees related to the 2023 proxy contest and a reduction in activities related to litigation, stock-based compensation expenses, and technology costs.

We project our selling, general and administrative expenses may decrease for the remainder of 2024, as compared to the corresponding prior year period, primarily driven by our cost-saving initiatives, including the impact of the 2024 Restructuring Plan, and similar reasons noted above.

#### Impairment of Long-Lived Assets

Impairment of long-lived assets for the three and nine months ended September 30, 2024, relate to certain leased facilities at our Alameda campus. During the third quarter of fiscal year 2024, we listed certain buildings for sublease. As a result, we assessed the impacted asset groups for impairment and concluded that the related right-of-use assets and leasehold improvements were not fully recoverable as of September 30, 2024 and recognized a \$51.7 million non-cash impairment charge. See "Note 5. Fair Value Measurements" of the "Notes to Condensed Consolidated Financial Statements" included in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information.

Impairment of long-lived assets were as follows (dollars in thousands):

	Thre	e Months Ended S	September 30,	Percent _	Nine Months Ende	Percent		
		2024	2023	Change	2024	2023	Change	
Impairment of long-lived assets	\$	51,672 \$		n/a S	51,672	\$ —	n/a	

## Restructuring Expenses

Restructuring expenses resulted from the execution of the 2024 Restructuring Plan to reduce our workforce and rebalance our cost structure in alignment with our strategic priorities. Restructuring expenses consist of severance and employee-related costs, asset impairment, and contract termination costs. We incurred the majority of the charges related to the 2024 Restructuring Plan during the first quarter of 2024 and substantially completed the 2024 Restructuring Plan as of the end of the second quarter of 2024. See "Note 11. Restructuring" of the "Notes to Condensed Consolidated Financial Statements" included in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information.

Restructuring expenses were as follows (dollars in thousands):

	7	Three Months	Ended	September 30,	Percent	Nine Months Ended September 30,				Percent
		2024		2023	Change		2024		2023	Change
Restructuring expenses	\$		96 \$	_	n/a	\$	33,406	\$	_	n/a

#### Non-Operating Income

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

	Three Months Ended September 30,				Percent Nine Months Ende				September 30,	Percent
		2024		2023	Change		2024		2023	Change
Interest income	\$	18,709	\$	23,112	-19 %	\$	55,861	\$	65,155	-14 %
Other income (expense), net		(29)		289	n/a		(405)		230	n/a
Non-operating income	\$	18,680	\$	23,401	-20 %	\$	55,456	\$	65,385	-15 %

The decreases in non-operating income for the three and nine months ended September 30, 2024, as compared to the corresponding prior year periods, were primarily the result of decreases in interest income due to lower average interest-bearing investment balances, partially offset by higher average interest rates.

#### **Provision for Income Taxes**

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

	Th	Three Months Ended September 30,			Percent Nine Months			led S	eptember 30,	Percent	
		2024		2023	Change		2024		2023	Change	
Provision for income taxes	\$	36,782	\$	4,777	670 %	\$	115,461	\$	32,235	258 %	
Effective tax rate		23.8 %		82.1 %			23.2 %		20.9 %		

The effective tax rate for the three and nine months ended September 30, 2024, differed from the U.S. federal statutory tax rate of 21% primarily due to state taxes, partially offset by the generation of federal tax credits. The effective tax rate for the three months ended September 30, 2023 differed from the U.S. federal statutory tax rate of 21% primarily due to non-deductible executive compensation and the branded prescription drug fee, partially offset by the generation of federal tax credits. The effective tax rate for the nine months ended September 30, 2023 differed from the U.S. federal statutory tax rate of 21% primarily due to the generation of federal tax credits, partially offset by non-deductible executive compensation and state taxes.

### **Liquidity and Capital Resources**

As of September 30, 2024, we had \$1.7 billion in cash, cash equivalents and marketable securities, as compared to \$1.7 billion as of December 31, 2023. 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.

We project our cash requirements for operating activities will not change significantly for the remainder of 2024, as compared to the corresponding period in 2023, in part due to the implementation of the 2024 Restructuring Plan to reduce our workforce and rebalance our cost structure in alignment with our strategic priorities.

Our primary cash requirements for operating activities 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; contract manufacturing payments; and restructuring cash payments related to the 2024 Restructuring Plan.

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. As a result, we anticipate a higher federal income tax liability in fiscal year 2024, which will require higher estimated federal tax payments by the end of 2024. 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 2024, as compared to the corresponding period in 2023; 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 2024, as compared to the corresponding period in 2023. The timing of cash generated from commercial collaborations and cash payments required for in-licensing collaborations relative to upfront license fee payments, research funding commitments, 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 XL495, 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 January 2024, our Board of Directors authorized the repurchase of up to \$450.0 million of our common stock before the end of 2024. As of June 30, 2024, we completed the repurchase of 20.3 million shares of common stock for an aggregate purchase price of \$450.0 million pursuant to our stock repurchase program. 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 the end of 2025. Under this program, during the third quarter of 2024, we repurchased 0.5 million shares of common stock for an aggregate purchase price of \$12.4 million. As of September 30, 2024, approximately \$487.6 million remained available for future stock repurchases before the end of 2025.

Stock repurchases under this program 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 program will be based on a variety of factors, including ongoing assessments of the capital needs of the business, alternative investment opportunities, the market price of Exelixis' common stock and general market conditions.

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):

	Sept	ember 30, 2024	December 31, 2023	Percent Change
Working capital	\$	1,155,372	\$ 923,681	25 %
Cash, cash equivalents and marketable securities	\$	1,712,582	\$ 1,724,019	-1 %

### **Working Capital**

The increase in working capital as of September 30, 2024, as compared to December 31, 2023, was primarily due to the favorable impact to our net current assets resulting from our increase in net product revenues and collaboration revenues, including a total of \$164.7 million in milestones earned from lpsen, partially offset by repurchases of our common stock. 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 4. 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 September 30, 2024, as compared to December 31, 2023, was primarily due to cash payments to repurchase our common stock, payments to support our development and discovery programs, cash payments for employee-related expenditures and restructuring, partially offset by cash inflows generated by our operations from sales of our products and our commercial collaboration arrangements, including \$150.0 million in cash received from Ipsen for a commercial milestone earned.

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

	Nine Months Ende	d Septe	mber 30,
	 2024		2023
Net cash provided by operating activities	\$ 459,708	\$	322,753
Net cash used in investing activities	\$ (23,582)	\$	(88,692)
Net cash used in financing activities	\$ (440,774)	\$	(339,879)

#### **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, non-cash lease expense and impairment of long-lived assets 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 for the nine months ended September 30, 2024 increased, as compared to the corresponding prior year period, primarily due to an increase in cash received on sales of our products and cash received upon achievement of milestones from Ipsen, partially offset by cash paid for certain operating expenses, including cash payments related to the 2024 Restructuring Plan.

## Investing Activities

The changes in cash flows from investing activities primarily relates to the timing of marketable securities investment activity, acquisition of acquired in-process 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 used in investing activities for the nine months ended September 30, 2024 decreased as compared to the corresponding prior year period. The decrease in cash used in investing activities was primarily due to a decrease in purchases of marketable securities and purchases of in-process research and development technology related to certain in-licensing collaboration arrangements, partially offset by a decrease in cash proceeds from maturities and sales of marketable securities.

## **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 for the nine months ended September 30, 2024 increased, as compared to the corresponding prior year period, primarily due to an increase in payments for repurchases of common stock.

### **Contractual Obligations**

The 2024 Restructuring Plan was initiated in the first quarter of 2024 and was substantially completed as of the end of the second quarter of 2024. As part of our 2024 Restructuring Plan, we have terminated certain in-licensing collaboration arrangements, and as a result our contingent payments for potential future development, regulatory and commercial milestones have decreased. See "Note 3. Collaboration Agreements and Business Development Activities" of the "Notes to Condensed Consolidated Financial Statements" included in Part I, Item I of this Quarterly Report on Form 10-Q. For more information about the 2024 Restructuring Plan impact to our leases and other contractual obligations, see "Note 11. Restructuring" of the "Notes to Condensed Consolidated Financial Statements" included in Part I, Item I of this Quarterly Report on Form 10-Q.

There were no other material changes outside of the ordinary course of business in our contractual obligations as of September 30, 2024 from those disclosed in our Fiscal 2023 Form 10-K. For more information about our leases and our other contractual obligations, see "Note 11. Commitments and Contingencies" of the "Notes to Consolidated Financial Statements" included in Part II, Item 8 of our Fiscal 2023 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 tho

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 nine months ended September 30, 2024, 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 2023 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 September 30, 2024 have not changed significantly from those described in Part II, Item 7A of our Fiscal 2023 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.

### **MSN I ANDA Litigation**

In September 2019, we received a notice letter regarding an ANDA submitted to the FDA by 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 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. In particular, the May 5, 2020 amended ANDA requested approval to market a generic version of CABOMETYX tablets prior to expiration of 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 arising from MSN's amended ANDA filing with the FDA. Neither of our complaints have alleged infringement of U.S. Patents No. 9,724,342, 10,034,873 and 10,039,757. On May 22, 2020, MSN filed its response to the complaint, alleging that the asserted claims of U.S. Patents No. 7,579,473 and 8,497,284 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.

On October 1, 2021, 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. 7,579,473 and 8,497,284, 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. 7,579,473 and 8,497,284 would also infringe certain claims of each patent, if those claims are not found to be invalid. Then, on October 12, 2021, pursuant to a separate stipulation between us and MSN, the Delaware District Court entered an order dismissing MSN's counterclaims with respect to U.S. Patent No. 9,809,549. In our MSN I complaints, we sought, among other relief, an order that the effective date of any FDA approval of MSN's ANDA be a date no earlier than the expiration of all of U.S. Patents No. 7,579,473, 8,497,284 and 8,877,776, the latest of which expires on October 8, 2030, and equitable relief enjoining MSN from infringing these patents. In an effort to streamline the case, the parties narrowed their assertions. On April 8, 2022, MSN withdrew its validity challenge to U.S. Patent No. 8,877,776. On April 14, 2022, we agreed not to assert U.S. Patent No. 8,497,284 at trial and MSN, correspondingly, agreed to withdraw its validity challenges to U.S. Patent No. 8,497,284, as well as claims 1-4 and 6-7 of U.S. Patent No. 7,579,473. As a result of this narrowing, the trial addressed two issues: (1) infringement of claim 1 of the U.S. Patent No. 8,877,776; and (2) validity of claim 5 of the U.S. Patent No. 7,579,473. 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.

### MSN II ANDA Litigation

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 the MSN Il litigation, numbered Civil Action Nos. 22-00228 and 22-00945, were consolidated in October 2022 and involve Exelixis paten

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. The Delaware District Court's judgment is also subject to appeal by either party. We are currently evaluating next

## Teva ANDA Litigation

In May 2021, we received notice letters regarding an ANDA submitted to the FDA by Teva Pharmaceutical Industries Limited, Teva Pharmaceuticals Development, Inc. and Teva Pharmaceuticals USA, Inc. (individually and collectively referred to as Teva), requesting approval to market a generic version of CABOMETYX tablets. Teva's notice letters included a Paragraph IV certification with respect to our U.S. Patents No. 9,724,342 (formulations), 10,034,873 (methods of treatment) and 10,039,757 (methods of treatment), which are listed in the Orange Book. Teva's notice letters did not provide a Paragraph IV certification against any additional CABOMETYX patents. On June 17, 2021, we filed a complaint in the Delaware District Court for patent infringement against Teva, asserting infringement of U.S. Patents No. 9,724,342, 10,034,873 and 10,039,757 arising from Teva's ANDA filing with the FDA. On August 27, 2021, Teva filed its answer and counterclaims to the complaint, alleging that the asserted claims of U.S. Patents No. 9,724,342, 10,034,873 and 10,039,757 are invalid and not infringed. On September 17, 2021, we filed an answer to Teva's counterclaims. On July 29, 2022, we received notice from Teva that it had amended its ANDA to assert an additional Paragraph IV certification. As amended, Teva'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 September 2, 2022, we filed a complaint in the Delaware District Court for patent infringement against Teva, asserting infringement of U.S. Patent No. 11,298,349 arising from Teva's amended ANDA filing

with the FDA. We sought, among other relief, an order that the effective date of any FDA approval of Teva's ANDA be a date no earlier than the expiration of all of U.S. Patents No. 9,724,342, 10,034,873, 10,039,757 and 11,298,349, the latest of which expires on July 9, 2033, and equitable relief enjoining Teva from infringing these patents. On September 30, 2022, the parties filed a stipulation to consolidate the two lawsuits, numbered Civil Action Nos. 21-00871 and 22-01168, and to stay all proceedings, which was granted by the Delaware District Court on October 3, 2022. Following a similar order granted by the Delaware District Court on February 9, 2022 to stay all proceedings with respect to Civil Action No. 21-00871, this case remained administratively closed, and Civil Action No. 22-01168 was administratively closed on October 3, 2022. In July 2023, we entered into a settlement and license agreement with Teva (the Teva Settlement Agreement) to end these litigations. Pursuant to the terms of the Teva Settlement Agreement, we will grant Teva a license to market its generic version of CABOMETYX in the U.S. beginning on January 1, 2031, if approved by the FDA and subject to conditions and exceptions common to agreements of this type. On September 15, 2023, the parties filed a joint stipulation of dismissal with the Delaware District Court, and on September 19, 2023, the Delaware District Court granted the parties' stipulation and dismissed the case without prejudice.

## Cipla ANDA Litigation

On February 6, 2023, we received a notice letter regarding an ANDA submitted to the FDA by Cipla, Ltd. and Cipla USA, Inc. (individually and collectively referred to as Cipla), including a Paragraph IV certification with respect to our U.S. Patents No. 8,877,776 (salt and polymorphic forms), 9,724,342 (formulations), 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). Cipla's notice letter did not provide a Paragraph IV certification against any additional CABOMETYX patents. On March 16, 2023, we filed a complaint in the Delaware District Court for patent infringement against Cipla asserting infringement of U.S. Patents No. 8,877,776, 11,091,439, 11,091,440, 11,098,015 and 11,298,349 arising from Cipla's ANDA filing with the FDA. Cipla's ANDA requests approval to market a generic version of CABOMETYX tablets prior to the expiration of the aforementioned patents. We sought, among other relief, an order that the effective date of any FDA approval of Cipla's ANDA would be a date no earlier than the expiration of all of U.S. Patents No. 8,877,776, 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 Cipla from infringing these patents. On May 4, 2023, we filed, under seal, a stipulation and proposed order to stay all proceedings, and the Delaware District Court, in a sealed order on the same day, granted the proposed order and administratively closed the case. On May 5, 2023, the Delaware District Court issued a redacted version of the May 4, 2023 stipulation and proposed order. On March 27, 2024, we received notice from Cipla that it had amended its ANDA to assert additional Paragraph IV certifications. The ANDA now requests approval to market generic versions of CABOMETYX tablets with 20 mg and 40 mg dosage strengths (in addition to the 60 mg dosage strength contemplated by Cipla's original ANDA) prior to expiration of U.S. Patents No. 8,877,776, 9,724,342, 10,039,757, 11,091,439, 11,091,440, 11,098,015 and 11,298,349. In May 2024, we entered into a settlement and license agreement (the Cipla Settlement Agreement) with Cipla to end these litigations. Pursuant to the terms of the Cipla Settlement Agreement, we granted Cipla a license to market its generic version of CABOMETYX in the U.S. beginning on January 1, 2031, if approved by the FDA and subject to conditions and exceptions common to agreements of this type. On July 8, 2024, the parties filed a joint stipulation of dismissal with the Delaware District Court, and on July 9, 2024, the Delaware District Court granted the parties' stipulation and dismissed the case without prejudice.

## Other

On September 17, 2024, we received a notice letter regarding an ANDA submitted to the FDA by Sun, including 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), the latest of which expires on February 10, 2032. Sun's ANDA requests approval to market a generic version of CABOMETYX tablets prior to the expiration of the aforementioned patents. We have not yet responded to this Paragraph IV certification notice but are evaluating it consistent with our intention to vigorously defend our intellectual property rights.

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 1A. Risk Factors.

In addition to the information discussed elsewhere in this Quarterly Report on Form 10-Q, you should carefully review and consider the risk factors disclosed in Part I, Item 1A of our Fiscal 2023 Form 10-K. These risks could materially and adversely affect our business, financial condition and results of operations. The risks and uncertainties described therein 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. As of the date of this Quarterly Report on Form 10-Q, there have been no material changes to the risk factors described in our Fiscal 2023 Form 10-K.

### 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 million of our outstanding common stock before the end of 2025. Under this program, during the third quarter of 2024, we repurchased 0.5 million shares of common stock for an aggregate purchase price of \$12.4 million. As of September 30, 2024, approximately \$487.6 million remained available for future stock repurchases before the end of 2025.

The following table summarizes the stock repurchase activity for the three months ended September 30, 2024 and the approximate dollar value of shares that may yet be purchased pursuant to our stock repurchase program (in thousands, except per share data):

	Total Number of Shares Purchased	Av	erage Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Program	of S	proximate Dollar Value Shares That May Yet Be Purchased Under the Program
June 29, 2024 - July 26, 2024	_	\$	_	_	\$	_
July 27, 2024 - August 23, 2024	_	\$	_	_	\$	500,000
August 24, 2024 - September 27, 2024	483	\$	25.61	483	\$	487,623
Total	483			483		

Stock repurchases under the program 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 program will be based on a variety of factors, including ongoing assessments of the capital needs of the business, alternative investment opportunities, the market price of our common stock and general market conditions. The program does not obligate us to acquire any particular amount of our common stock, and the stock repurchase program 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.

Patrick J. Haley, our Executive Vice President, Commercial, an officer for purposes of Section 16 of the Exchange Act, entered into a pre-arranged stock trading plan on August 19, 2024. Mr. Haley's trading plan provides for the sale of up to 72,207 shares of our common stock between November 18, 2024 and August 19, 2025. 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 September 30, 2024, no other directors or Section 16 officers of the Company 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				
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 Officer Pursuant to 18 U.S.C. Section 1350</u>					Х			
101.INS	XBRL Instance Document				ppear in the Interac thin the Inline XBR				
101.SCH	Inline XBRL Taxonomy Extension Schema Document					Χ			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document X				Χ				
101.LAB	B Inline XBRL Taxonomy Extension Labels Linkbase Document				Х				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					Х			
‡	This certification accompanies this Quarterly Report on Form 10-Q, into any filing of Exelixis, Inc. under the Securities Act of 1933, as a made before or after the date of this Quarterly Report on Form 10-filing.	nended, o	r the Securities E	xchange Act of 1	L934, as amended	(whether			

# **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.

		Exelixis, Inc.
October 29, 2024	Ву:	/s/ Christopher J. Senner
Date		Christopher J. Senner
		Executive Vice President and Chief Financial Officer
		(Duly Authorized Officer and Principal Financial and Accountina 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: October 29, 2024

# 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: October 29, 2024

# 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 September 27, 2024, 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 29th day of October 2024.

/s/ Michael M. Morrissey

Michael M. Morrissey, Ph.D.

President and Chief Executive Officer
(Principal Executive Officer)

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