Table of Contents

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 31, 2023
or

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

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 $.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 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 Securities 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 May 1, 2023, there were 325,636,738 shares of the registrant's common stock outstanding.

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

		Page
	PART I - FINANCIAL INFORMATION	
Item 1.	Financial Statements	3
	Condensed Consolidated Balance Sheets (Unaudited)	3
	Condensed Consolidated Statements of Income (Unaudited)	4
	Condensed Consolidated Statements of Comprehensive Income (Unaudited)	4
	Condensed Consolidated Statements of Stockholders' Equity (Unaudited)	5
	Condensed Consolidated Statements of Cash Flows (Unaudited)	6
	Notes to Condensed Consolidated Financial Statements (Unaudited)	7
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	20
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	34
Item 4.	Controls and Procedures	34
	PART II - OTHER INFORMATION	
Item 1.	Legal Proceedings	36
Item 1A.	Risk Factors	38
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	40
Item 3.	Defaults Upon Senior Securities	41
Item 4.	Mine Safety Disclosures	41
Item 5.	Other Information	41
Item 6.	Exhibits	41
	SIGNATURES	

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

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

	March 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 540,597	$ 501,195
Short-term investments	772,536	807,273
Trade receivables, net	233,923	214,784
Inventory	29,908	33,299
Prepaid expenses and other current assets	60,654	62,211
Total current assets	1,637,618	1,618,762
Long-term investments	806,615	756,731
Property and equipment, net	116,212	110,624
Deferred tax assets, net	229,603	231,110
Goodwill	63,684	63,684
Right-of-use assets and other	289,627	290,578
Total assets	$ 3,143,359	$ 3,071,489
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 32,621	$ 32,667
Accrued compensation and benefits	56,551	77,158
Accrued clinical trial liabilities	64,210	65,072
Rebates and fees due to customers	66,405	50,350
Accrued collaboration liabilities	18,324	20,188
Other current liabilities	89,486	78,924
Total current liabilities	327,597	324,359
Long-term portion of deferred revenue	6,299	6,582
Long-term portion of operating lease liabilities	186,948	190,170
Other long-term liabilities	67,379	61,951
Total liabilities	588,223	583,062
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: 324,985 and 323,951 at March 31, 2023, and December 31, 2022, respectively	325	324
Additional paid-in capital	2,558,297	2,536,849
Accumulated other comprehensive loss	(9,289)	(14,521)
Retained earnings (Accumulated deficit)	5,803	(34,225)
Total stockholders' equity	2,555,136	2,488,427
Total liabilities and stockholders' equity	$ 3,143,359	$ 3,071,489

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,	
	2023	**2022**
Revenues:		
Net product revenues	$ 363,400	$ 310,298
License revenues	38,292	32,067
Collaboration services revenues	7,096	13,615
Total revenues	408,788	355,980
Operating expenses:		
Cost of goods sold	14,315	13,203
Research and development	234,246	156,671
Selling, general and administrative	131,397	102,863
Total operating expenses	379,958	272,737
Income from operations	28,830	83,243
Interest income	19,502	1,822
Other income (expense), net	(54)	164
Income before income taxes	48,278	85,229
Provision for income taxes	8,250	16,656
Net income	$ 40,028	$ 68,573
Net income per share:		
Basic	$ 0.12	$ 0.21
Diluted	$ 0.12	$ 0.21
Weighted-average common shares outstanding:		
Basic	324,420	319,582
Diluted	326,279	323,289

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,	
	2023	**2022**
Net income	$ 40,028	$ 68,573
Other comprehensive income (loss):		
Net unrealized gains (losses) on available-for-sale debt securities, net of tax impact of $(1,507) and $1,656, respectively	5,232	(5,907)
Comprehensive income	$ 45,260	$ 62,666

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, 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

	Three Months Ended March 31, 2022					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	318,842	$ 319	$ 2,427,561	$ (758)	$ (216,507)	$ 2,210,615
Net income	—	—	—	—	68,573	68,573
Other comprehensive loss	—	—	—	(5,907)	—	(5,907)
Issuance of common stock under equity incentive plans	1,426	1	5,512	—	—	5,513
Stock transactions associated with taxes withheld on equity awards	—	—	(4,960)	—	—	(4,960)
Stock-based compensation	—	—	20,017	—	—	20,017
Balance at March 31, 2022	320,268	$ 320	$ 2,448,130	$ (6,665)	$ (147,934)	$ 2,293,851

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,	
	2023	**2022**
Net income	$ 40,028	$ 68,573
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	6,855	4,490
Stock-based compensation	16,661	19,759
Non-cash lease expense	6,731	1,385
Deferred taxes	—	15,318
Acquired in-process research and development technology	36,500	—
Other, net	(3,743)	1,580
Changes in operating assets and liabilities:		
Trade receivables, net	(19,178)	91,793
Inventory	(8,370)	(3,520)
Prepaid expenses and other assets	10,372	(3,605)
Deferred revenue	(707)	(1,169)
Accrued collaboration liabilities	(1,864)	(54,261)
Accounts payable and other liabilities	1,123	7,376
Net cash provided by operating activities	84,408	147,719
Cash flows from investing activities:		
Purchases of property, equipment and other	(12,024)	(5,609)
Acquired in-process research and development technology	(36,500)	—
Purchases of investments	(311,837)	(336,545)
Proceeds from maturities and sales of investments	310,769	267,615
Net cash used in investing activities	(49,592)	(74,539)
Cash flows from financing activities:		
Proceeds from issuance of common stock under equity incentive plans	7,143	4,891
Taxes paid related to net share settlement of equity awards	(2,557)	(4,686)
Net cash provided by financing activities	4,586	205
Net increase in cash, cash equivalents and restricted cash equivalents	39,402	73,385
Cash, cash equivalents and restricted cash equivalents at beginning of period	502,677	663,891
Cash, cash equivalents and restricted cash equivalents at end of period	$ 542,079	$ 737,276

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, antibody-drug conjugates and other biotherapeutics.

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 67 other countries as of the date of this Quarterly Report on Form 10-Q: as CABOMETYX® (cabozantinib) tablets for advanced renal cell carcinoma (both alone and in combination with Bristol-Myers Squibb Company's OPDIVO® (nivolumab)), for previously treated hepatocellular carcinoma and for previously treated, radioactive iodine-refractory differentiated thyroid cancer; 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 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.

The accompanying unaudited 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, 2023 are not necessarily indicative of the results that may be expected for the year ending December 31, 2023 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, 2022, included in Part II, Item 8 of our Annual Report on Form 10-K, filed with the SEC on February 7, 2023 (Fiscal 2022 Form 10-K).

We have adopted a 52- or 53-week fiscal year policy that ends on the Friday closest to December 31st. Fiscal year 2023, which is a 52-week fiscal year, will end on December 29, 2023 and fiscal year 2022, which was a 52-week fiscal year, ended on December 30, 2022. For convenience, references in this report as of and for the fiscal period ended April 1, 2022, and as of and for the fiscal years ending December 29, 2023 and ended December 30, 2022 are indicated as being as of and for the period ended March 31, 2022, and the years ending December 31, 2023 and ended December 31, 2022, respectively.

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 sales of products, 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.

Significant Accounting Policies

There have been no material changes to our significant accounting policies during the three months ended March 31, 2023, 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 2022 Form 10-K.

Recently Adopted Accounting Pronouncements

There were no new accounting pronouncements adopted by us since our filing of the Fiscal 2022 Form 10-K, which could have a significant effect on our Condensed Consolidated Financial Statements.

Recent Accounting Pronouncements Not Yet Adopted

There were no new accounting pronouncements issued since our filing of the Fiscal 2022 Form 10-K, which could have a significant effect on our Condensed Consolidated Financial Statements.

NOTE 2. REVENUES

Revenues consisted of the following (in thousands):

	Three Months Ended March 31,	
	2023	**2022**
Product revenues:		
Gross product revenues	$ 521,322	$ 448,237
Discounts and allowances	(157,922)	(137,939)
Net product revenues	363,400	310,298
Collaboration revenues:		
License revenues	38,292	32,067
Collaboration services revenues	7,096	13,615
Total collaboration revenues	45,388	45,682
Total revenues	$ 408,788	$ 355,980

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,	
	2023	2022
Affiliates of McKesson Corporation	17 %	19 %
Affiliates of CVS Health Corporation	17 %	17 %
Affiliates of AmerisourceBergen Corporation	17 %	17 %
Accredo Health, Incorporated	12 %	9 %
Affiliates of Optum Specialty Pharmacy	10 %	10 %
Ipsen Pharma SAS	8 %	10 %

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

	March 31, 2023	December 31, 2022
Affiliates of McKesson Corporation	24 %	22 %
Affiliates of AmerisourceBergen Corporation	19 %	18 %
Ipsen Pharma SAS	18 %	20 %
Affiliates of CVS Health Corporation	13 %	18 %
Cardinal Health, Inc.	9 %	11 %

Revenues by geographic region were as follows (in thousands):

	Three Months Ended March 31,	
	2023	2022
U.S.	$ 367,441	$ 314,065
Europe	33,534	34,527
Japan	7,813	7,388
Total revenues	$ 408,788	$ 355,980

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 Agreements*. 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 pay 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,	
	2023	2022
CABOMETYX	$ 361,773	$ 302,812
COMETRIQ	1,627	7,486
Net product revenues	$ 363,400	$ 310,298

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, 2022	$ 26,881	$ 14,924	$ 35,426	$ 77,231
Provision related to sales made in:				
Current period	94,959	14,913	49,113	158,985
Prior periods	141	(1,117)	(87)	(1,063)
Payments and customer credits issued	(100,831)	(13,637)	(33,130)	(147,598)
Balance at March 31, 2023	$ 21,150	$ 15,083	$ 51,322	$ 87,555

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, 2023	December 31, 2022
Contract assets [1]	$ 1,387	$ 1,659
Contract liabilities:		
Current portion [2]	$ 7,064	$ 7,488
Long-term portion [3]	6,299	6,582
Total contract liabilities	$ 13,363	$ 14,070

[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 the long-term portion of deferred revenues in the accompanying Condensed Consolidated Balance Sheets.

During the three months ended March 31, 2023 and 2022, we recognized $2.0 million and $2.4 million, respectively, in revenues that were included in the beginning deferred revenues balance for those periods.

During the three months ended March 31, 2023 and 2022, we recognized $37.9 million and $31.7 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, 2023, $69.0 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 2022 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 2022 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 for the commercialization and further development of cabozantinib. Under the collaboration and license 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 and license agreement, as amended, with Ipsen were as follows (in thousands):

	Three Months Ended March 31,	
	2023	**2022**
License revenues	$ 29,812	$ 24,614
Collaboration services revenues	3,722	9,913
Total collaboration revenues	$ 33,534	$ 34,527

As of March 31, 2023, $33.9 million of the transaction price for this collaboration and license 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 for the commercialization and further development of cabozantinib. Under the collaboration and license 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 and license agreement, as amended, with Takeda were as follows (in thousands):

	Three Months Ended March 31,	
	2023	2022
License revenues	$ 2,849	$ 2,365
Collaboration services revenues	3,374	3,702
Total collaboration revenues	$ 6,223	$ 6,067

As of March 31, 2023, $35.0 million of the transaction price for this collaboration and license 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 (GSK), that required us to pay a 3% royalty to GSK on the worldwide net sales of any product incorporating 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 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 $15.4 million and $13.1 million during the three months ended March 31, 2023 and 2022, 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 drug candidates or 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, development, regulatory and commercial milestone payments, and royalty payments, in each case contingent upon the occurrence of certain future events linked to the success of the asset in development. Certain of our research collaborations provide us exclusive options that give us the right to license programs or acquire the intellectual property developed under the research collaborations for further discovery and development. When we decide to exercise the options, we are required to pay an exercise fee and then assume the responsibilities for all subsequent development, manufacturing and commercialization.

During the three months ended March 31, 2023, we recognized $44.7 million within research and development expenses on the Condensed Consolidated Statements of Income, primarily related to development milestones, research and development funding and other fees, including a $35.0 million development milestone to our partner, Sairopa B.V., upon the effective date of the initial new drug application (IND) for the ADU-1805 program.

As of March 31, 2023, in conjunction with these collaborative in-licensing arrangements we are subject to potential future development milestones of up to $650.6 million, regulatory milestones of up to $634.4 million and commercial milestones of up to $3.2 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 Restricted Cash Equivalents

A reconciliation of cash, cash equivalents and restricted cash equivalents reported in the accompanying Condensed Consolidated Balance Sheets to the amount reported within the accompanying Condensed Consolidated Statements of Cash Flows was as follows (in thousands):

	March 31, 2023	December 31, 2022
Cash and cash equivalents	$ 540,597	$ 501,195
Restricted cash equivalents included in other long-term assets	1,482	1,482
Cash, cash equivalents and restricted cash equivalents as reported within the accompanying Condensed Consolidated Statements of Cash Flows	$ 542,079	$ 502,677

Restricted cash equivalents are used to collateralize letters of credit agreements and are invested primarily in certificates of deposit with original maturity of 90 days or less. The restricted cash equivalents are classified as other long-term assets.

Cash, Cash Equivalents, Restricted Cash Equivalents and Investments

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

	March 31, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Debt securities available-for-sale:				
Commercial paper	$ 684,917	$ —	$ —	$ 684,917
Corporate bonds	823,100	2,105	(10,274)	814,931
U.S. Treasury and government-sponsored enterprises	367,479	466	(3,859)	364,086
Municipal bonds	11,480	—	(144)	11,336
Total debt securities available-for-sale	1,886,976	2,571	(14,277)	1,875,270
Cash	64	—	—	64
Money market funds	165,941	—	—	165,941
Certificates of deposit	79,955	—	—	79,955
Total cash, cash equivalents, restricted cash equivalents and investments	$ 2,132,936	$ 2,571	$ (14,277)	$ 2,121,230

	December 31, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Debt securities available-for-sale:				
Commercial paper	$ 722,018	$ —	$ —	$ 722,018
Corporate bonds	810,439	541	(13,132)	797,848
U.S. Treasury and government-sponsored enterprises	338,218	48	(5,679)	332,587
Municipal bonds	16,385	—	(223)	16,162
Total debt securities available-for-sale	1,887,060	589	(19,034)	1,868,615
Cash	41	—	—	41
Money market funds	94,344	—	—	94,344
Certificates of deposit	103,681	—	—	103,681
Total cash, cash equivalents, restricted cash equivalents and investments	$ 2,085,126	$ 589	$ (19,034)	$ 2,066,681

Interest receivable was $10.1 million and $7.3 million as of March 31, 2023 and December 31, 2022, 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, 2023 and 2022.

We manage credit risk associated with our investment portfolio through our investment policy, which limits purchases to high-quality issuers and limits 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, 2023	
	Fair Value	Gross Unrealized Losses
Corporate Bonds	$ 551,038	$ (10,274)
U.S. Treasury and government-sponsored enterprises	283,051	(3,859)
Municipal bonds	11,336	(144)
Total	$ 845,425	$ (14,277)

	December 31, 2022	
	Fair Value	Gross Unrealized Losses
Corporate bonds	$ 706,711	$ (13,132)
U.S. Treasury and government-sponsored enterprises	308,307	(5,679)
Municipal bonds	15,792	(223)
Total	$ 1,030,810	$ (19,034)

There were 237 and 285 debt securities available-for-sale in an unrealized loss position as of March 31, 2023 and December 31, 2022, respectively. As of March 31, 2023, all securities have been in an unrealized loss position for less than twelve months except for 91 debt securities available-for-sale with an aggregate fair value of $317.1 million and an aggregate $6.3 million unrealized loss. As of December 31, 2022, all securities have been in an unrealized loss position for less than twelve months except for 81 debt securities available-for-sale with an aggregate fair value of $237.6 million and an aggregate $6.1 million unrealized loss.

During the three months ended March 31, 2023, 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 value of debt securities available-for-sale by contractual maturity was as follows (in thousands):

	March 31, 2023	December 31, 2022
Maturing in one year or less	$ 1,071,653	$ 1,114,884
Maturing after one year through five years	803,617	753,731
Total debt securities available-for-sale	$ 1,875,270	$ 1,868,615

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, 2023		
	Level 1	Level 2	Total
Commercial paper	$ —	$ 684,917	$ 684,917
Corporate bonds	—	814,931	814,931
U.S. Treasury and government-sponsored enterprises	—	364,086	364,086
Municipal bonds	—	11,336	11,336
Total debt securities available-for-sale	—	1,875,270	1,875,270
Money market funds	165,941	—	165,941
Certificates of deposit	—	79,955	79,955
Total financial assets carried at fair value	$ 165,941	$ 1,955,225	$ 2,121,166

	December 31, 2022		
	Level 1	Level 2	Total
Commercial paper	$ —	$ 722,018	$ 722,018
Corporate bonds	—	797,848	797,848
U.S. Treasury and government-sponsored enterprises	—	332,587	332,587
Municipal bonds	—	16,162	16,162
Total debt securities available-for-sale	—	1,868,615	1,868,615
Money market funds	94,344	—	94,344
Certificates of deposit	—	103,681	103,681
Total financial assets carried at fair value	$ 94,344	$ 1,972,296	$ 2,066,640

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.

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

Forward Foreign Currency Contracts

We have entered into forward contracts 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, 2023, we had one forward contract outstanding to sell €4.1 million. The forward contract with a maturity of three months is recorded at fair value and is included in prepaid expenses and other current assets in the Condensed Consolidated Balance Sheets. The unrealized loss on the forward contract is immaterial as of March 31, 2023. The forward contract is considered a Level 2 in the fair value hierarchy of our fair value measurements. The realized loss and gain we recognized on the maturity of our forward contract was immaterial for each of the three months ended March 31, 2023 and 2022, respectively, and are included in other income (expense), net on our Condensed Consolidated Statements of Income.

NOTE 6. INVENTORY

Inventory consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
Raw materials	$ 8,777	$ 8,077
Work in process	53,610	43,564
Finished goods	8,490	10,635
Total	$ 70,877	$ 62,276
Balance Sheet classification:		
Current portion included in inventory	$ 29,908	$ 33,299
Long-term portion included in other long-term assets	40,969	28,977
Total	$ 70,877	$ 62,276

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, 2023, 31,678,788 shares were available for grant under the Exelixis, Inc. 2017 Equity Incentive Plan (as amended and restated, the 2017 Plan). The share reserve is reduced by 1 share for each share issued pursuant to a stock option and 2 shares for full value awards, including RSUs.

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

	Three Months Ended March 31,	
	2023	2022
Research and development	$ 3,252	$ 8,899
Selling, general and administrative	13,409	10,860
Total stock-based compensation expense	$ 16,661	$ 19,759

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

	Three Months Ended March 31,	
	2023	2022
Stock options	$ 2,207	$ 3,678
Restricted stock units	12,607	13,073
Performance stock units	794	1,709
ESPP	1,053	1,299
Total stock-based compensation expense	$ 16,661	$ 19,759

As of March 31, 2023, there were 9,738,700 stock options outstanding and $14.0 million of related unrecognized compensation expense.

During the three months ended March 31, 2023, we granted 576,960 service-based RSUs with a weighted average grant date fair value of $17.08 per share. As of March 31, 2023, there were 11,315,085 RSUs outstanding, including RSUs that are subject to a total shareholder return (TSR) market condition (the TSR-based RSUs), and $172.0 million of related unrecognized compensation expense. Service-based RSUs granted to employees during the three months ended March 31, 2023 have vesting conditions and contractual lives of a similar nature to those described in “Note 8. Employee Benefit Plans” of the “Notes to Consolidated Financial Statements” included in Part II, Item 8 of our Fiscal 2022 Form 10-K.

As of March 31, 2023, there were 4,688,349 PSUs outstanding, of which 1,277,755 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, 2023, the remaining unrecognized stock-based compensation expense for the PSUs either achieved or deemed probable of achievement was $9.0 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 $76.2 million. For more information about our PSUs, see “Note 8. Employee Benefit Plans” of the “Notes to Consolidated Financial Statements” included in Part II, Item 8 of our Fiscal 2022 Form 10-K.

Share Repurchase Program

In March 2023, our Board of Directors authorized a share repurchase program to acquire up to $550 million of our outstanding common stock before the end of 2023. The timing and amount of any share repurchases under the share 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. Share 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, accelerated share repurchase transactions, 10b5-1 trading plans, exchange transactions, or any combination of such methods. The program does not obligate us to acquire any particular amount of our common stock, and the share repurchase program may be modified, suspended or discontinued at any time without prior notice. During the three months ended March 31, 2023, we did not repurchase any shares.

NOTE 8. PROVISION FOR INCOME TAXES

The effective tax rate for the three months ended March 31, 2023, was 17.1%, as compared to 19.5% for the corresponding period in 2022. The effective tax rate for each of the three months ended March 31, 2023 and 2022, 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 periods 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,	
	2023	2022
Numerator:		
Net income	$ 40,028	$ 68,573
Denominator:		
Weighted-average common shares outstanding — basic	324,420	319,582
Dilutive securities	1,859	3,707
Weighted-average common shares outstanding — diluted	326,279	323,289
Net income per share — basic	$ 0.12	$ 0.21
Net income per share — diluted	$ 0.12	$ 0.21

Dilutive securities included outstanding stock options, unvested RSUs (including TSR-based RSUs), PSUs and ESPP contributions.

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,	
	2023	2022
Anti-dilutive securities and contingently issuable shares excluded	15,592	16,522

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 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. A bench trial for MSN II has been scheduled for October 2023.

Teva ANDA Litigation

In May 2021, we received notice letters from Teva Pharmaceutical Industries Limited, Teva Pharmaceuticals Development, Inc. and Teva Pharmaceuticals USA, Inc. (individually and collectively referred to as Teva) regarding an ANDA Teva submitted to the FDA, 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 are seeking, 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.

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. Cipla's response to the complaint is due on May 19, 2023. 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, granted the proposed order and administratively closed the case.

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.

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 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 our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the Securities and Exchange Commission (SEC) on February 7, 2023 (Fiscal 2022 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, antibody-drug conjugates (ADCs) and other biotherapeutics.

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 67 other countries as of the date of this Quarterly Report on Form 10-Q: as CABOMETYX® (cabozantinib) tablets for advanced renal cell carcinoma (RCC) (both alone and in combination with Bristol-Myers Squibb Company's (BMS) OPDIVO® (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.

We plan to continue leveraging our operating cash flows to support the ongoing investigation of cabozantinib in phase 3 trials for new indications and the advancement of a broad array of diverse biotherapeutics and small molecule programs for the treatment of cancer exploring multiple modalities and mechanisms of action. Of the clinical-stage assets that have emerged from our drug discovery and preclinical activities thus far, the furthest along are zanzalintinib, a next-generation oral tyrosine kinase inhibitor (TKI), and XB002, an ADC that targets tissue factor (TF). Both of these programs are next-generation approaches that build on our prior clinical experience, which we believe reduces program risk. We are also focused on conserving cash and managing risks of clinical failure by securing options to acquire other investigational drug candidates from third parties if those assets demonstrate evidence of clinical success. Two examples of this approach are: CBX-12 (alphalex™ exatecan), a clinical-stage, first-in-class peptide-drug conjugate (PDC) invented by Cybrexa Therapeutics (Cybrexa) that utilizes Cybrexa's proprietary alphalex technology to enhance the delivery of exatecan, a highly potent, second-generation topoisomerase I inhibitor, to tumor cells; and ADU-1805, a clinical-stage and potentially best-in-class monoclonal antibody developed by Sairopa B.V. (Sairopa) that targets SIRPα. The FDA cleared Sairopa's Investigational New Drug (IND) filing in February 2023, paving the way for an exploration of ADU-1805's applicability across multiple tumor types, as well as the potential to combine ADU-1805 with zanzalintinib and approved ICIs.

Cabozantinib Franchise

The FDA first approved CABOMETYX 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 OPDIVO, 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 CABOMETYX and COMETRIQ outside the U.S., we have entered into license agreements with Ipsen Pharma SAS (Ipsen) and Takeda Pharmaceutical Company Limited (Takeda). We granted to Ipsen the rights to develop and commercialize cabozantinib outside of the U.S. and Japan, and to Takeda we granted the rights to develop and commercialize cabozantinib 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 and for HCC in adults who have previously been treated with sorafenib. In addition, in March 2021, Ipsen and BMS received regulatory approval from the EC for CABOMETYX in combination with OPDIVO as a first-line treatment for patients with advanced RCC, followed by additional regulatory approvals for the combination in other territories beyond the EU. Most recently, in May 2022, we announced that Ipsen received regulatory approval from the EC for CABOMETYX as a monotherapy for the treatment of adult patients with locally advanced or metastatic, RAI-refractory or ineligible DTC and who have progressed during or after prior systemic therapy, which followed an approval from Health Canada in April 2022 for a similar DTC indication. With respect to the Japanese market, Takeda received Manufacturing and Marketing Approvals in 2020 from the Japanese Ministry of Health, Labour and Welfare (MHLW) of CABOMETYX as a treatment of patients with curatively unresectable or metastatic RCC and as a treatment of patients with unresectable HCC who progressed after cancer chemotherapy. In August 2021, Takeda and Ono Pharmaceutical Co., Ltd., BMS' development and commercialization partner in Japan, received Manufacturing and Marketing Approval from the MHLW of CABOMETYX in combination with OPDIVO as a treatment for unresectable or metastatic RCC.

In addition to our regulatory and commercialization efforts in the U.S. and the support provided to our collaboration partners for rest-of-world regulatory and commercialization activities, 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. We are continuing to evaluate cabozantinib in combination with ICIs in late-stage clinical trials that we sponsor across RCC and metastatic castration-resistant prostate cancer (mCRPC). Beyond clinical trials that we or our collaboration partners sponsor, independent investigators also conduct 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 (IST) program. Over time, the data we have obtained from these investigator-sponsored clinical trials have helped advance our development program for the cabozantinib franchise by informing subsequent label-enabling trials, including COSMIC-311, our phase 3 pivotal trial evaluating cabozantinib in previously treated patients with RAI-refractory DTC, from which positive results served as the basis for the FDA's and EC's approvals of CABOMETYX for DTC. Moreover, these data sets may also prove valuable by informing our development plans for zanzalintinib.

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 OPDIVO compared to sunitinib in previously untreated, advanced or metastatic RCC, and positive results from CheckMate -9ER served as the basis for the FDA's, EC's and MHLW's approvals of CABOMETYX in combination with OPDIVO 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 BMS' CTLA-4 ICI, ipilimumab, versus the combination of nivolumab and ipilimumab in patients with previously untreated advanced intermediate- or poor-risk RCC. We announced top-line results from COSMIC-313 in July 2022, and in September 2022 we presented the data at the Presidential Symposium III at the 2022 European Society for Medical Oncology Congress (the 2022 ESMO Congress). The trial met its primary endpoint, demonstrating significant improvement in blinded independent radiology committee (BIRC)-assessed progression-free survival (PFS) at the primary analysis for the triplet combination. At a prespecified interim analysis for the secondary endpoint of overall survival (OS), the triplet combination did not demonstrate a significant benefit, and therefore, the trial will continue to the next analysis of OS, expected in the second half of 2023. The safety profile observed in the trial was reflective of the known safety profiles for each single agent, as well as the combination regimens used in this study. Based on feedback from the FDA, we do not intend to submit a supplemental new drug application (sNDA) for the combination regimen based on the currently available data, and we plan to discuss a potential regulatory submission with the FDA when the results of the next OS analysis are available, provided such results are supportive.

To further expand our exploration of combinations with ICIs, we also initiated multiple trials evaluating cabozantinib in combination with F. Hoffmann-La Roche Ltd. (Roche)'s ICI, atezolizumab, beginning in 2017 with COSMIC-021, a broad phase 1b study evaluating the safety and tolerability of the cabozantinib and atezolizumab combination with atezolizumab in patients with a wide variety of locally advanced or metastatic solid tumors. The encouraging efficacy and safety data that emerged from COSMIC-021 have been instrumental in guiding our clinical development strategy for cabozantinib in combination with ICIs. We are currently evaluating the cabozantinib and atezolizumab combination in CONTACT-02, a phase 3 pivotal trial that we sponsor and is co-funded by Roche, which focuses on patients with mCRPC who have been previously treated with one novel hormonal therapy (NHT). We anticipate completing enrollment for CONTACT-02 and announcing results of the primary PFS analysis in the second half of 2023. Two other phase 3 trials sponsored by Roche and co-founded by us, CONTACT-01, which focused on patients with metastatic non-small cell lung cancer (NSCLC) who have been previously treated with an ICI and platinum-containing chemotherapy, and CONTACT-03, which focused on patients with inoperable, locally advanced or metastatic RCC who have progressed during or following treatment with an ICI as the immediate preceding therapy, did not meet their respective primary endpoints. Detailed findings from CONTACT-01 were presented at the European Lung Cancer Congress in March 2023, and detailed findings from CONTACT-03 will be presented at a future medical meeting.

Pipeline Activities

Zanzalintinib

The first compound to enter the clinic following our re-initiation of drug discovery activities in 2017 was zanzalintinib, a next-generation oral TKI that targets VEGF receptors, MET, AXL, MER and other kinases implicated in cancer's growth and spread. In designing zanzalintinib, we sought to build upon our experience with cabozantinib, retaining a similar target profile while improving key characteristics, including the pharmacokinetic half-life. To date, we have initiated two large phase 1b clinical trials studying zanzalintinib: STELLAR-001 and STELLAR-002. STELLAR-001 is a phase 1b clinical trial evaluating zanzalintinib, both as a monotherapy and in combination with atezolizumab. We have established a recommended dose of 100 mg for both single-agent zanzalintinib and zanzalintinib in combination with atezolizumab, and we have completed enrollment in an expansion cohort for patients with clear cell RCC while continuing to enroll patients in expansion cohorts for patients with non-clear cell RCC, hormone-receptor positive breast cancer, mCRPC and colorectal cancer (CRC). STELLAR-001 had previously included additional dose-escalation cohorts evaluating the combination of zanzalintinib and avelumab, an ICI developed by Merck KGaA, Darmstadt, Germany and Pfizer Inc., but those cohorts have since been discontinued. We previously presented data from STELLAR-001 during poster sessions at the 2022 ESMO Congress in September 2022, which showed zanzalintinib has demonstrated preliminary clinical activity similar to that observed with cabozantinib in phase 1 across a range of solid tumors and dose levels, with a manageable safety profile. In addition, preliminary efficacy data from the clear cell RCC expansion cohort from STELLAR-001, with a median follow-up of seven months, demonstrated an objective response rate (ORR) of 34% for the full cohort and an ORR of 50% for those patients who had not been previously treated with cabozantinib. We also continue to be encouraged by zanzalintinib's emerging safety profile and plan to submit these data for presentation at an upcoming medical conference, likely later in 2023. STELLAR-002 is a phase 1b clinical trial evaluating zanzalintinib in combination with either nivolumab, nivolumab and ipilimumab, or a fixed-dose combination of nivolumab and BMS' relatlimab. We have established a recommended dose of 100 mg for zanzalintinib in combination with nivolumab, and we have begun enrolling patients in expansion cohorts for patients with clear cell and non-clear cell RCC, HCC, NSCLC and squamous cell carcinoma of head and neck (SCCHN). The dose-escalation stage for zanzalintinib in the other combination regimens is ongoing and is continuing to enroll patients with advanced solid tumors in dose-escalation cohorts. Depending on the dose-escalation results, these other combination regimens in STELLAR-002 may enroll expansion cohorts for patients with clear cell and non-clear cell RCC, mCRPC, urothelial carcinoma, HCC, NSCLC, CRC and SCCHN. To better understand the individual contribution of the therapies, treatment arms in the expansion cohorts may include zanzalintinib as a single agent in addition to the ICI combination regimens.

We also initiated two phase 3 pivotal trials evaluating zanzalintinib in combination with ICIs in 2022. The first 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 trial aims to enroll approximately 600 patients worldwide with documented RAS status at approximately 137 sites globally. The primary objective of STELLAR-303 is to evaluate the efficacy of the combination in patients with RAS wild-type disease, and outcomes in patients with RAS-mutated disease will also be evaluated. The primary efficacy endpoint of STELLAR-303 is OS, and additional efficacy endpoints include PFS, ORR and duration of response (DOR) per Response Evaluation Criteria in Solid Tumors (RECIST) v. 1.1, in each case as assessed by the investigator. The second 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. The trial aims to enroll

approximately 291 patients at approximately 170 sites globally. The primary efficacy endpoints of STELLAR-304 are PFS and ORR per RECIST v 1.1, in each case as assessed by BIRC. The secondary efficacy endpoint is OS. Beyond STELLAR-303 and STELLAR-304, we intend to explore a series of 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 payload drugs 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. Furthest along amongst our biotherapeutics programs is XB002, our lead TF-targeting ADC program, in-licensed from Iconic Therapeutics, Inc. (Iconic), now a wholly owned subsidiary of Endpoint Health, Inc. We are evaluating XB002, both as a single agent and in combination with either nivolumab or Roche's bevacizumab, in JEWEL-101, a phase 1 study in patients with advanced solid tumors for which therapies are unavailable, ineffective or intolerable. In October 2022, we announced promising initial dose-escalation results from JEWEL-101 during the Antibody-drug Conjugates Poster Session at the 2022 ENA Symposium. The data demonstrated that XB002 was well-tolerated at multiple dose levels, and a pharmacokinetic analysis confirmed that XB002 was stable with low levels of free payload. The planned cohort-expansion phase, which we expect to initiate during 2023, is designed to further explore the selected dose of XB002, both as a single agent and in combination with either nivolumab or bevacizumab, in individual tumor cohorts, which may include forms of NSCLC, cervical cancer, ovarian cancer, UC, SCCHN, pancreatic cancer, esophageal cancer, mCRPC, triple negative breast cancer and hormone-receptor positive breast cancer, and we also intend to initiate additional dose-escalation and expansion cohorts to evaluate the potential of XB002 in combination with additional ICIs and other targeted therapies across a wide range of tumor types, including indications other than those currently addressed by commercially available TF-targeted therapies.

In November 2022, we executed two option deals that exemplify our strategy to access clinical- or near-clinical-stage assets: an exclusive collaboration agreement with Cybrexa providing us with the right to acquire CBX-12; and an exclusive clinical development and option agreement with Sairopa to develop ADU-1805. Both CBX-12 and ADU-1805 are currently being evaluated in phase 1 clinical trials to explore each compound's pharmacokinetics, safety, tolerability and preliminary anti-tumor activity in patients with advanced or metastatic refractory solid tumors.

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 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. In addition to the option deals with Cybrexa and 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;
- BioInvent International AB (BioInvent), which is intended to expand our portfolio of antibody-based therapies and will utilize BioInvent's proprietary n-CoDeR antibody library and patient-centric F.I.R.S.T screening platform, which together are designed to allow for parallel target and antibody discovery;
- Catalent, Inc. (Catalent), which is focused on the discovery and development of multiple ADCs using Catalent's proprietary SMARTag site-specific bioconjugation technology;
- Invenra, Inc. (Invenra), which is focused on the discovery and development of novel binders and multispecific antibodies for the treatment of cancer; and
- NBE-Therapeutics AG (NBE), which is focused on the discovery and development of multiple ADCs by leveraging NBE's unique expertise and proprietary platforms in ADC discovery, including NBE's SMAC-Technology and novel payloads.

We have already made significant progress under these and other research collaborations and in-licensing arrangements and believe we will continue to do so in 2023 and in future years. For example, as a direct result of these arrangements, we are advancing four biotherapeutics development candidates: XB010, XB014, XB628 and XB371. XB010, our first ADC advanced internally, targets the tumor antigen 5T4 and incorporates antibodies sourced from Invenra and was constructed using Catalent's SMARTag site-specific bioconjugation platform. XB014 and XB628 are bispecific antibodies: XB014 combines a PD-L1 targeting arm with a CD47 targeting arm to block a macrophage checkpoint; and XB628 targets PD-L1 and NKG2A, identified as key regulator of natural killer cell activity. Both XB014 and XB628 were developed through our

collaboration with Invenra. XB371 is a next-generation, TF-targeting ADC, which is differentiated from XB002 by its topoisomerase inhibitor payload, and was developed through our collaboration with Catalent.

Other Small Molecules

Since its formation in 2000, our drug discovery group has advanced 25 compounds to the IND stage, either independently or with collaboration partners, and today we deploy our drug discovery expertise to advance small molecule drug candidates toward and through preclinical development. These efforts are led by our experienced scientists, including some of the same scientists who led the efforts to discover cabozantinib, cobimetinib and esaxerenone, each of which are now commercially distributed drug products. For example, zanzalintinib, which was discovered at Exelixis, has now entered into phase 3 clinical trials. We augment our small molecule discovery activities through research collaborations and in-licensing arrangements with other companies engaged in small molecule discovery, including:

- STORM Therapeutics LTD (STORM), which is focused on the discovery and development of inhibitors of novel RNA modifying enzymes, including ADAR1;
- Aurigene Oncology, Ltd. (Aurigene), which is focused on the discovery and development of novel small molecules as therapies for cancer; and
- StemSynergy Therapeutics, Inc. (StemSynergy), which is focused on the discovery and development of novel oncology compounds aimed to inhibit tumor growth by targeting CK1α and the Notch pathway.

The most advanced compounds to emerge from these arrangements is XL102, our lead program targeting CDK7, in-licensed from Aurigene. We are evaluating XL102, both as a single agent and in combination with other anti-cancer therapies, in QUARTZ-101, a phase 1 study in patients with inoperable, locally advanced or metastatic solid tumors. In December 2022, we announced initial dose-escalation results from QUARTZ-101 during the Poster Session at the 2022 San Antonio Breast Cancer Symposium. The data demonstrated that XL102 was well-tolerated at multiple dose levels and a pharmacokinetic analysis supported adding investigation of twice-daily oral dosing. We are continuing to evaluate the efficacy of XL102 in additional patients during this initial dose-escalation phase. The subsequent cohort-expansion phase is designed to further explore the selected dose of XL102 as a single agent and in combination regimens in individual tumor cohorts, including ovarian cancer, triple-negative breast cancer, hormone-receptor positive breast cancer and mCRPC.

As of the date of this Quarterly Report on Form 10-Q, we are currently working on more than 20 discovery programs and, pending data warranting further exploration, we anticipate advancing up to five new development candidates into preclinical development during 2023. In addition, we will continue to engage in business development initiatives with the goal of acquiring and in-licensing promising oncology platforms and assets and then further characterize and develop them utilizing our established preclinical and clinical development infrastructure.

First Quarter 2023 Business Updates and Financial Highlights

During the first quarter of 2023**,** 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 2023, the United States District Court for the District of Delaware (the Delaware District Court) issued a ruling in our patent infringement lawsuit against MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. (individually and collectively referred to as MSN, and such lawsuit referred to as MSN I), rejecting MSN's challenge to U.S. Patent No. 7,759,473, which expires August 14, 2026. The Delaware District Court also ruled that MSN's proposed Abbreviated New Drug Application (ANDA) product does not infringe U.S. Patent No. 8,877,776, which expires October 8, 2030, 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. This ruling in MSN I does not address the parties' claims in our separate, consolidated patent infringement lawsuit filed in the Delaware District Court against MSN in 2022 (MSN II). For a more detailed discussion of the MSN litigation matters, see "Legal Proceedings" in Part II, Item 1 of this Quarterly Report on Form 10-Q.
- In February 2023, cabozantinib in patients with forms of RCC was the subject of multiple data presentations at the 2023 ASCO Genitourinary Cancers Symposium.

- In March 2023, Sairopa initiated a phase 1 clinical trial evaluating ADU-1805, a potentially best-in-class monoclonal antibody developed by Sairopa that targets SIRPα, following the FDA's clearance Sairopa's IND filing in February 2023.
- In March 2023, we announced results from the phase 3 CONTACT-03 trial evaluating cabozantinib in combination with atezolizumab versus cabozantinib alone in patients with locally advanced or metastatic clear cell or non-clear cell, papillary or unclassified only, RCC who progressed during or after immune checkpoint inhibitor therapy, either combination or monotherapy, in which the combination did not meet its primary endpoint of PFS.
- In March 2023, we filed a patent lawsuit in the Delaware District Court against Cipla, Ltd. and Cipla USA, Inc. (individually and collectively referred to as 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 February 2023 notice letter, which notified us that Cipla filed an ANDA with the FDA requesting approval to market a generic version of CABOMETYX tablets prior to the expiration of the aforementioned patents. For a more detailed discussion of the Cipla litigation matter, see "Legal Proceedings" in Part II, Item 1 of this Quarterly Report on Form 10-Q.
- In March 2023, we announced the repurchase of up to $550 million of the company's common stock before the end of 2023.

Financial Highlights

- Net product revenues for the first quarter of 2023 were $363.4 million, as compared to $310.3 million for the first quarter of 2022.
- Total revenues for the first quarter of 2023 were $408.8 million, as compared to $356.0 million for the first quarter of 2022.
- Research and development expenses for the first quarter of 2023 were $234.2 million, as compared to $156.7 million for the first quarter of 2022.
- Selling, general and administrative expenses for the first quarter of 2023 were $131.4 million, as compared to $102.9 million for the first quarter of 2022.
- Provision for income taxes for the first quarter of 2023 was $8.3 million, as compared to $16.7 million for the first quarter of 2022.
- Net income for the first quarter of 2023 was $40.0 million, or $0.12 per share, basic and diluted, as compared to net income of $68.6 million, or $0.21 per share, basic and diluted, for the first quarter of 2022.

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, including those evaluating cabozantinib in combination with an ICI in mCRPC or evaluating zanzalintinib in combination with an ICI in CRC and RCC, 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 Pharmaceutical Industries Limited, Teva Pharmaceuticals Development, Inc. and Teva Pharmaceuticals USA, Inc. (individually and collectively referred to as Teva) 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 drug candidates 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.

Fiscal Year Convention

We have adopted a 52- or 53-week fiscal year policy that ends on the Friday closest to December 31st. Fiscal year 2023, which is a 52-week fiscal year, will end on December 29, 2023 and fiscal year 2022, which was a 52-week fiscal year, ended on December 30, 2022. For convenience, references in this report as of and for the fiscal period ended April 1, 2022, and as of and for the fiscal years ending December 29, 2023 and ended December 30, 2022 are indicated as being as of and for the period ended March 31, 2022, and the years ending December 31, 2023 and ended December 31, 2022, respectively.

Results of Operations

Revenues

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

	Three Months Ended March 31,		Percent Change
	2023	2022	
Net product revenues	$ 363,400	$ 310,298	17 %
License revenues	38,292	32,067	19 %
Collaboration services revenues	7,096	13,615	-48 %
Total revenues	$ 408,788	$ 355,980	15 %

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
	2023	2022	
Gross product revenues	$ 521,322	$ 448,237	16 %
Discounts and allowances	(157,922)	(137,939)	14 %
Net product revenues	$ 363,400	$ 310,298	17 %

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

	Three Months Ended March 31,		Percent Change
	2023	2022	
CABOMETYX	$ 361,773	$ 302,812	19 %
COMETRIQ	1,627	7,486	-78 %
Net product revenues	$ 363,400	$ 310,298	17 %

The increase in net product revenues for the three months ended March 31, 2023, as compared to the corresponding prior year period, was primarily related to a 10% increase in the number of CABOMETYX units sold as a result of the FDA's approval of CABOMETYX in combination with OPDIVO as a first-line treatment of patients with advanced RCC, in part due to 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, and, to a lesser extent, a 8% increase in the average net selling price of CABOMETYX.

We project that our net product revenues may increase for the remainder of 2023, 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" to our "Notes to Consolidated Financial Statements" included in Part II, Item 8 of our Fiscal 2022 Form 10-K.

Discounts and allowances as a percentage of gross revenues have 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, 2023, as compared to the corresponding prior year period, was primarily the result of an increase in volume of units sold and an increase in Medicare utilization.

We project our discounts and allowances as a percentage of gross revenues will increase during the remainder of 2023, 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 during the three months ended March 31, 2023 and 2022. Royalty revenues increased primarily as a result of increases in Ipsen's net sales of cabozantinib outside of the U.S. and Japan. Ipsen royalties were $29.8 million for the three months ended March 31, 2023, as compared to $24.6 million for the corresponding prior year period. Ipsen's net sales of cabozantinib have continued to grow since Ipsen's first commercial sale of CABOMETYX in the fourth quarter of 2016, primarily due to regulatory approvals in new territories, including regulatory approval in the EU for the combination therapy of CABOMETYX and OPDIVO received in March 2021. Royalty revenues for the three months ended March 31, 2023 also included $2.9 million related to Takeda's net sales of CABOMETYX, as compared to $2.4 million for the corresponding prior year period. Takeda royalty revenues have continued to grow since Takeda's first commercial sale of CABOMETYX in Japan in 2020. CABOMETYX is approved and is commercially available in 67 countries outside the U.S. as of the date of this Quarterly Report on Form 10-Q.

Our share of profits on the U.S. commercialization of COTELLIC under our collaboration agreement with Genentech was $2.9 million for the three months ended March 31, 2023, respectively, as compared to $2.1 million for the corresponding prior year period. We also earned royalties on ex-U.S. net sales of COTELLIC by Genentech of $1.1 million for the three months ended March 31, 2023 as compared to $1.6 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 $10.5 million for the three months ended March 31, 2023 as compared to $17.3 million for the corresponding prior year period. The decrease in development cost reimbursements for the three months ended March 31, 2023, as compared to the corresponding prior year period, was primarily attributable to decreases in spending on the COSMIC-312, COSMIC-021 and COSMIC-311 studies.

Collaboration services revenues were reduced by $4.5 million for the three months ended March 31, 2023 as compared to $3.8 million for the corresponding prior year period, for the 3% royalty we are required to pay on the net sales by Ipsen and Takeda of any product incorporating cabozantinib. As royalty generating sales of cabozantinib by Ipsen and Takeda have increased as described above, our royalty payments have also increased.

We project our collaboration services revenues may decrease for the remainder of 2023, as compared to the corresponding prior year period, primarily as a result of a decrease in development cost reimbursement revenues.

Cost of Goods Sold

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

	Three Months Ended March 31,		Percent Change
	2023	2022	
Cost of goods sold	$ 14,315	$ 13,203	8 %
Gross margin %	96 %	96 %	

Cost of goods sold is related to our product revenues and consists of a 3% royalty payable on U.S. net sales of any product incorporating 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, 2023, as compared to the corresponding prior year period, was primarily due to an increase in royalties as a result of increased U.S. CABOMETYX sales. We project our gross margin will not change significantly during the remainder of 2023.

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 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 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
	2023	2022	
Research and development expenses:			
Development:			
Clinical trial costs	$ 56,493	$ 59,998	-6 %
Personnel expenses	41,698	34,266	22 %
Consulting and outside services	9,481	6,436	47 %
Other development costs	18,818	9,369	101 %
Total development	126,490	110,069	15 %
Drug discovery:			
License and other collaboration costs	44,736	9,651	364 %
Other drug discovery costs	30,360	17,831	70 %
Total drug discovery	75,096	27,482	173 %
Stock-based compensation	3,252	8,899	-63 %
Other research and development	29,408	10,221	188 %
Total research and development expenses	$ 234,246	$ 156,671	50 %

The increase in research and development expenses for the three months ended March 31, 2023, as compared to the corresponding prior year period, was primarily related to increases in license and other collaboration costs, personnel expenses, other development costs and other research and development expenses, partially offset by lower stock-based compensation expense.

Drug discovery-related license and other collaboration costs increased primarily due to a $35.0 million milestone payment to Sairopa upon the IND effective date for ADU-1805. Personnel expenses increased primarily due to an increase in headcount to support our expanding discovery and development organization. Other development costs increased primarily due to manufacturing costs to support our drug development candidates. Other research and development expenses increased primarily related to technology costs, including our investments in business technology initiatives to support productivity and efficiency in our organization, and an increase in facility expenses. Stock-based compensation expense decreased for the three months ended March 31, 2023, as compared to the corresponding prior year period, primarily due to higher forfeitures.

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 drug candidates, preliminary data and final results from clinical trials, the potential market indications and overall clinical and commercial potential for our drug candidates, and competitive dynamics. We also make our research and development decisions in the context of our overall business strategy.

We continue to focus our development efforts on cabozantinib to maximize the therapeutic and commercial potential of this compound and, as a result, we project that a substantial portion of our research and development expenses will relate to the clinical development of our small molecule drug candidate zanzalintinib and our first biotherapeutics product candidate, XB002. Notable ongoing company-sponsored studies resulting from this program 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.

We are expanding our oncology product pipeline through drug discovery efforts, which encompass both biotherapeutics and small molecule programs with multiple modalities and mechanisms of action, with the goal of identifying new product candidates to advance into clinical trials. We also continue to engage in business development initiatives aimed at acquiring and in-licensing promising oncology platforms and assets, with the goal of utilizing our established preclinical and clinical development infrastructure to further characterize and develop such platforms and assets.

We project our research and development expenses may increase for the remainder of 2023, as compared to the corresponding prior year period, primarily driven by an increase in personnel expenses to support our expanding discovery and development organization and an increase in clinical trial costs including the planned initiation of multiple additional phase 3 pivotal trials and current early-stage trials evaluating zanzalintinib, as well as business development activities.

Selling, General and Administrative Expenses

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

	Three Months Ended March 31,		Percent Change
	2023	2022	
Selling, general and administrative expenses[(1)]	$ 117,988	$ 92,003	28 %
Stock-based compensation	13,409	10,860	23 %
Total selling, general and administrative expenses	$ 131,397	$ 102,863	28 %

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

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

The increase in selling, general and administrative expenses for the three months ended March 31, 2023, as compared to the corresponding prior year period, was primarily related to increases in personnel expenses, technology costs and facility expenses. Personnel expenses increased primarily due to an increase in administrative headcount to support our commercial and research and development organizations. The increase in technology costs include our investments in business technology initiatives to support productivity and efficiency in our organization. The increase in facility expenses was primarily due to the commencement of new leases in 2022.

We project our selling, general and administrative expenses may increase for the remainder of 2023, as compared to the corresponding prior year period, primarily driven by our continuing commercial investment in CABOMETYX and the growth of the broader organization.

Non-Operating Income

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

	Three Months Ended March 31,		Percent Change
	2023	2022	
Interest income	$ 19,502	$ 1,822	970 %
Other income (expense), net	(54)	164	-133 %
Non-operating income	$ 19,448	$ 1,986	879 %

The increase in non-operating income for the three months ended March 31, 2023, as compared to the corresponding prior year period, was primarily the result of an increase in interest income due to higher interest rates and higher investment balances.

Provision for Income Taxes

The provision for income taxes were as follows (dollars in thousands):

	Three Months Ended March 31,		Percent Change
	2023	2022	
Provision for income taxes	$ 8,250	$ 16,656	-50 %
Effective tax rate	17.1 %	19.5 %	

The effective tax rates for the three months ended March 31, 2023 and 2022, differed from the U.S. federal statutory rate of 21%, respectively, 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, 2023 and December 31, 2022, we had $2.1 billion in cash, cash equivalents, restricted cash equivalents and investments. 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.

Our primary cash requirements for operating activities, which we project will increase for the remainder of 2023, as compared to the corresponding period in 2022, are for: employee related expenditures; costs related to our development and discovery programs; royalty payments on our net product sales; and our leased facilities.

The Tax Cuts and Jobs Act, signed into law on December 22, 2017, modified the tax treatment of research and development expenditures beginning in 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 2023 and expect to pay higher estimated federal taxes by the end of 2023. 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 sales, which we project will increase for the remainder of 2023, as compared to the corresponding period in 2022; cash collections related to royalties earned from our commercial collaboration arrangements with Ipsen, Takeda and others; and cash collections for cost reimbursements under certain of our development programs which we project may decrease for the remainder of 2023, as compared to the corresponding period in 2022. 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 also have cash requirements related to capital expenditures to support the planned growth of our business including investments in facilities and equipment. We project that we may continue to spend significant amounts of cash to fund the development and commercialization of cabozantinib and the development of other product candidates in our pipeline, including zanzalintinib. In addition, we intend to continue to expand our oncology product pipeline through our drug discovery efforts, including additional research collaborations, in-licensing arrangements and other strategic transactions that align with our oncology drug development, and regulatory and commercial expertise. In March 2023, our Board of Directors authorized the repurchase of up to $550 million of our common stock before the end of 2023. The timing and amount of any share repurchases under the share 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.

Letters of Credit

We have obtained standby letters of credit related to our lease obligations and certain other obligations for $1.5 million as of March 31, 2023 and December 31, 2022.

Sources and Uses of Cash (dollars in thousands):

	March 31, 2023	December 31, 2022	Percent Change
Working capital	$ 1,310,021	$ 1,294,403	1 %
Cash, cash equivalents, restricted cash equivalents and investments	$ 2,121,230	$ 2,066,681	3 %

***Working capital**:* The increase in working capital as of March 31, 2023, as compared to December 31, 2022, was primarily due to the favorable impact to our net current assets resulting from our net income, partially offset by purchases of long-term investments, purchases of property and equipment and the reclassification of certain inventory to long-term assets. In the future, our working capital may be impacted by one of these factors or other factors, including common stock repurchases, the amounts and timing of which are variable.

Cash, cash equivalents, restricted cash equivalents and investments: Cash and cash equivalents primarily consist of cash deposits held at major banks, commercial paper, money market funds and other securities with original maturities 90 days or less. Restricted cash equivalents relate to our letters of credit agreements and are invested primarily in short-term certificates of deposit. Investments primarily consist of debt securities available-for-sale. For additional information regarding our cash, cash equivalents, restricted cash equivalents and investments, see "Note 4. Cash and Investments," in our "Notes to Condensed Consolidated Financial Statements" included in Part I, Item 1 of this Quarterly Report on Form 10-Q. The increase in cash, cash equivalents, restricted cash equivalents and investments at March 31, 2023 as compared to December 31, 2022, was primarily due to cash inflows generated by our operations from sales of our products and our commercial collaboration arrangements, partially offset by operating cash payments for employee-related expenditures, cash payments to support our development and discovery programs, cash payments for capital expenditures and lease payments.

Cash flow activities were as follows (in thousands):

	Three Months Ended March 31,	
	2023	**2022**
Net cash provided by operating activities	$ 84,408	$ 147,719
Net cash used in investing activities	$ (49,592)	$ (74,539)
Net cash provided by financing activities	$ 4,586	$ 205

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 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, 2023 decreased, as compared to the corresponding prior year period, primarily due to the collection of a $100.0 million milestone payment from Ipsen in the first quarter of 2022 and an increase in cash paid for certain operating expenses, which was 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 used in investing activities for the three months ended March 31, 2023 decreased, as compared to the corresponding prior year period, primarily due to an increase in cash proceeds from maturities and sales of investments and a decrease in purchases of investments, which were partially offset by an increase in purchases of in-process research and development technology related to certain of our in-licensing collaboration arrangements.

Financing Activities

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

Net cash provided by financing activities for the three months ended March 31, 2023 increased, as compared to the corresponding prior year period, primarily due to an increase in proceeds received from the issuance of common stock

under our equity incentive plans and a decrease in withholding taxes remitted to the government related to net share settlements of equity awards.

Contractual Obligations

There were no material changes outside of the ordinary course of business in our contractual obligations as of March 31, 2023 from those disclosed in our Fiscal 2022 Form 10-K. For more information about our Leases, and our other contractual obligations, see "Note 10. Commitments and contingencies" in "Notes to Condensed Consolidated Financial Statements" included in Part I, Item I of this Quarterly Report on Form 10-Q and see "Note 11. Commitments and contingencies" of the "Notes to Consolidated Financial Statements" included in Part II, Item 8 of our Fiscal 2022 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 amounts of revenues and expenses under our profit and loss sharing agreement; recoverability of inventory; the accrual for certain liabilities including accrued clinical trial liabilities; valuations of equity awards used to determine stock-based compensation, including certain awards with vesting subject to market and/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 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, inventory, clinical trial accruals, stock-based compensation and income taxes reflect the most 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, 2023, 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 2022 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" in 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, 2023 have not changed significantly from those described in Item 7A of our Fiscal 2022 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, or the Exchange Act) required by Rules 13a-15(b) or 15d-15(b) of the Exchange Act, our Chief Executive Officer and Chief Financial Officer

have concluded that as of the end of the period covered by this report, our disclosure controls and procedures were effective at the reasonable assurance level.

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

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

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

MSN I ANDA Litigation

In September 2019, we received a notice letter regarding an ANDA submitted to the FDA by MSN, requesting approval to market a generic version of CABOMETYX tablets. MSN's initial notice letter included a Paragraph IV certification with respect to our U.S. Patents No. 8,877,776 (salt and polymorphic forms), 9,724,342 (formulations), 10,034,873 (methods of treatment) and 10,039,757 (methods of treatment), which are listed in the Orange Book, for CABOMETYX. MSN's initial notice letter did not provide a Paragraph IV certification against U.S. Patents No. 7,579,473 (composition of matter) or 8,497,284 (methods of treatment), each of which is listed in the Orange Book. On October 29, 2019, we filed a complaint in the Delaware District Court for patent infringement against MSN asserting infringement of U.S. Patent No. 8,877,776 arising from MSN's ANDA filing with the FDA. On November 20, 2019, MSN filed its response to the complaint, alleging that the asserted claims of U.S. Patent No. 8,877,776 are invalid and not infringed. On May 5, 2020, we received notice from MSN that it had amended its ANDA to include additional Paragraph IV certifications. In particular, the May 5, 2020 amended ANDA requested approval to market a generic version of CABOMETYX tablets prior to expiration of two previously unasserted CABOMETYX patents: U.S. Patents No. 7,579,473 and 8,497,284. On May 11, 2020, we filed a complaint in the Delaware District Court for patent infringement against MSN asserting infringement of U.S. Patents No. 7,579,473 and 8,497,284 arising from MSN's amended ANDA filing with the FDA. Neither of our complaints have alleged infringement of U.S. Patents No. 9,724,342, 10,034,873 and 10,039,757. On May 22, 2020, MSN filed its response to the complaint, alleging that the asserted claims of U.S. Patents No. 7,579,473 and 8,497,284 are invalid and not infringed. On March 23, 2021, MSN filed its First Amended Answer and Counterclaims (amending its prior filing from May 22, 2020), seeking, among other things, a declaratory judgment that U.S. Patent No. 9,809,549 (salt and polymorphic forms) is invalid and would not be infringed by MSN if its generic version of CABOMETYX tablets were approved by the FDA. U.S. Patent No. 9,809,549 is not listed in the Orange Book. On April 7, 2021, we filed our response to MSN's First Amended Answer and Counterclaims, denying, among other things, that U.S. Patent No. 9,809,549 is invalid or would not be infringed. The two lawsuits comprising 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. A bench trial for MSN II has been scheduled for October 2023.

Teva ANDA Litigation

In May 2021, we received notice letters from Teva regarding an ANDA Teva submitted to the FDA, 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 are seeking, 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.

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. Cipla's response to the complaint is due on May 19, 2023. 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, granted the proposed order and administratively closed the case.

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 and the risks set forth below in this report, you should carefully review and consider the "Risk Factors" included under Item 1A to Part I of our Fiscal 2022 Form 10-K. Other than the risks set forth below, there have been no material changes to the risk factors disclosed in our Fiscal 2022 Form 10-K. The risks and uncertainties described therein and below are not the only ones we face. Additional risks and uncertainties not currently known to us or that we deem immaterial also may impair our business operations.

Risks Related to the Commercialization of Our Products

Pricing for pharmaceutical products in the U.S. has come under increasing attention and scrutiny by federal and state governments, legislative bodies and enforcement agencies. Initiatives arising from this scrutiny may result in changes that have the effect of reducing our revenue or harming our business or reputation.

There continue to be U.S. Congressional inquiries, hearings and proposed and enacted federal legislation and rules, as well as executive orders, designed to, among other things: reevaluate, reduce or limit the prices of drugs and make them more affordable for patients (including, for example, by tying drug prices to the prices of drugs in other countries); reform the structure and financing of Medicare Part D pharmaceutical benefits; implement additional data collection and transparency reporting regarding drug pricing, rebates, fees and other remuneration provided by drug manufacturers; enable the government to negotiate prices under Medicare; revise rules associated with the calculation of average manufacturer price and best price under Medicaid and make other changes to the Medicaid Drug Rebate Program that could increase manufacturer rebate liability; eliminate the Anti-Kickback Statute (AKS) discount safe harbor protection for manufacturer rebate arrangements with Medicare Part D plan sponsors; create new AKS safe harbors applicable to certain point-of-sale discounts to patients and fixed fee administrative fee payment arrangements with pharmacy benefit managers. For instance in August 2022, President Biden signed the Inflation Reduction Act, which among other things: allows for the Centers for Medicare & Medicaid Services (CMS) to control the prices of certain single-source drugs and biotherapeutics reimbursed under Medicare Part B and Part D; subjects drug manufacturers to potential civil monetary penalties and a significant excise tax for offering a price that is not equal to or less than the government-imposed "maximum fair price" under the law; imposes Medicare rebates for certain Part B and Part D drugs where relevant pricing metrics associated with the products increase faster than inflation; and redesigns the funding and benefit structure of the Medicare Part D program, potentially increasing manufacturer liability while capping annual out-of-pocket drug expenses for Medicare beneficiaries. These provisions have started taking effect incrementally in late 2022 and may be subject to various legal challenges. As of the date of this report, CMS has begun to implement aspects of the Inflation Reduction Act and, in February 2023, CMS released initial guidance addressing the Medicare Part B and Medicare Part D inflation rebate provisions of the Inflation Reduction Act. These provisions generally require manufacturers of Medicare Part B and Part D rebatable drugs to pay inflation rebates to the Medicare program if pricing metrics associated with their products increase faster than the rate of inflation. In addition, in March 2023, CMS released initial guidance setting forth the requirements and procedures for implementing the Medicare Drug Price Negotiation Program for the first round of drug pricing negotiations, which will occur during 2023 and 2024 and result in prices effective in 2026. Among other things, the initial guidance specifies how CMS intends to identify selected drugs, consider factors in negotiation, conduct the negotiation process, and establish the requirements for manufacturers of selected drugs. Overtime, the Inflation Reduction Act could reduce the revenues we are able to collect from sales of our products and increase our government discount and rebate liabilities; however, the degree of impact that the Inflation Reduction Act will ultimately have upon our business remains unclear. In addition, we cannot know the final form or timing of any other legislative, regulatory and/or administrative measures, and some of these pending and enacted legislative proposals or executive rulemaking, if implemented without successful legal challenges, would likely have a significant and far-reaching impact on the biopharmaceutical industry and therefore also likely have a material adverse impact on our business, financial condition and results of operations.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biotherapeutic product pricing, including restrictions on pricing or reimbursement at the state government level, limitations on discounts to patients, marketing cost disclosure and transparency measures, and, in some cases, policies to encourage importation from other countries (subject to federal approval) and bulk purchasing, including the National Medicaid Pooling Initiative. In particular, the obligation to provide notices of price increases to purchasers under laws such as California's SB-17 may influence customer ordering patterns for CABOMETYX and COMETRIQ, which in turn may increase the volatility of our revenues as a reflection of changes in inventory volumes. Furthermore, adoption of these drug pricing transparency regulations, and our associated compliance obligations, may increase our general and administrative costs and/or diminish our revenues. Implementation of these federal and/or state cost-containment measures or other healthcare reforms may limit our ability to generate product revenue or commercialize our products, and in the case of drug pricing transparency regulations, may result in fluctuations in our results of operations.

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

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

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

Any clinical trial may fail to produce results satisfactory to the FDA or regulatory authorities in other jurisdictions. The FDA has substantial discretion in the approval process and may refuse to approve any NDA or sNDA or decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, we may encounter delays or rejections based upon changes in policy, which could cause delays in the approval or rejection of an application for cabozantinib or for zanzalintinib or our other product candidates. For example, the FDA launched Project Optimus in 2021 as an initiative to reform the dose optimization and dose selection paradigm in oncology drug development, which was driven by the FDA's concerns that the current paradigm for dose selection may result in doses and schedules of molecularly targeted therapies that are inadequately characterized before initiating pivotal trials. Through collaboration with the biopharmaceutical industry, academia and other stakeholders, the FDA's goal for this initiative is to advance an oncology dose-finding and dose optimization paradigm that emphasizes dose selections that maximize efficacy as well as safety and tolerability. In support of this initiative, the FDA may request sponsors of oncology product candidates to conduct dose optimization studies pre- or post-approval, and the FDA also continues to develop and finalize guidance documents and implement initiatives regarding the development and clinical research of oncology product candidates. In January 2023, the FDA issued Draft Guidance for Industry, Optimizing the Dosage of Human Prescription Drugs and Biological Products for the Treatment of Oncologic Diseases, intended to assist sponsors in identifying the optimal dosages for these products during clinical development and prior to submitting an application for approval for a new indication and usage.

Recently, in part due to questions raised by the process underlying the approval of an Alzheimer's disease drug, government authorities and other stakeholders have been scrutinizing the accelerated approval pathway, with some stakeholders advocating for reforms. Even prior to this, the FDA has held Oncologic Drugs Advisory Committee meetings to discuss accelerated approvals for which confirmatory trials have not verified clinical benefit. Such scrutiny, among other factors, has resulted in voluntary withdrawals of certain products and indications approved on an accelerated basis. Spurred by the Alzheimer's drug controversy, the HHS Office of Inspector General has also initiated, and partially completed, an assessment of how the FDA implements the accelerated approval pathway. In addition, Section 3210 of the Food and Drug Omnibus Reform Act of 2022 (incorporated in the 2023 Appropriations Act) revised the accelerated approval pathway. Although this legislation did not change the standard for accelerated approval, it, among other things: requires the FDA to specify the conditions for required post-marketing trials; permits the FDA to require such trials to be underway prior to approval, or within a specific period after approval; requires sponsors to provide reports on post-marketing trial progress no later than 180 days after approval and every 180 days thereafter until such trials are completed; makes the failure to

conduct required post-marketing trials with due diligence and the failure to submit the required reports prohibited acts; and details procedures the FDA must follow to withdraw an accelerated approval on an expedited basis. While it is not clear at this time how these legislative and regulatory initiatives will affect our plans to pursue accelerated approval for one or more of our product candidates, these developments may have a material adverse impact on our business, financial condition and results of operations.

Even if the FDA or a comparable authority in another jurisdiction approves cabozantinib for one or more new indications or approves one of our other product candidates, including zanzalintinib, for use, such approval may be limited, imposing significant restrictions on the indicated uses, conditions for use, labeling, distribution, and/or production of the product and could impose requirements for post-marketing studies, including additional research and clinical trials, all of which may result in significant expense and limit our and our collaboration partners' ability to commercialize cabozantinib, zanzalintinib or our other product candidates in any new indications. Failure to complete post-marketing requirements of the FDA in connection with a specific approval in accordance with the timelines and conditions set forth by the FDA could significantly increase costs or delay, limit or ultimately restrict the commercialization of cabozantinib, zanzalintinib or another product candidate in the approved indication. Regulatory agencies could also impose various administrative, civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval. Further, current or any future laws or executive orders governing FDA or foreign regulatory approval processes that may be enacted or executed could have a material adverse impact on our business, financial condition and results of operations.

Risks Related to Our Relationships with Third Parties

We lack our own manufacturing and distribution capabilities necessary for us to produce materials required for certain preclinical activities and to produce and distribute our products for clinical development or for commercial sale, and our reliance on third parties for these services subjects us to various risks.

We do not operate our own current GMP manufacturing or distribution facilities for chemistry, manufacturing and control (CMC) development activities, preclinical, clinical or commercial production and distribution for our current products and new product candidates. Instead, we mostly rely on various third-party contract manufacturing organizations to conduct these operations on our behalf. As our operations continue to grow in these areas, we are advancing internal CMC development laboratories to augment our external network, while continuing to expand our external manufacturing and supply chain network through additional third-party contract manufacturers, distributors and suppliers. To establish and manage our supply chain requires a significant financial commitment, the creation of numerous third-party contractual relationships and continued oversight of these third parties to fulfill compliance with applicable regulatory requirements. Although we maintain significant resources to directly and effectively oversee the activities and relationships with the companies in our supply chain, we do not have direct control over their operations.

Our third-party contract manufacturers may not be able to produce or deliver material on a timely basis or manufacture material with the required quality standards, or in the quantity required to meet our preclinical, clinical development and commercial needs and applicable regulatory requirements. Although we have not yet experienced significant production delays or seen significant impairment to our supply chain as a result of the COVID-19 pandemic or the ongoing Russo-Ukrainian War, our third-party contract manufacturers, distributors and suppliers could experience operational delays due to lack of capacity or resources, facility closures and other hardships as a result of these types of global events, which could impact our supply chain by potentially causing delays to or disruptions in the supply of our preclinical, clinical or commercial products. If our third-party contract manufacturers, distributors and suppliers do not continue to supply us with our products or product candidates in a timely fashion and in compliance with applicable quality and regulatory requirements, or if they otherwise fail or refuse to comply with their obligations to us under our manufacturing, distribution and supply arrangements, we may not have adequate remedies for any breach. Furthermore, their failure to supply us could impair or preclude meeting commercial or clinical product supply requirements for us or our partners, which could delay product development and future commercialization efforts and have a material adverse impact on our business, financial condition and results of operations. In addition, through our third-party contract manufacturers and data service providers, we continue to provide serialized commercial products as required to comply with the Drug Supply Chain Security Act (DSCSA) and its foreign equivalents where applicable. If our third-party contract manufacturers or data service providers fail to support our efforts to continue to comply with DSCSA and its foreign equivalents, as well as any future electronic pedigree requirements, we may face legal penalties or be restricted from selling our products.

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

Not applicable.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

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	Amended and Restated Bylaws of Exelixis, Inc.	8-K	000-30235	3.1	3/3/2021	
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.

May 9, 2023
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)

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

Date: May 9, 2023

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: May 9, 2023

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 31, 2023, 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 9th day of May 2023.

/s/ Michael M. Morrissey, Ph.D.
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)