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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 29, 2024
or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission File Number: 000-30235

EXELIXIS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**04-3257395**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

1851 Harbor Bay Parkway
Alameda, CA 94502
(650) 837-7000

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 Par Value per Share	**EXEL**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days). Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of April 22, 2024, there were 291,292,704 shares of the registrant's common stock outstanding.

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

	March 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 259,561	$ 262,994
Short-term investments	703,695	732,308
Trade receivables, net	240,577	237,407
Inventory	21,106	17,323
Prepaid expenses and other current assets	67,490	67,926
Total current assets	1,292,429	1,317,958
Long-term investments	629,561	728,717
Property and equipment, net	127,222	128,731
Deferred tax assets, net	361,578	361,145
Goodwill	63,684	63,684
Right-of-use assets and other	329,278	342,122
Total assets	$ 2,803,752	$ 2,942,357
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 26,069	$ 33,768
Accrued compensation and benefits	72,958	93,325
Accrued clinical trial liabilities	59,337	71,615
Rebates and fees due to customers	75,651	59,619
Accrued collaboration liabilities	34,704	27,533
Other current liabilities	104,291	108,417
Total current liabilities	373,010	394,277
Long-term portion of operating lease liabilities	201,466	189,944
Other long-term liabilities	101,268	94,224
Total liabilities	675,744	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: 295,032 and 302,793 at March 31, 2024, and December 31, 2023, respectively	295	303
Additional paid-in capital	2,391,865	2,440,710
Accumulated other comprehensive loss	(5,204)	(3,750)
Accumulated deficit	(258,948)	(173,351)
Total stockholders' equity	2,128,008	2,263,912
Total liabilities and stockholders' equity	$ 2,803,752	$ 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 March 31,	
	2024	**2023**
Revenues:		
Net product revenues	$ 378,523	$ 363,400
License revenues	44,676	38,292
Collaboration services revenues	2,027	7,096
Total revenues	425,226	408,788
Operating expenses:		
Cost of goods sold	21,256	14,315
Research and development	227,689	234,246
Selling, general and administrative	113,984	131,397
Restructuring	32,835	—
Total operating expenses	395,764	379,958
Income from operations	29,462	28,830
Interest income	19,894	19,502
Other expense, net	(89)	(54)
Income before income taxes	49,267	48,278
Provision for income taxes	11,950	8,250
Net income	$ 37,317	$ 40,028
Net income per share:		
Basic	$ 0.12	$ 0.12
Diluted	$ 0.12	$ 0.12
Weighted-average common shares outstanding:		
Basic	300,757	324,420
Diluted	305,530	326,279

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

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

	Three Months Ended March 31,	
	2024	**2023**
Net income	$ 37,317	$ 40,028
Other comprehensive income (loss):		
Net unrealized gains (losses) on available-for-sale debt securities, net of tax impact of $433 and $(1,507), respectively	(1,454)	5,232
Comprehensive income	$ 35,863	$ 45,260

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

	Three Months Ended March 31, 2023					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Retained Earnings (Accumulated Deficit)	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2022	323,951	$ 324	$ 2,536,849	$ (14,521)	$ (34,225)	$ 2,488,427
Net income	—	—	—	—	40,028	40,028
Other comprehensive income	—	—	—	5,232	—	5,232
Issuance of common stock under equity incentive plans	1,034	1	7,079	—	—	7,080
Stock transactions associated with taxes withheld on equity awards	—	—	(2,523)	—	—	(2,523)
Stock-based compensation	—	—	16,892	—	—	16,892
Balance at March 31, 2023	324,985	$ 325	$ 2,558,297	$ (9,289)	$ 5,803	$ 2,555,136

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

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

	Three Months Ended March 31,	
	2024	**2023**
Net income	$ 37,317	$ 40,028
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	6,378	6,855
Stock-based compensation	19,113	16,661
Non-cash lease expense	6,764	6,731
Acquired in-process research and development technology	19,500	36,500
Other, net	9,206	(3,743)
Changes in operating assets and liabilities:		
Trade receivables, net	(3,170)	(19,178)
Inventory	1,715	(8,370)
Prepaid expenses and other assets	10,075	10,372
Accrued collaboration liabilities	(3,829)	(1,864)
Accounts payable and other liabilities	(34,247)	416
Net cash provided by operating activities	68,822	84,408
Cash flows from investing activities:		
Purchases of property, equipment and other, net	(9,691)	(12,024)
Acquired in-process research and development technology	(8,500)	(36,500)
Purchases of investments	(138,468)	(311,837)
Proceeds from maturities and sales of investments	268,452	310,769
Net cash provided by (used in) investing activities	111,793	(49,592)
Cash flows from financing activities:		
Payments for repurchases of common stock	(185,375)	—
Proceeds from issuance of common stock under equity incentive plans	8,315	7,143
Taxes paid related to net share settlement of equity awards	(6,988)	(2,557)
Net cash provided by (used in) financing activities	(184,048)	4,586
Net increase (decrease) in cash and cash equivalents	(3,433)	39,402
Cash and cash equivalents at beginning of period	262,994	502,677
Cash and cash equivalents at end of period	$ 259,561	$ 542,079

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. Through the commitment of our drug discovery, development and commercialization resources, we have produced four marketed pharmaceutical products, two of which are formulations of our flagship molecule, cabozantinib. We continue to evolve our product portfolio, leveraging our investments, expertise and strategic partnerships, to target an expanding range of tumor types and indications with our clinically differentiated pipeline of small molecules and biotherapeutics, including 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 31st. 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 period ended March 29, 2024, 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 period ended March 31, 2024, and the years ending December 31, 2024 and ended December 31, 2023, respectively.

The accompanying Condensed Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the U.S. for interim financial information and pursuant to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (SEC). Accordingly, they do not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements. In our opinion, all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation of our financial statements for the periods presented have been included. Operating results for the three months ended March 31, 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, 2023 (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 three months ended March 31, 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 ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which enhances the disclosures required for operating segments in our annual and interim consolidated financial statements. 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 Disclosure*s, 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 March 31,	
	2024	2023
Product revenues:		
Gross product revenues	$ 563,785	$ 521,322
Discounts and allowances	(185,262)	(157,922)
Net product revenues	378,523	363,400
Collaboration revenues:		
License revenues	44,676	38,292
Collaboration services revenues	2,027	7,096
Total collaboration revenues	46,703	45,388
Total revenues	$ 425,226	$ 408,788

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

	Three Months Ended March 31,	
	2024	2023
Affiliates of AmerisourceBergen Corporation	19 %	17 %
Affiliates of McKesson Corporation	18 %	17 %
Affiliates of CVS Health Corporation	17 %	17 %
Accredo Health, Incorporated	12 %	12 %
Affiliates of Optum Specialty Pharmacy	10 %	10 %

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

	March 31, 2024	December 31, 2023
Affiliates of McKesson Corporation	26 %	21 %
Affiliates of AmerisourceBergen Corporation	20 %	17 %
Ipsen Pharma SAS	19 %	19 %
Affiliates of CVS Health Corporation	15 %	20 %
Cardinal Health, Inc.	10 %	11 %

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

	Three Months Ended March 31,	
	2024	2023
U.S.	$ 381,937	$ 367,441
Europe	35,703	33,534
Japan	7,586	7,813
Total revenues	$ 425,226	$ 408,788

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*. 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 Ended March 31,	
	2024	2023
CABOMETYX	$ 376,417	$ 361,773
COMETRIQ	2,106	1,627
Net product revenues	$ 378,523	$ 363,400

Product Sales Discounts and Allowances

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

	Chargebacks, Discounts for Prompt Payment and Other	Other Customer Credits/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	115,134	17,725	54,093	186,952
Prior periods	(625)	(1,162)	97	(1,690)
Payments and customer credits issued	(111,424)	(17,768)	(36,953)	(166,145)
Balance at March 31, 2024	$ 28,306	$ 18,516	$ 57,135	$ 103,957

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

Contract Assets and Liabilities

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

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

	March 31, 2024	December 31, 2023
Contract assets [1]	$ 1,343	$ 1,321
Contract liabilities:		
Current portion [2]	$ 4,054	$ 5,406
Long-term portion [3]	4,922	5,524
Total contract liabilities	$ 8,976	$ 10,930

[1] Presented in other long-term assets in the accompanying Condensed Consolidated Balance Sheets.
[2] Presented in other current liabilities in the accompanying Condensed Consolidated Balance Sheets.
[3] Presented in other long-term liabilities in the accompanying Condensed Consolidated Balance Sheets.

During the three months ended March 31, 2024 and 2023, we recognized $1.6 million and $2.0 million, respectively, in revenues that were included in the beginning deferred revenues balance for those periods.

During the three months ended March 31, 2024 and 2023, we recognized $45.9 million and $37.9 million, respectively, in revenues for performance obligations satisfied in previous periods. Such revenues were primarily related to royalty payments allocated to our license performance obligations for our collaborations with Ipsen, Takeda, Daiichi Sankyo and Genentech.

As of March 31, 2024, $52.8 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.

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

	Three Months Ended March 31,	
	2024	2023
License revenues	$ 36,861	$ 29,812
Collaboration services revenues	(1,158)	3,722
Total collaboration revenues	$ 35,703	$ 33,534

As of March 31, 2024, $28.4 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 Ended March 31,	
	2024	2023
License revenues	$ 2,710	$ 2,849
Collaboration services revenues	3,185	3,374
Total collaboration revenues	$ 5,895	$ 6,223

As of March 31, 2024, $24.4 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 $16.7 million and $15.4 million during the three months ended March 31, 2024 and 2023, respectively.

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

We enter into collaborative arrangements with other pharmaceutical or biotechnology companies to develop and commercialize oncology assets or other intellectual property. Our research collaborations and in-licensing arrangements are intended to enhance our early-stage pipeline and expand our ability to discover, develop and commercialize novel therapies with the goal of providing new treatment options for cancer patients 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, BioInvent International AB, Cybrexa Therapeutics LLC, NBE-Therapeutics AG and STORM Therapeutics LTD. The termination of these agreements will be effective in April 2024.

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

As of March 31, 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 $365.4 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 INVESTMENTS

Cash, Cash Equivalents and Investments

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

	March 31, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Debt securities available-for-sale:				
Commercial paper	$ 203,117	$ —	$ —	$ 203,117
Corporate bonds	808,010	670	(4,712)	803,968
U.S. Treasury and government-sponsored enterprises	384,773	63	(2,376)	382,460
Municipal bonds	7,880	—	(32)	7,848
Total debt securities available-for-sale	1,403,780	733	(7,120)	1,397,393
Cash	19	—	—	19
Money market funds	133,132	—	—	133,132
Certificates of deposit	62,273	—	—	62,273
Total cash, cash equivalents and investments	$ 1,599,204	$ 733	$ (7,120)	$ 1,592,817

	December 31, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross 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 investments	$ 1,728,519	$ 2,076	$ (6,576)	$ 1,724,019

Interest receivable was $11.9 million and $13.1 million as of March 31, 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 investments were immaterial during the three months ended March 31, 2024 and 2023.

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

	March 31, 2024					
	In an Unrealized Loss Position Less than 12 Months		In an Unrealized Loss Position 12 Months or Greater		Total	
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
Corporate bonds	$ 358,757	$ (1,814)	$ 215,894	$ (2,898)	$ 574,651	$ (4,712)
U.S. Treasury and government-sponsored enterprises	217,026	(951)	109,223	(1,425)	326,249	(2,376)
Municipal bonds	1,879	(1)	5,969	(31)	7,848	(32)
Total	$ 577,662	$ (2,766)	$ 331,086	$ (4,354)	$ 908,748	$ (7,120)

	December 31, 2023					
	In an Unrealized Loss Position Less than 12 Months		In an Unrealized Loss Position 12 Months or Greater		Total	
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross 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 263 and 230 debt securities available-for-sale in an unrealized loss position as of March 31, 2024 and December 31, 2023, respectively. During the three months ended March 31, 2024, we did not record an allowance for credit losses or other impairment charges on our investment 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 investments, we determined that it was more likely than not that we will hold these investments 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):

	March 31, 2024	December 31, 2023
Maturing in one year or less	$ 767,832	$ 768,706
Maturing after one year through five years	629,561	728,717
Total debt securities available-for-sale	$ 1,397,393	$ 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
- Level 3 - unobservable inputs that are supported by little or no market activity that are significant to the fair value measurement.

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

	March 31, 2024		
	Level 1	Level 2	Total
Commercial paper	$ —	$ 203,117	$ 203,117
Corporate bonds	—	803,968	803,968
U.S. Treasury and government-sponsored enterprises	—	382,460	382,460
Municipal bonds	—	7,848	7,848
Total debt securities available-for-sale	—	1,397,393	1,397,393
Money market funds	133,132	—	133,132
Certificates of deposit	—	62,273	62,273
Total financial assets carried at fair value	$ 133,132	$ 1,459,666	$ 1,592,798

	December 31, 2023		
	Level 1	Level 2	Total
Commercial paper	$ —	$ 214,016	$ 214,016
Corporate bonds	—	868,245	868,245
U.S. Treasury and government-sponsored enterprises	—	407,321	407,321
Municipal bonds	—	7,841	7,841
Total debt securities available-for-sale	—	1,497,423	1,497,423
Money market funds	154,287	—	154,287
Certificates of deposit	—	72,309	72,309
Total financial assets carried at fair value	$ 154,287	$ 1,569,732	$ 1,724,019

When available, we value investments based on quoted prices for those financial instruments, which is a Level 1 input. Our remaining investments 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.

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.

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

Forward Foreign Currency Contracts

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

As of March 31, 2024, we had one forward contract outstanding to sell €3.6 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 gain on the forward contract is immaterial as of March 31, 2024. The forward contract is considered a Level 2 in the fair value hierarchy of our fair value measurements. The net realized gains (losses) we recognized on the maturity of forward contracts were immaterial for each of the three months ended March 31, 2024 and 2023 and are included in other expense, net on our Condensed Consolidated Statements of Income.

NOTE 6. INVENTORY

Inventory consisted of the following (in thousands):

	March 31, 2024	December 31, 2023
Raw materials	$ 3,117	$ 7,313
Work in process	56,906	59,422
Finished goods	14,795	9,581
Total	$ 74,818	$ 76,316
Balance Sheet classification:		
Current portion included in inventory	$ 21,106	$ 17,323
Long-term portion included in other long-term assets	53,712	58,993
Total	$ 74,818	$ 76,316

NOTE 7. STOCKHOLDERS' EQUITY

Stock-based Compensation

We have several equity incentive plans under which we granted stock options and restricted stock units (RSUs), including performance-based restricted stock units (PSUs), to employees and directors. As of March 31, 2024, 22.5 million shares were available for grant under the 2017 Equity Incentive Plan (as amended and restated, the 2017 Plan). The share reserve is reduced by 1 share for each share issued pursuant to a stock option and 2 shares for full value awards, including RSUs and PSUs.

We allocated the stock-based compensation expense for our equity incentive plans and our 2000 Employee Stock Purchase Plan (ESPP) as follows (in thousands):

	Three Months Ended March 31,	
	2024	2023
Research and development	$ 3,892	$ 3,252
Selling, general and administrative	15,221	13,409
Total stock-based compensation expense	$ 19,113	$ 16,661

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

	Three Months Ended March 31,	
	2024	2023
Stock options	$ 1,738	$ 2,207
Restricted stock units	15,434	12,607
Performance stock units	727	794
Employee stock purchase plan	1,214	1,053
Total stock-based compensation expense	$ 19,113	$ 16,661

During the three months ended March 31, 2024, we granted 0.1 million stock options with a weighted-average exercise price of $23.24 per share and a weighted-average grant date fair value of $10.08 per share. As of March 31, 2024, there were 7.7 million stock options outstanding and $8.1 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 at 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		— %

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 three months ended March 31, 2024, we granted 2.8 million service-based RSUs with a weighted- average grant date fair value of $21.87 per share. As of March 31, 2024, there were 15.5 million RSUs outstanding, including RSUs that are subject to a TSR market condition, and $221.8 million of related unrecognized compensation expense. Service-based RSUs granted to employees during the three months ended March 31, 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 March 31, 2024, there were 2.5 million PSUs outstanding, of which 0.9 million PSUs relate to awards that 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 March 31, 2024, the remaining unrecognized stock-based compensation expense for the PSUs that were either achieved or deemed probable of achievement was $3.5 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 $37.8 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 million of our outstanding common stock before the end of 2024. During the three months ended March 31, 2024, we repurchased 8.6 million shares of common stock under our stock repurchase program for an aggregate purchase price of $190.7 million. As of March 31, 2024, approximately $259.3 million remained available for future stock repurchases before the end of 2024, pursuant to our stock repurchase program.

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, 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 rate for the three months ended March 31, 2024, was 24.3%, as compared to 17.1% for the corresponding period in 2023. The effective tax rate for the three months ended March 31, 2024, differed from the U.S. federal statutory tax rate of 21% primarily due to state taxes and interest on uncertain tax positions, offset by the generation of federal tax credits. The effective tax rates for the three months ended March 31, 2023, differed from the U.S. federal statutory tax rate of 21%, primarily due to excess tax benefits related to the exercise of certain stock options during the period and the generation of federal tax credits, partially offset by 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 Ended March 31,	
	2024	**2023**
Numerator:		
Net income	$ 37,317	$ 40,028
Denominator:		
Weighted-average common shares outstanding — basic	300,757	324,420
Dilutive securities	4,773	1,859
Weighted-average common shares outstanding — diluted	305,530	326,279
Net income per share — basic	$ 0.12	$ 0.12
Net income per share — diluted	$ 0.12	$ 0.12

Basic net income per share is computed using the weighted-average number of common shares outstanding during the period. The diluted net income per share is computed using the weighted-average number of shares and dilutive potential common shares outstanding during the period. Dilutive 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 March 31,	
	2024	**2023**
Anti-dilutive securities and contingently issuable shares excluded	8,893	15,592

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 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 and 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 does not impact our separate and ongoing 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 2022 and involve Exelixis patents that are different from those asserted in the MSN I litigation described above.

On June 21, 2022, pursuant to a stipulation between us and MSN, the Delaware District Court entered an order that (i) MSN's submission of its ANDA constitutes infringement of certain claims relating to U.S. Patents No. 11,091,439, 11,091,440 and 11,098,015, if those claims are not found to be invalid, and (ii) upon approval, MSN's commercial manufacture, use, sale or offer for sale within the U.S., and importation into the U.S., of MSN's 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 are seeking, 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 a judgment is expected during the first half of 2024.

Teva ANDA Litigation

In May 2021, we received notice letters regarding an ANDA Teva 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.

On July 18, 2023, we entered into a settlement and license agreement (the Teva Settlement Agreement) with Teva 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 are seeking, 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. We are evaluating Cipla's additional Paragraph IV certifications.

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. During the three months ended March 31, 2024, we recognized $32.8 million 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" for additional information.

We incurred the majority of the charges related to the 2024 Restructuring Plan in the three months ended March 31, 2024, and expect the 2024 Restructuring Plan to be substantially completed by 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 three months ended March 31, 2024 were as follows (in thousands):

		Three Months Ended March 31, 2024					
	Accrued at December 31, 2023	Initial Costs	Non-cash Charges	Cash Payments	Accrued at March 31, 2024[2]	Total Costs Incurred to Date	Total Expected Plan Costs
Severance and employee-related costs	$ —	$ 15,656	$ —	$ (13,868)	$ 1,788	$ 15,656	$ 15,656
Contract termination and other exit costs[1]	—	4,861	—	(18)	4,843	4,861	5,044
Asset impairment	—	12,318	(12,318)	—	—	12,318	12,318
Total restructuring	$ —	$ 32,835	$ (12,318)	$ (13,886)	$ 6,631	$ 32,835	$ 33,018

(1) Contract termination costs consist of accruals for costs to be incurred without future economic benefit, and other exit costs expensed as incurred.
(2) As of March 31, 2024, substantially all restructuring liabilities have been recorded in other current liabilities in the accompanying Condensed Consolidated Balance Sheets.

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. Through the commitment of our drug discovery, development and commercialization resources, we have produced four marketed pharmaceutical products, two of which are formulations of our flagship molecule, cabozantinib. We continue to evolve our product portfolio, leveraging our investments, expertise and strategic partnerships to target an expanding range of tumor types and indications with our clinically differentiated pipeline of small molecules and biotherapeutics, including 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.

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. The product candidates furthest along in our pipeline are: zanzalintinib, a novel, potent, third-generation oral tyrosine kinase inhibitor (TKI) that targets VEGF receptors, MET and the TAM kinases (TYRO3, AXL and MER), and XB002, a next-generation tissue factor (TF)-targeting ADC, administered via intravenous infusion and composed of a human monoclonal antibody (mAb) against TF that is conjugated to a microtubulin inhibitor (MTI) payload. Our internal drug discovery efforts are supplemented through in-licensing investigational oncology assets or obtaining options to acquire other investigational oncology assets from third parties if they demonstrate evidence of clinical success. Examples are: XL309, a clinical-stage and potentially best-in-class small molecule inhibitor of USP1, which has emerged as a synthetic lethal target in the context of BRCA-mutated tumors; and ADU-1805, a clinical-stage and potentially best-in-class 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. 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. Building on preclinical and clinical observations that cabozantinib in combination with ICIs may promote a more immune-permissive tumor environment, we initiated several pivotal studies to further explore these combination regimens. The first of these studies to deliver results was CheckMate -9ER, a phase 3 pivotal trial evaluating the combination of CABOMETYX and nivolumab compared to sunitinib in patients with previously untreated, advanced or metastatic RCC. Positive results from CheckMate -9ER served as the basis for the FDA, European Commission (EC) and MHLW approvals of CABOMETYX in combination with nivolumab as a first-line treatment of patients with advanced RCC in January 2021, March 2021 and August 2021, respectively. We are also collaborating with BMS on COSMIC-313, a phase 3 pivotal trial evaluating the triplet combination of cabozantinib, nivolumab and ipilimumab, versus the combination of nivolumab and ipilimumab in patients with previously untreated advanced intermediate- or poor-risk RCC. In July 2022, we announced that the trial met its primary endpoint, demonstrating significant improvement in blinded independent radiology committee-assessed progression-free survival (PFS) at the primary analysis for the triplet combination.

To further expand our exploration of combinations with ICIs, we also initiated multiple trials evaluating cabozantinib in combination with F. Hoffmann-La Roche Ltd.'s (Roche) ICI, atezolizumab, beginning in 2017 with COSMIC-021, a broad phase 1b study evaluating the safety and tolerability of cabozantinib in combination with atezolizumab in patients with a wide variety of locally advanced or metastatic solid tumors. The encouraging efficacy and safety data from COSMIC-021 have been guiding our clinical development strategy for cabozantinib in combination with ICIs. 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 cabozantinib and atezolizumab combination versus a second novel hormonal therapy (NHT) in patients with metastatic castration-resistant prostate cancer (mCRPC) and soft-tissue disease who have progressed after treatment with one prior NHT, and detailed findings from CONTACT-02 were presented at the American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium in January 2024. The trial met one of two primary endpoints, demonstrating a statistically significant improvement in PFS. At a prespecified interim analysis for the primary endpoint of overall survival (OS), a trend toward improvement of OS was observed; however, the data were immature and did not meet the threshold for statistical significance. Therefore, the trial continues to the next planned OS analysis, anticipated later in 2024. The safety profile observed in the trial was reflective of the known safety profiles for each single agent, as well as the combination regimen used in this study. We are discussing a potential regulatory submission with the FDA.

Independent investigators also conduct clinical trials evaluating cabozantinib through our Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute's Cancer Therapy Evaluation Program (NCI-CTEP) or our investigator-sponsored trial program. As reflected by the results from completed trials and ongoing clinical trials, we believe our CRADA with NCI-CTEP has facilitated and may continue to facilitate the expansion of the cabozantinib franchise in a cost-efficient manner. In August 2023, we announced positive results from the CABINET phase 3 pivotal study under our CRADA and conducted by the Alliance for Clinical Trials in Oncology that evaluated cabozantinib versus placebo in patients who experienced progression after prior systemic therapy in two independently powered cohorts: one for patients with advanced pancreatic neuroendocrine tumors (pNET); and another for patients with extra-pancreatic neuroendocrine tumors (epNET, historically referred to as carcinoid tumors). Data from CABINET demonstrated that cabozantinib substantially prolonged the time to disease progression or death in both pNET and epNET cohorts, and that the safety profile of cabozantinib observed in the trial was consistent with its known safety profile. Detailed findings from CABINET were presented during a Proffered Paper Session at the European Society for Medical Oncology Congress in October 2023. We are discussing these results with the FDA to support a potential regulatory submission later in 2024. In addition to facilitating label expansion for the cabozantinib franchise, data sets from these externally sponsored clinical trials may also prove valuable by informing our development plans for zanzalintinib.

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, and we have also 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), one targeted phase 1b/2 trial studying zanzalintinib in combination with AB521, an inhibitor of the transcription factor HIF-2a developed by Arcus Biosciences, Inc. (STELLAR-009), and three phase 3 or phase 2/3 pivotal trials evaluating zanzalintinib in combination with ICIs (STELLAR-303, STELLAR-304 and STELLAR-305).

STELLAR-001 is a phase 1b/2 clinical trial evaluating zanzalintinib, both as a monotherapy and in combination with atezolizumab. We have established the recommended dose of 100 mg for both monotherapy zanzalintinib and zanzalintinib in combination with atezolizumab, and we have completed enrollment in expansion cohorts. In November 2023, we presented promising initial results evaluating monotherapy zanzalintinib in patients with previously treated clear cell RCC during the Oral Abstracts session at the International Kidney Cancer Symposium. Follow-up continues in this cohort as well as the other completed cohorts, and we continue to be encouraged by zanzalintinib's emerging safety and efficacy profile, both as a monotherapy and in combination with ICIs. STELLAR-002 is a phase 1b/2 clinical trial evaluating zanzalintinib in combination with either nivolumab, nivolumab and ipilimumab, or a fixed-dose combination of nivolumab and relatlimab.

We have established a recommended dose of zanzalintinib for these combination regimens and are exploring these combinations in a diverse array of solid tumor expansion cohorts, including clear cell RCC, non-clear cell RCC, HCC, mCRPC and colorectal cancer (CRC); patient enrollment into expansion cohorts is ongoing. Monotherapy zanzalintinib is also being evaluated to support regulatory requirements for dosing and contribution of components. Most recently, in December 2023, we initiated STELLAR-009, an open-label phase 1b/2 trial evaluating zanzalintinib in combination with AB521 in patients with advanced solid tumors, including clear cell RCC. STELLAR-009 is divided into dose-escalation and expansion phases, and patient enrollment into dose-escalation cohorts is ongoing.

Our first zanzalintinib pivotal trial, STELLAR-303, was initiated in June 2022 and is evaluating zanzalintinib in combination with atezolizumab versus regorafenib in patients with metastatic non-microsatellite instability-high or non-mismatch repair-deficient CRC who have progressed after or are intolerant to the current standard of care. 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. Most recently, in December 2023, we initiated STELLAR-305, a phase 2/3 pivotal trial evaluating zanzalintinib in combination with Merck & Co., Inc.'s pembrolizumab versus monotherapy pembrolizumab in patients with previously untreated PD-L1-positive recurrent or metastatic Squamous Cell Cancers of the head and neck (SCCHN). Beyond STELLAR-303, STELLAR-304 and STELLAR-305, we intend to initiate additional early-stage and pivotal trials evaluating zanzalintinib in novel combination regimens across a broad array of future potential indications.

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 deliver anti-cancer drug payloads to targets with increased precision while minimizing impact on healthy tissues. This approach has been validated by multiple regulatory approvals for the commercial sale 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 entered into other strategic transactions, aimed at conserving capital and managing risks, that provide us with access to antibodies, binders, payloads and conjugation technologies, which are the components employed to generate next-generation ADCs or multispecific antibodies.

Furthest along amongst our biotherapeutics programs is XB002, our lead TF-targeting ADC program. XB002 is a next-generation ADC composed of a human mAb against TF that is conjugated to an MTI payload. We are evaluating XB002, both as a single agent and in combination with nivolumab, in JEWEL-101, a phase 1 study in patients with advanced solid tumors. The early clinical data has demonstrated that XB002 is generally well-tolerated at multiple dose levels, and a pharmacokinetic analysis confirmed that XB002 was stable with low levels of free payload. We have initiated the cohort-expansion phase of JEWEL-101 for monotherapy XB002, which is designed to further explore two doses of XB002 in individual tumor cohorts, including non-small cell lung cancer, SCCHN, cervical cancer and ovarian cancer. Additional cohorts being evaluated with a single dose of XB002 include endometrial cancer, pancreatic cancer, esophageal cancer, mCRPC, triple negative breast cancer and hormone-receptor positive breast cancer, as well as a TF-expressing tumor-agnostic cohort. We are continuing to enroll patients in combination dose-escalation cohorts with nivolumab and will explore the combination potential with zanzalintinib. Additional expansion cohorts are planned for evaluating these various combinations as part of our goal to advance XB002 into full development. We intend to evaluate the potential of XB002 as monotherapy and in combination with other therapies across a wide range of tumor types, including indications other than those currently addressed by commercially available TF-targeting therapies.

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. In addition to the option deal with Sairopa, some of our active research collaborations for biotherapeutics programs include collaborations with:

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

- Invenra, Inc. (Invenra), which is focused on the discovery and development of novel binders and multispecific antibodies for the treatment of cancer.

We have made significant progress under these and other 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, as a direct result of these arrangements, we are advancing five biotherapeutics development candidates toward potential Investigational New Drug (IND) filings in 2024, 2025 and 2026: XB010, XB628, XB371, XB064, and XB033. XB010, our first ADC advanced internally, targets the tumor antigen 5T4 and incorporates an antibody sourced from Invenra and was constructed using Catalent's SMARTag site-specific bioconjugation platform. XB628 is a bispecific antibody that targets PD-L1 and NKG2A, identified as key regulators of adaptive and innate immunity, and was discovered, in part, in collaboration with Invenra. XB371 is a next-generation TF-targeting ADC that is differentiated from XB002 by its topoisomerase inhibitor payload, and was discovered, in part, in collaboration with Catalent. XB064 is a high-affinity mAb that targets ILT2, which is associated with resistance to PD-1 pathway inhibitors, with potential to combine broadly with our internal pipeline and approved immunotherapy agents, and was discovered, in part, in collaboration with Invenra. XB033 is an ADC targeting the tumor antigen IL13Ra2, and was discovered, in part, in collaboration with Invenra and Catalent.

Other Small Molecules

Since its formation in 2000, our drug discovery group has advanced over 25 compounds to the IND stage, either independently or with collaboration partners, and today we deploy our drug discovery expertise to advance small molecule programs toward and through preclinical development. 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. Zanzalintinib, which was discovered at Exelixis, is furthest along in its clinical development and is now being evaluated in three phase 3 clinical trials. XL309, a potentially best-in-class small molecule inhibitor of USP1, a synthetic lethal target in the context of BRCA-mutated tumors, is currently being evaluated in a phase 1 clinical trial in patients with advanced solid tumors with enrollment ongoing. Our priorities for XL309 include accelerating its development as a potential therapy for tumors that have become refractory to PARP inhibitors (PARPi), including forms of ovarian, breast and prostate cancers, pursuing potential PARPi combination regimens, and potentially moving beyond the PARPi market into new patient populations. We are also advancing our small molecule development candidate, XL495, toward a potential IND filing later in 2024. XL495 is an inhibitor of PKMYT1 with best-in-class potential to treat solid tumors due to its improved selectivity and pharmacokinetics. Moreover, 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 later in 2024 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 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 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 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.

First Quarter 2024 Business Updates and Financial Highlights

During the first 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 January 2024, we appointed Mary C. Beckerle, Ph.D. and S. Gail Eckhardt, M.D. to our Board of Directors. Dr. Beckerle currently serves as Chief Executive Officer of the Huntsman Cancer Institute and Distinguished Professor of Biological and Oncological Sciences at the University of Utah. Dr. Eckhardt currently serves as Associate Dean of Experimental Therapeutics at Baylor College of Medicine and Associate Director of Translational Research at the College's Dan L. Duncan Comprehensive Cancer Center.
- In January 2024, we presented detailed results from CONTACT-02 and four-year follow-up results from CheckMate -9ER at the 2024 ASCO Genitourinary Cancers Symposium.
- In January 2024, we announced that our Board of Directors had authorized a corporate restructuring plan (the 2024 Restructuring Plan) to reduce our workforce and rebalance our cost structure in alignment with our strategic priorities, including reducing real estate commitments and costs, and terminating certain licensing partnerships. The 2024 Restructuring Plan was initiated in the first quarter of 2024, and we anticipate the plan will be substantially complete in the second quarter of 2024.
- On March 27, 2024, we received a notice letter from Cipla Ltd. and Cipla USA, Inc. (individually and collectively referred to as Cipla) asserting additional Paragraph IV Certifications arising from Cipla's amendment of its Abbreviated New Drug Application (ANDA), originally filed with the FDA more than one year ago. For a more detailed discussion of the Cipla matter, see "Legal Proceedings" in Part II, Item 1 of this Quarterly Report on Form 10-Q
- As of March 31, 2024, we have repurchased $190.7 million of our common stock. In January 2024, we announced that our Board of Directors had authorized the repurchase of up to $450 million of our common stock before the end of 2024.

Financial Highlights

- Net product revenues for the first quarter of 2024 were $378.5 million, as compared to $363.4 million for the first quarter of 2023.
- Total revenues for the first quarter of 2024 were $425.2 million, as compared to $408.8 million for the first quarter of 2023.
- Research and development expenses for the first quarter of 2024 were $227.7 million, as compared to $234.2 million for the first quarter of 2023.
- Selling, general and administrative expenses for the first quarter of 2024 were $114.0 million, as compared to $131.4 million for the first quarter of 2023.
- Provision for income taxes for the first quarter of 2024 was $12.0 million, as compared to $8.3 million for the first quarter of 2023.
- Net income for the first quarter of 2024 was $37.3 million, or $0.12 per share, basic and diluted, as compared to net income of $40.0 million, or $0.12 per share, basic and diluted, for the first 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. are increasingly expressing 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) and Cipla. 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 31st. 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 period ended March 29, 2024, 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 period ended March 31, 2024, 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):

	Three Months Ended March 31,		Percent Change
	2024	2023	
Net product revenues	$ 378,523	$ 363,400	4 %
License revenues	44,676	38,292	17 %
Collaboration services revenues	2,027	7,096	-71 %
Total revenues	$ 425,226	$ 408,788	4 %

Net Product Revenues

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

	Three Months Ended March 31,		Percent Change
	2024	2023	
Gross product revenues	$ 563,785	$ 521,322	8 %
Discounts and allowances	(185,262)	(157,922)	17 %
Net product revenues	$ 378,523	$ 363,400	4 %

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

	Three Months Ended March 31,		Percent Change
	2024	2023	
CABOMETYX	$ 376,417	$ 361,773	4 %
COMETRIQ	2,106	1,627	29 %
Net product revenues	$ 378,523	$ 363,400	4 %

The increase in net product revenues for the three months ended March 31, 2024, as compared to the corresponding prior year period, was primarily related to a 5% increase 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, partially offset by a 1% decrease 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 as a percentage of gross revenues have generally increased over time as the number of patients participating in government programs has increased and as the discounts given and rebates paid to government payers have also increased. The increase in the amount of discounts and allowances for the three months ended March 31, 2024, as compared to the corresponding prior year period, was primarily the result of increases in volume of units sold and higher utilization by covered entities in the 340B Drug Pricing Program.

We project our discounts and allowances as a percentage of gross revenues 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.

There were no milestone payments recognized in license revenues or collaboration services revenues during the three months ended March 31, 2024 and 2023. 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 $36.9 million for the three months ended March 31, 2024, as compared to $29.8 million for the corresponding prior year period.

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 months ended March 31, 2024 related to Takeda's net sales of cabozantinib were $2.7 million, as compared to $2.9 million for the corresponding prior year period, and were unfavorably impacted by foreign currency rate fluctuations. Takeda's net sales of cabozantinib have continued to grow since Takeda's first commercial sale of CABOMETYX in Japan in 2020. 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 was $2.6 million for the three months ended March 31, 2024, as compared to $2.9 million for the corresponding prior year period. We also earned royalties on ex-U.S. net sales of COTELLIC by Genentech of $0.8 million for the three months ended March 31, 2024, as compared to $1.1 million for the corresponding prior year period.

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 $6.3 million for the three months ended March 31, 2024, as compared to $10.5 million for the corresponding prior year period. The decrease in development cost reimbursements was primarily attributable to decreases in spending on the CONTACT-02 and COSMIC-021 studies.

Collaboration services revenues were reduced by $5.4 million for the three months ended March 31, 2024, as compared to $4.5 million for the corresponding prior year period, 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 Ended March 31,		Percent Change
	2024	2023	
Cost of goods sold	$ 21,256	$ 14,315	48 %
Gross margin %	94 %	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 increase in cost of goods sold for the three months ended March 31, 2024, as compared to the corresponding prior year period, was primarily due to an increase in certain period costs, including an increase in write-downs for excess inventory. 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 comprised 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 comprised of upfront license fees, research funding commitments, development milestones and other payments associated with our in-licensing collaboration programs in preclinical development stage. Other drug discovery costs include personnel expenses, consulting and outside services and laboratory supplies. Other research and development expenses include the allocation of general corporate costs to research and development services and development cost reimbursements in connection with certain of our collaboration arrangements.

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

	Three Months Ended March 31,		Percent Change
	2024	2023	
Development:			
Clinical trial costs	$ 74,718	$ 56,493	32 %
Personnel expenses	45,516	41,698	9 %
License and other collaboration costs	17,500	—	n/a
Consulting and outside services	11,126	9,481	17 %
Other development costs	24,027	18,818	28 %
Total development	172,887	126,490	37 %
Drug discovery:			
License and other collaboration costs	5,295	44,736	-88 %
Other drug discovery costs	17,195	30,360	-43 %
Total drug discovery	22,490	75,096	-70 %
Stock-based compensation	3,892	3,252	20 %
Other research and development	28,420	29,408	-3 %
Total research and development expenses	$ 227,689	$ 234,246	-3 %

The decrease in research and development expenses for the three months ended March 31, 2024, as compared to the corresponding prior year period, was primarily related to decreases in license and other collaboration costs and other drug discovery costs, partially offset by increases in clinical trial costs and manufacturing costs to support Exelixis' development candidates (presented as part of other development costs).

License and other collaboration costs decreased primarily due to lower drug-discovery development milestone achievement related to a $35.0 million milestone achieved by Sairopa upon the IND effective date for ADU-1805 in the prior year, partially offset by higher development-related milestone achievement in our clinical-stage in-licensing collaboration programs. Other drug discovery costs decreased primarily due to decreases in 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, increased primarily due to higher costs associated with studies evaluating zanzalintinib and XB002, partially offset by decreases in 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 increase for the remainder of 2024, as compared to the corresponding prior year period, primarily driven by higher costs associated with various studies evaluating zanzalintinib, XB002 and XL309, partially offset by decreases in costs associated with cabozantinib studies. We continue our development efforts with cabozantinib to maximize the therapeutic and commercial potential of this compound. Notable ongoing company-sponsored cabozantinib studies include: CONTACT-02, for which Roche is sharing the development costs and providing atezolizumab free of charge; and COSMIC-313, for which BMS is providing nivolumab and ipilimumab free of charge.

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, XB002 and XL309. 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 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 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 the remainder of 2024, as compared to the corresponding prior year period, primarily driven by decreases in license and collaboration expenses and consulting and outside services that result from the implementation of the 2024 Restructuring Plan to prioritize the advancement of clinical and near-clinical programs, partially offset by higher manufacturing costs to support development candidates and clinical trial costs, including the current and planned trials evaluating zanzalintinib, XB002 and XL309.

Selling, General and Administrative Expenses

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

	Three Months Ended March 31,		Percent Change
	2024	2023	
Selling, general and administrative expenses[(1)]	$ 98,763	$ 117,988	-16 %
Stock-based compensation	15,221	13,409	14 %
Total selling, general and administrative expenses	$ 113,984	$ 131,397	-13 %

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

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

The decrease in selling, general and administrative expenses for the three months ended March 31, 2024, as compared to the corresponding prior year period, was primarily related to decreases in corporate giving, legal and advisory fees, the Branded Prescription Drug Fee and personnel expenses, partially offset by an increase in marketing and stock-based compensation expenses. Legal and advisory fees decreased primarily due to a reduction in activities related to litigation. Personnel expenses decreased primarily due to the implementation of the 2024 Restructuring Plan. Stock-based compensation expense increased primarily due to higher expense associated with RSUs, partially offset by higher forfeitures.

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.

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 in the three months ended March 31, 2024, and expect the plan to be substantially completed in 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):

	Three Months Ended March 31,		Percent Change
	2024	2023	
Restructuring expenses	$ 32,835	$ —	n/a

Non-Operating Income

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

	Three Months Ended March 31,		Percent Change
	2024	2023	
Interest income	$ 19,894	$ 19,502	2 %
Other expense, net	(89)	(54)	65 %
Non-operating income	$ 19,805	$ 19,448	2 %

The increase in non-operating income for the three months ended March 31, 2024, as compared to the corresponding prior year period, was primarily the result of an increase in interest income due to higher interest rates, partially offset by lower average interest-bearing investment balances.

Provision for Income Taxes

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

	Three Months Ended March 31,		Percent Change
	2024	2023	
Provision for income taxes	$ 11,950	$ 8,250	45 %
Effective tax rate	24.3 %	17.1 %	42 %

The effective tax rate for the three months ended March 31, 2024, differed from the U.S. federal statutory tax rate of 21%, primarily due to state taxes and interest on uncertain tax positions, offset by the generation of federal tax credits. The effective tax rate for the three months ended March 31, 2023, differed from the U.S. federal statutory tax rate of 21%, primarily due to excess tax benefits related to the exercise of certain stock options during the period and the generation of federal tax credits, partially offset by state taxes.

Liquidity and Capital Resources

As of March 31, 2024, we had $1.6 billion in cash, cash equivalents and investments, as compared to $1.7 billion as of December 31, 2023. We anticipate that the aggregate of our current cash and cash equivalents, short-term investments 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 may decrease 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 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, XB002 and XL309, 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 million of our common stock before the end of 2024. As of March 31, 2024, approximately $259.3 million remained available for future stock repurchases before the end of 2024, pursuant to our stock repurchase program. 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):

	March 31, 2024	December 31, 2023	Percent Change
Working capital	$ 919,419	$ 923,681	0 %
Cash, cash equivalents and investments	$ 1,592,817	$ 1,724,019	-8 %

Working Capital

The modest decrease in working capital as of March 31, 2024, as compared to December 31, 2023, was primarily due to repurchases of our common stock, partially offset by the favorable impact to our net current assets resulting from our net income. 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 Investments

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.

Investments primarily consist of debt securities available-for-sale. For additional information regarding our cash, cash equivalents and investments, see "Note 4. Cash and Investments," 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 investments as of March 31, 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.

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

	Three Months Ended March 31,	
	2024	2023
Net cash provided by operating activities	$ 68,822	$ 84,408
Net cash provided by (used in) investing activities	$ 111,793	$ (49,592)
Net cash provided by (used in) financing activities	$ (184,048)	$ 4,586

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 long-lived assets impairment 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 three months ended March 31, 2024 decreased, as compared to the corresponding prior year period, primarily due to an increase in cash paid for certain operating expenses, including cash payments related to the 2024 Restructuring Plan, partially offset by an increase in cash received on sales of our products.

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 investments to expand our operations and acquire assets that further support our research and development activities.

Net cash was provided by investing activities for the three months ended March 31, 2024, as compared to net cash used in investing activities in the corresponding prior year period. The increase in cash provided by investing activities was primarily due to a decrease in purchases of investments 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 investments.

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 was used in financing activities for the three months ended March 31, 2024, as compared to cash provided by financing activities in the corresponding prior year period. During the three months ended March 31, 2024, cash used in financing activities was primarily related to payments for repurchases of common stock, which were $185.4 million. During the three months ended March 31, 2023, cash provided by financing activities was primarily related to proceeds from employee stock programs that were offset by withholding taxes remitted to the government related to net share settlements of equity awards.

Contractual Obligations

The 2024 Restructuring Plan was initiated in the first quarter of 2024, and we anticipate the plan will be substantially complete in 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 March 31, 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 those estimates.

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

There have been no significant changes in our critical accounting policies and estimates during the three months ended March 31, 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 March 31, 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 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 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 Approved Drug Products with Therapeutic Equivalence Evaluations, also referred to as the Orange Book, for CABOMETYX. 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 the MSN I litigation, 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 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 and 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 does not impact our separate and ongoing 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 II litigation, numbered Civil Action Nos. 22-00228 and 22-00945, were consolidated in October 2022 and involve Exelixis patents that are different from those asserted in the MSN I litigation described above.

On June 21, 2022, pursuant to a stipulation between us and MSN, the Delaware District Court entered an order that (i) MSN's submission of its ANDA constitutes infringement of certain claims relating to U.S. Patents No. 11,091,439, 11,091,440 and 11,098,015, if those claims are not found to be invalid, and (ii) upon approval, MSN's commercial manufacture, use, sale or offer for sale within the U.S., and importation into the U.S., of MSN's 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 are seeking, 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 a judgment is expected during the first half of 2024.

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.

On July 18, 2023, we entered into 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, 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 are seeking, 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. We are evaluating Cipla's additional Paragraph IV certifications.

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 January 2024, our Board of Directors authorized a stock repurchase program to acquire up to $450 million of our outstanding common stock before the end of 2024. As of March 31, 2024, approximately $259.3 million remained available for future stock repurchases before the end of 2024, pursuant to our stock repurchase program.

Stock repurchases under the 2024 program may be made from time to time through a variety of methods, which may include open market purchases, in block trades, 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 following table summarizes the stock repurchase activity for the three months ended March 31, 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	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Program	Approximate Dollar Value of Shares That May Yet Be Purchased Under the Program
December 30, 2023 – January 26, 2024	—	$ —	—	$ 450,000
January 27, 2024 – February 23, 2024	2,902	$ 20.59	2,902	$ 390,254
February 24, 2024 – March 29, 2024	5,736	$ 22.83	5,736	$ 259,296
Total	8,638		8,638	

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Dana T. Aftab, our Executive Vice President, Discovery and Translational Research, and Chief Scientific Officer, an officer for purposes of Section 16 of the Exchange Act, entered into a pre-arranged stock trading plan on May 25, 2023, which was subsequently modified on February 27, 2024. As modified, Dr. Aftab's trading plan provides for the sale of up to 194,656 shares of our common stock (including shares obtained from the exercise of vested stock options covered by the trading plan) between May 30, 2024 and September 30, 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.

Jeffrey J. Hessekiel, our Executive Vice President, General Counsel and Secretary, an officer for purposes of Section 16 of the Exchange Act, entered into a pre-arranged stock trading plan on February 28, 2024. Mr. Hessekiel's trading plan provides for the sale of up to 200,000 shares of our common stock (including shares obtained from the exercise of vested stock options covered by the trading plan) between May 29, 2024 and December 31, 2024. 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.

Jack L Wyszomierski, a member of our Board of Directors, entered into a pre-arranged stock trading plan on February 12, 2024. Mr. Wyszomierski's trading plan provides for the sale of up to 19,973 shares of our common stock (including shares obtained from the exercise of vested stock options covered by the trading plan) between May 13, 2024 and June 12, 2024. This trading plan is intended to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act and Exelixis' policies regarding transactions in Exelixis securities.

During the three months ended March 31, 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.

Exhibit Number	Exhibit Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit/ Appendix Reference	Filing Date	
3.1	Restated Certificate of Incorporation of Exelixis, Inc.	10-Q	000-30235	3.1	8/5/2021	
3.2	Certificate of Change of Registered Agent and/or Registered Office of Exelixis, Inc.					X
3.3	Amended and Restated Bylaws of Exelixis, Inc.	8-K	000-30235	3.1	12/20/2023	
31.1	Certification of Principal Executive Officer Pursuant to Exchange Act Rules 13a-14(a) and Rule 15d-14(a)					X
31.2	Certification of Principal Financial Officer Pursuant to Exchange Act Rules 13a-14(a) and Rule 15d-14(a)					X
32.1‡	Certifications of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350					X
101.INS	XBRL Instance Document	The XBRL instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X

‡ This certification accompanies this Quarterly Report on Form 10-Q, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of Exelixis, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of this Quarterly Report on Form 10-Q), irrespective of any general incorporation language contained in such filing.

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.

April 30, 2024
Date

By: /s/ Christopher J. Senner
Christopher J. Senner
Executive Vice President and Chief Financial Officer
(Duly Authorized Officer and Principal Financial and Accounting Officer)

STATE OF DELAWARE
CERTIFICATE OF CHANGE OF REGISTERED AGENT
AND/OR REGISTERED OFFICE

The corporation organized and existing under the General Corporation Law of the State of Delaware, hereby certifies as follows:

1. The name of the corporation is EXELIXIS, INC.

2. The Registered Office of the corporation in the State of Delaware is changed to Corporation Trust Center, 1209 Orange Street, in the City of Wilmington, County of New Castle, Zip Code 19801. The name of the Registered Agent at such address upon whom process against this Corporation may be served is THE CORPORATION TRUST COMPANY.

3. The foregoing change to the registered office/agent was adopted by a resolution of the Board of Directors of the corporation.

By: /s/ Rachel O'Connor
Authorized Officer

Name: Rachel O'Connor
Print or Type

Exhibit 31.1

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: April 30, 2024

Exhibit 31.2

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: April 30, 2024

Exhibit 32.1

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 March 29, 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 30th day of April 2024.

/s/ Michael M. Morrissey
Michael M. Morrissey, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Christopher J. Senner
Christopher J. Senner
Executive Vice President and Chief Financial Officer
(Principal Financial Officer)