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 September 30, 2022
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 October 24, 2022, there were 322,561,418 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)	7
	Notes to Condensed Consolidated Financial Statements (Unaudited)	8
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	22
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	37
Item 4.	Controls and Procedures	37
	PART II - OTHER INFORMATION	
Item 1.	Legal Proceedings	39
Item 1A.	Risk Factors	40
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	59
Item 3.	Defaults Upon Senior Securities	59
Item 4.	Mine Safety Disclosures	59
Item 5.	Other Information	59
Item 6.	Exhibits	59
	SIGNATURES	

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 675,286	$ 647,169
Short-term investments	871,706	819,905
Trade receivables, net	215,015	282,650
Inventory	26,711	27,493
Prepaid expenses and other current assets	52,903	57,530
Total current assets	1,841,621	1,834,747
Long-term investments	551,735	371,112
Property and equipment, net	107,909	104,031
Deferred tax assets, net	116,415	111,663
Goodwill	63,684	63,684
Other long-term assets	280,008	131,002
Total assets	$ 2,961,372	$ 2,616,239
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 30,572	$ 24,258
Accrued compensation and benefits	66,927	61,969
Accrued clinical trial liabilities	62,057	77,544
Rebates and fees due to customers	43,791	33,700
Accrued collaboration liabilities	18,277	86,753
Other current liabilities	80,109	53,366
Total current liabilities	301,733	337,590
Long-term portion of deferred revenues	6,491	8,739
Long-term portion of operating lease liabilities	159,838	51,272
Other long-term liabilities	1,908	8,023
Total liabilities	469,970	405,624
Commitments and contingencies		
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: 322,541 and 318,842 at September 30, 2022, and December 31, 2021, respectively	323	319
Additional paid-in capital	2,512,669	2,427,561
Accumulated other comprehensive loss	(17,538)	(758)
Accumulated deficit	(4,052)	(216,507)
Total stockholders' equity	2,491,402	2,210,615
Total liabilities and stockholders' equity	$ 2,961,372	$ 2,616,239

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 amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenues:				
Net product revenues	$ 366,482	$ 263,117	$ 1,023,824	$ 774,577
License revenues	34,384	49,694	123,977	116,862
Collaboration services revenues	10,872	15,612	39,344	92,391
Total revenues	411,738	328,423	1,187,145	983,830
Operating expenses:				
Cost of goods sold	15,305	11,874	41,989	39,956
Research and development	198,837	163,370	554,989	471,448
Selling, general and administrative	114,983	101,558	340,605	302,404
Total operating expenses	329,125	276,802	937,583	813,808
Income from operations	82,613	51,621	249,562	170,022
Interest income	9,498	1,658	16,077	6,231
Other income (expense), net	(69)	(19)	140	(120)
Income before income taxes	92,042	53,260	265,779	176,133
Provision for income taxes	18,832	15,056	53,324	40,236
Net income	$ 73,210	$ 38,204	$ 212,455	$ 135,897
Net income per share:				
Basic	$ 0.23	$ 0.12	$ 0.66	$ 0.43
Diluted	$ 0.23	$ 0.12	$ 0.65	$ 0.42
Weighted-average common shares outstanding:				
Basic	322,148	315,380	320,949	313,990
Diluted	325,066	322,022	324,420	322,084

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net income	$ 73,210	$ 38,204	$ 212,455	$ 135,897
Other comprehensive loss:				
Net unrealized losses on available-for-sale debt securities, net of tax impact of $2,457, $193, $4,752 and $949, respectively	(8,621)	(504)	(16,780)	(2,995)
Comprehensive income	$ 64,589	$ 37,700	$ 195,675	$ 132,902

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

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

	Three Months Ended September 30, 2022					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at June 30, 2022	321,800	$ 322	$2,477,117	$ (8,917)	$ (77,262)	$ 2,391,260
Net income	—	—	—	—	73,210	73,210
Other comprehensive loss	—	—	—	(8,621)	—	(8,621)
Issuance of common stock under equity incentive plans	741	1	2,847	—	—	2,848
Stock transactions associated with taxes withheld on equity awards	—	—	(4,906)	—	—	(4,906)
Stock-based compensation	—	—	37,611	—	—	37,611
Balance at September 30, 2022	322,541	$ 323	$2,512,669	$ (17,538)	$ (4,052)	$ 2,491,402

	Three Months Ended September 30, 2021					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at June 30, 2021	314,822	$ 315	$2,390,654	$ 1,985	$ (349,877)	$ 2,043,077
Net income	—	—	—	—	38,204	38,204
Other comprehensive loss	—	—	—	(504)	—	(504)
Issuance of common stock under equity incentive plans	1,483	1	3,304	—	—	3,305
Stock transactions associated with taxes withheld on equity awards	—	—	(5,958)	—	—	(5,958)
Stock-based compensation	—	—	34,323	—	—	34,323
Balance at September 30, 2021	316,305	$ 316	$2,422,323	$ 1,481	$ (311,673)	$ 2,112,447

Continued on next page

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

	Nine Months Ended September 30, 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	—	—	—	—	212,455	212,455
Other comprehensive loss	—	—	—	(16,780)	—	(16,780)
Issuance of common stock under equity incentive plans and stock purchase plan	3,699	4	18,676	—	—	18,680
Stock transactions associated with taxes withheld on equity awards	—	—	(16,091)	—	—	(16,091)
Stock-based compensation	—	—	82,523	—	—	82,523
Balance at September 30, 2022	322,541	$ 323	$2,512,669	$ (17,538)	$ (4,052)	$ 2,491,402

	Nine Months Ended September 30, 2021					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2020	311,627	$ 312	$2,321,895	$ 4,476	$ (447,570)	$ 1,879,113
Net income	—	—	—	—	135,897	135,897
Other comprehensive loss	—	—	—	(2,995)	—	(2,995)
Issuance of common stock under equity incentive plans and stock purchase plan	4,678	4	18,788	—	—	18,792
Stock transactions associated with taxes withheld on equity awards	—	—	(15,371)	—	—	(15,371)
Stock-based compensation	—	—	97,011	—	—	97,011
Balance at September 30, 2021	316,305	$ 316	$2,422,323	$ 1,481	$ (311,673)	$ 2,112,447

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

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

	Nine Months Ended September 30,	
	2022	**2021**
Net income	$ 212,455	$ 135,897
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	14,929	11,699
Stock-based compensation	81,718	96,654
Non-cash lease expense	11,931	3,952
Deferred taxes	—	32,365
Other, net	7,390	35,871
Changes in operating assets and liabilities:		
Trade receivables, net	66,890	(20,124)
Inventory	(9,836)	(26,956)
Prepaid expenses and other assets	(35,166)	(24,252)
Deferred revenue	(3,130)	11,434
Accrued collaboration liabilities	(64,976)	13,947
Accounts payable and other liabilities	6,715	33,865
Net cash provided by operating activities	288,920	304,352
Cash flows from investing activities:		
Purchases of property, equipment and other	(25,989)	(48,265)
Purchases of investments	(1,079,411)	(1,077,377)
Proceeds from maturities and sales of investments	826,768	1,095,813
Net cash used in investing activities	(278,632)	(29,829)
Cash flows from financing activities:		
Proceeds from issuance of common stock under equity incentive plans	18,680	18,242
Taxes paid related to net share settlement of equity awards	(16,091)	(15,049)
Net cash provided by financing activities	2,589	3,193
Net increase in cash, cash equivalents, and restricted cash equivalents	12,877	277,716
Cash, cash equivalents and restricted cash equivalents at beginning of period	663,891	320,772
Cash, cash equivalents and restricted cash equivalents at end of period	$ 676,768	$ 598,488
Supplemental cash flow disclosures:		
Non-cash operating activities:		
Right-of-use assets obtained in exchange for lease obligations	$ 121,958	$ 4,893
Non-cash investing activities:		
Unpaid liabilities incurred for purchases of property and equipment	$ 1,643	$ 5,143
Unpaid liabilities incurred in asset acquisition	$ 500	$ 9,000

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-focused biotechnology company that strives to accelerate the discovery, development and commercialization of new medicines for patients with difficult-to-treat cancers. Using our considerable drug discovery, development and commercialization resources and capabilities, we have invented and brought to market innovative therapies that appropriately balance patient benefits and risks; we will continue to build on this foundation as we strive to provide cancer patients with new treatment options that improve upon current standards of care.

Today, four products that originated in Exelixis laboratories are available to be prescribed to patients. Sales related to our flagship molecule, cabozantinib, account for the large 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 62 other countries as: CABOMETYX® (cabozantinib) tablets approved 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, currently by the FDA and European Commission (EC), for previously treated, radioactive iodine (RAI)-refractory differentiated thyroid cancer (DTC); and COMETRIQ® (cabozantinib) capsules approved for progressive, metastatic medullary thyroid cancer (MTC). For physicians treating these types of cancer, cabozantinib has become or is becoming an important medicine in their selection of effective therapies.

The other two products resulting from our discovery efforts are: COTELLIC® (cobimetinib), an inhibitor of MEK approved as part of multiple combination regimens to treat specific forms of advanced melanoma and marketed under a collaboration with Genentech, Inc. a member of the Roche Group (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 nine months ended September 30, 2022 are not necessarily indicative of the results that may be expected for the year ending December 31, 2022 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 included in Part II, Item 8 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the SEC on February 18, 2022 (Fiscal 2021 Form 10-K).

We have adopted a 52- or 53-week fiscal year policy that generally ends on the Friday closest to December 31st. Fiscal year 2022, which is a 52-week fiscal year, will end on December 30, 2022 and fiscal year 2021, which was a 52-week fiscal year, ended on December 31, 2021. For convenience, references in this report as of and for the fiscal period ended October 1, 2021, and as of and for the fiscal year ending December 30, 2022 are indicated as being as of and for the period ended September 30, 2021, and the year ending 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 product sales, revenues from major customers and revenues by geographic region.

Use of Estimates

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

Reclassifications

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

Significant Accounting Policies

There have been no material changes to our significant accounting policies during the nine months ended September 30, 2022, 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 2021 Form 10-K.

Recently Adopted Accounting Pronouncements

There were no new accounting pronouncements adopted by us since the filing of our Fiscal 2021 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 the filing of our Fiscal 2021 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Product revenues:				
Gross product revenues	$ 496,141	$ 357,462	$ 1,427,451	$ 1,051,871
Discounts and allowances	(129,659)	(94,345)	(403,627)	(277,294)
Net product revenues	366,482	263,117	1,023,824	774,577
Collaboration revenues:				
License revenues	34,384	49,694	123,977	116,862
Collaboration services revenues	10,872	15,612	39,344	92,391
Total collaboration revenues	45,256	65,306	163,321	209,253
Total revenues	$ 411,738	$ 328,423	$ 1,187,145	$ 983,830

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Affiliates of McKesson Corporation	18 %	15 %	18 %	15 %
Affiliates of CVS Health Corporation	19 %	16 %	17 %	15 %
Affiliates of AmerisourceBergen Corporation	18 %	16 %	16 %	14 %
Ipsen Pharma SAS	8 %	12 %	11 %	17 %
Accredo Health, Incorporated	11 %	9 %	10 %	8 %

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

	September 30, 2022	December 31, 2021
Affiliates of McKesson Corporation	23 %	10 %
Ipsen Pharma SAS	21 %	50 %
Affiliates of AmerisourceBergen Corporation	20 %	11 %
Affiliates of CVS Health Corporation	15 %	9 %

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
U.S.	$ 369,480	$ 266,436	$ 1,033,160	$ 783,583
Europe	34,818	38,095	131,585	162,822
Japan	7,440	23,892	22,400	37,425
Total revenues	$ 411,738	$ 328,423	$ 1,187,145	$ 983,830

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 ASC Topic 606, *Revenue from Contracts with Customers* (Topic 606). License revenues include the recognition of the portion of milestone payments allocated to the transfer of intellectual property licenses for which it had become probable in the current period that the milestone would be achieved and a significant reversal of revenues would not occur, as well as royalty revenues and our share of profits under our collaboration agreement with Genentech. Collaboration services revenues were recorded in accordance with ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606* and by analogy to Topic 606. Collaboration services revenues include the recognition of deferred revenues for the portion of upfront and milestone payments allocated to our research and development services performance obligations, development cost reimbursements earned under our collaboration agreements, product supply revenues, net of product supply costs, and the royalties we paid on sales of products containing cabozantinib by our collaboration partners.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
CABOMETYX	$ 361,385	$ 259,791	$ 1,003,356	$ 759,000
COMETRIQ	5,097	3,326	20,468	15,577
Net product revenues	$ 366,482	$ 263,117	$ 1,023,824	$ 774,577

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, 2021	$ 14,625	$ 8,875	$ 24,825	$ 48,325
Provision related to sales made in:				
Current period	261,143	36,847	105,280	403,270
Prior periods	632	(169)	(106)	357
Payments and customer credits issued	(255,002)	(32,765)	(98,996)	(386,763)
Balance at September 30, 2022	$ 21,398	$ 12,788	$ 31,003	$ 65,189

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):

	September 30, 2022	December 31, 2021
Contract assets [1]	$ 364	$ 1,665
Contract liabilities:		
Current portion [2]	$ 6,932	$ 7,814
Long-term portion [3]	6,491	8,739
Total contract liabilities	$ 13,423	$ 16,553

(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 nine months ended September 30, 2022 and 2021, we recognized $6.6 million and $6.8 million, respectively, in revenues that were included in the beginning deferred revenues balance for those periods.

During the three and nine months ended September 30, 2022, we recognized $33.9 million and $125.0 million, respectively, in revenues for performance obligations satisfied in previous periods, as compared to $48.4 million and $116.2 million for the corresponding prior year periods. Such revenues were primarily related to royalty payments allocated to the license performance obligations for our collaborations with Ipsen, Takeda, Daiichi Sankyo and Genentech and the recognition of license revenue for the achievement of milestones during the second quarter of 2022, allocated to the license performance obligations for our collaboration with Ipsen.

As of September 30, 2022, $83.1 million of the combined transaction prices for our Ipsen and Takeda collaborations were allocated to our 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 2021 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 pharmaceutical companies for the commercialization and further development of our cabozantinib franchise. Additionally, we have entered into several research collaborations, in-licensing arrangements and other strategic transactions 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 pharmaceutical 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 2021 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 agreement with Ipsen for the commercialization and further development of cabozantinib. Under the terms of the collaboration agreement, as amended, Ipsen received exclusive commercialization rights for current and potential future cabozantinib indications outside of the U.S. and Japan. We have also agreed to collaborate with Ipsen on the development of cabozantinib for current and potential future indications. The parties’ efforts are governed through a joint steering committee and appropriate subcommittees established to guide and oversee the collaboration’s operation and strategic direction; provided, however, that we retain final decision-making authority with respect to cabozantinib’s ongoing development.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
License revenues	$ 27,607	$ 25,139	$ 103,389	$ 81,246
Collaboration services revenues	7,211	12,956	28,196	81,576
Total	$ 34,818	$ 38,095	$ 131,585	$ 162,822

During the nine months ended September 30, 2022, we recognized $25.8 million in revenues in connection with two regulatory milestones totaling $27.0 million upon approval by the European Commission and Health Canada, of cabozantinib as monotherapy for the treatment of adult patients with locally advanced or metastatic differentiated thyroid carcinoma (DTC), refractory or not eligible to RAI who have progressed during or after prior systemic therapy.

As of September 30, 2022, $49.3 million of the transaction price for this collaboration was allocated to our research and development services performance obligations that have 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. Pursuant to this collaboration and license agreement, as amended, Takeda has exclusive commercialization rights for current and potential future cabozantinib indications in Japan, and the parties have agreed to collaborate on the clinical development of cabozantinib in Japan. The operation and strategic direction of the parties’ collaboration is governed through a joint executive committee and appropriate subcommittees.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
License revenues	$ 2,690	$ 20,078	$ 7,755	$ 23,476
Collaboration services revenues	3,661	2,656	11,148	10,815
Total	$ 6,351	$ 22,734	$ 18,903	$ 34,291

As of September 30, 2022, $33.8 million of the transaction price for this collaboration 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. Royalties earned by Royalty Pharma in connection with our sales of cabozantinib are included in cost of goods sold and in connection with sales by our collaboration partners are included as a reduction of collaboration services revenues. Such royalties were $14.9 million and $42.6 million during the three and nine months ended September 30, 2022, respectively, as compared to $11.5 million and $33.7 million for the corresponding prior year periods.

Other Commercial Collaborations

Genentech Collaboration

In December 2006, we out-licensed the development and commercialization of cobimetinib to Genentech under a worldwide collaboration agreement. In November 2015, the FDA approved cobimetinib, under the brand name COTELLIC, in combination with Genentech's ZELBORAF® (vemurafenib) for the treatment of patients with BRAF V600E or V600K mutation-positive advanced melanoma. COTELLIC in combination with ZELBORAF has also been approved in the European Union and multiple additional countries for use in the same indication. In July 2020, the FDA also approved COTELLIC for use in combination with ZELBORAF and TECENTRIQ® (atezolizumab) for the treatment of patients with BRAF V600 mutation-positive advanced melanoma in previously untreated patients.

License revenues under the collaboration agreement with Genentech were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Profits on U.S. commercialization	$ 1,504	$ 1,743	$ 5,325	$ 5,697
Royalty revenues on ex-U.S. sales	$ 1,494	$ 1,576	$ 4,011	$ 3,309

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

Our research collaborations, in-licensing arrangements and other strategic transactions include upfront payments, which are generally paid upon the closing of the transaction, and also milestone payments (in connection with development, regulatory or commercial achievements) and royalty payments, which are contingent upon the occurrence of certain future events linked to the success of the asset in development. Certain of our research collaborations and in-licensing arrangements provide us exclusive options that give us the right to license programs developed under the research collaborations for further discovery and development. When we decide to exercise an option, we are required to pay an exercise fee and then, in most instances, we will assume the responsibilities for all subsequent clinical development, manufacturing and commercialization of the licensed asset.

In June 2022, we entered into an exclusive option and license agreement with BioInvent International AB (BioInvent), upon which we paid an upfront payment of $25.0 million. Upon option exercise, we will pay BioInvent an option exercise fee, and BioInvent will be eligible for additional payments from us for future development and commercial milestones, as well as royalties on our future net product sales. In July 2022, we entered into an exclusive license agreement with Ryvu Therapeutics S.A. (Ryvu) and paid an upfront payment of $3.0 million. Ryvu is eligible for potential future development and commercial milestones as well as royalties on future net product sales.

As of September 30, 2022, in conjunction with each of our research collaborations and in-licensing arrangements, and an asset purchase agreement entered into in 2021, we are subject to contingent payments for potential future development milestones of up to $364.7 million, regulatory milestones of up to $453.4 million and commercial milestones of up to $2,443.4 million, each in the aggregate per product or target, as well as royalties on future net product sales.

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):

	September 30, 2022	December 31, 2021
Cash and cash equivalents	$ 675,286	$ 647,169
Restricted cash equivalents included in other long-term assets	1,482	16,722
Cash, cash equivalents, and restricted cash equivalents as reported in the accompanying Condensed Consolidated Statements of Cash Flows	$ 676,768	$ 663,891

Restricted cash equivalents are used to collateralize letters of credit and consist of money-market funds and certificates of deposit with original maturities of 90 days or less. The restricted cash equivalents are classified as other long-term assets based upon the remaining term of the underlying restriction. The standby letter of credit entered in January 2021, as a guarantee of our obligation to fund our portion of the tenant improvements related to our Alameda build-to-suit lease was terminated and the related collateral was returned in the third quarter of 2022, following the substantial completion of the building and the commencement of the lease.

Cash, Cash Equivalents, Restricted Cash Equivalents and Investments

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

	September 30, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Debt securities available-for-sale:				
Commercial paper	$ 874,220	$ —	$ (364)	$ 873,856
Corporate bonds	633,617	—	(15,495)	618,122
U.S. Treasury and government-sponsored enterprises	307,494	—	(6,157)	301,337
Municipal bonds	16,565	—	(312)	16,253
Total debt securities available-for-sale	1,831,896	—	(22,328)	1,809,568
Cash	113,492	—	—	113,492
Money market funds	62,968	—	—	62,968
Certificates of deposit	114,181	—	—	114,181
Total cash, cash equivalents, restricted cash equivalents and investments	$ 2,122,537	$ —	$ (22,328)	$ 2,100,209

	December 31, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Debt securities available-for-sale:				
Commercial paper	$ 945,801	$ 42	$ (2)	$ 945,841
Corporate bonds	541,774	876	(1,672)	540,978
U.S. Treasury and government-sponsored enterprises	33,965	1	(21)	33,945
Municipal bonds	12,924	15	(35)	12,904
Total debt securities available-for-sale	1,534,464	934	(1,730)	1,533,668
Cash	135,653	—	—	135,653
Money market funds	66,531	—	—	66,531
Certificates of deposit	119,056	—	—	119,056
Total cash, cash equivalents, restricted cash equivalents and investments	$ 1,855,704	$ 934	$ (1,730)	$ 1,854,908

Interest receivable was $4.8 million and $2.9 million as of September 30, 2022 and December 31, 2021, 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 insignificant during the three and nine months ended September 30, 2022 and 2021.

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):

	September 30, 2022	
	Fair Value	Gross Unrealized Losses
Corporate bonds	$ 613,122	$ (15,495)
U.S. Treasury and government-sponsored enterprises	301,337	(6,157)
Commercial paper	36,636	(364)
Municipal bonds	16,073	(312)
Total	$ 967,168	$ (22,328)

	December 31, 2021	
	Fair Value	Gross Unrealized Losses
Corporate bonds	$ 385,053	$ (1,672)
Commercial paper	43,290	(2)
U.S. Treasury and government-sponsored enterprises	18,962	(21)
Municipal bonds	7,475	(35)
Total	$ 454,780	$ (1,730)

There were 276 and 133 investments in an unrealized loss position as of September 30, 2022 and December 31, 2021, respectively. All securities presented above have been in an unrealized loss position for less than twelve months except for 25 corporate bond securities and 1 municipal bond security with an aggregate fair value of $64.0 million and an aggregate $2.4 million unrealized loss as of September 30, 2022. During the nine months ended September 30, 2022 and 2021, 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):

	September 30, 2022	December 31, 2021
Maturing in one year or less	$ 1,260,834	$ 1,168,256
Maturing after one year through five years	548,734	365,412
Total debt securities available-for-sale	$ 1,809,568	$ 1,533,668

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):

	September 30, 2022		
	Level 1	Level 2	Total
Commercial paper	$ —	$ 873,856	$ 873,856
Corporate bonds	—	618,122	618,122
U.S. Treasury and government-sponsored enterprises	—	301,337	301,337
Municipal bonds	—	16,253	16,253
Total debt securities available-for-sale	—	1,809,568	1,809,568
Money market funds	62,968	—	62,968
Certificates of deposit	—	114,181	114,181
Total financial assets carried at fair value	$ 62,968	$ 1,923,749	$ 1,986,717

	December 31, 2021		
	Level 1	Level 2	Total
Commercial paper	$ —	$ 945,841	$ 945,841
Corporate bonds	—	540,978	540,978
U.S. Treasury and government-sponsored enterprises	—	33,945	33,945
Municipal bonds	—	12,904	12,904
Total debt securities available-for-sale	—	1,533,668	1,533,668
Money market funds	66,531	—	66,531
Certificates of deposit	—	119,056	119,056
Total financial assets carried at fair value	$ 66,531	$ 1,652,724	$ 1,719,255

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 exchanges rates associated with assets or liabilities denominated in foreign currencies, primarily the Euro.

As of September 30, 2022, we had one forward contract outstanding to sell €10.0 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 not material as of September 30, 2022. The forward contract is considered a Level 2 in the fair value hierarchy of our fair value measurements. For the nine months period ended September 30, 2022, and 2021, we recognized $1.5 million and $0.5 million, respectively, of net gains on the maturity of our forward contracts, which is included in other income (expense), net on our Condensed Consolidated Statements of Income.

NOTE 6. INVENTORY

Inventory consisted of the following (in thousands):

	September 30, 2022	December 31, 2021
Raw materials	$ 9,447	$ 8,867
Work in process	39,380	27,717
Finished goods	11,325	12,927
Total	$ 60,152	$ 49,511
Balance Sheet classification:		
Current portion included in inventory	$ 26,711	$ 27,493
Long-term portion included in other long-term assets	33,441	22,018
Total	$ 60,152	$ 49,511

NOTE 7. STOCK-BASED COMPENSATION

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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	$ 16,438	$ 11,487	$ 34,886	$ 37,550
Selling, general and administrative	20,899	22,479	46,832	59,104
Total stock-based compensation expense	$ 37,337	$ 33,966	$ 81,718	$ 96,654

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Stock options	$ 3,299	$ 4,607	$ 10,470	$ 15,203
Restricted stock units	22,233	13,721	54,234	40,802
Performance stock units	11,331	14,971	14,621	37,616
ESPP	474	667	2,393	3,033
Total stock-based compensation expense	$ 37,337	$ 33,966	$ 81,718	$ 96,654

On May 25, 2022, at the 2022 Annual Meeting of Stockholders, our stockholders approved the amendment and restatement of Exelixis, Inc. 2017 Equity Incentive Plan (as amended and restated, the 2017 Plan). The amendment and restatement increased the share reserve under the 2017 Plan by 28,500,000 shares. As of September 30, 2022, 31,485,656 shares were available for grant under 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 restricted stock units (RSUs).

During the nine months ended September 30, 2022, we granted 588,862 stock options with a weighted average exercise price of $19.99 per share and a weighted average grant date fair value of $8.36 per share. As of September 30, 2022, there were 11,416,151 stock options outstanding and $19.6 million of related unrecognized compensation expense.

In March 2022, we awarded to certain employees an aggregate of 1,003,482 (the target amount) RSUs that are subject to a total shareholder return (TSR) market condition (the TSR-based RSUs). The TSR market condition is based on our relative TSR percentile rank compared to companies in the NASDAQ Biotechnology Index during the performance period, which is January 1, 2022 through January 3, 2025. Depending on the results relative to the TSR market condition, the holders of the TSR-based RSUs may earn up to 175% of the target amount of shares. 50% of the shares earned pursuant to the TSR-based RSU awards will vest at the end of the performance period, and the remainder will vest approximately one year later, subject to employee's continuous service. These TSR-based RSUs will be forfeited if the market condition at or above a threshold level is not achieved at the end of the performance period on January 3, 2025.

We used a Monte Carlo simulation model and the following assumptions to determine the grant date fair value of $33.17 per share for the TSR-based RSUs:

Fair value of the Company's common stock on grant date	$ 20.70
Expected volatility	46.85 %
Risk-free interest rate	1.59 %
Dividend yield	— %

The Monte Carlo simulation model also assumed correlations of returns of the stock prices of the Company's common stock and the common stock of a peer group of companies and historical stock price volatility of the peer group of companies. The valuation model also used terms based on the length of the performance period and compound annual growth rate goals for total stockholder return based on the provisions of the award.

During the nine months ended September 30, 2022, we granted 5,292,088 service-based RSUs with a weighted average grant date fair value of $20.56 per share. As of September 30, 2022, there were 11,864,173 RSUs outstanding, including the TSR-based RSUs, and $193.8 million of related unrecognized compensation expense.

Stock options and service-based RSUs granted to employees during the nine months ended September 30, 2022 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 2021 Form 10-K.

As of September 30, 2022, there were 5,367,906 performance-based restricted stock units (PSUs) outstanding and $101.0 million of related unrecognized stock-based compensation expense. Expense recognition for PSUs commences when it is determined that achievement of the performance target is probable. During the three months ended September 30, 2022, we achieved a performance condition for threshold achievement for 495,886 PSUs granted during 2020 (the 2020 PSUs) and have recognized $9.7 million of stock-based compensation expense related to the 2020 PSUs during the three

months ended September 30, 2022. 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 2021 Form 10-K.

NOTE 8. PROVISION FOR INCOME TAXES

The effective tax rates for the three and nine months ended September 30, 2022, were 20.5% and 20.1% respectively, as compared to 28.3% and 22.8% for the corresponding periods in 2021. The effective tax rates for the three and nine months ended September 30, 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, which were partially offset by state taxes.

The effective tax rates for the three and nine months ended September 30, 2021 differed from the U.S. federal statutory tax rate of 21% primarily due to non-deductible executive compensation, which was partially offset by excess tax benefits related to the exercise of certain stock options during the periods and the generation of federal tax credits.

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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Numerator:				
Net income	$ 73,210	$ 38,204	$ 212,455	$ 135,897
Denominator:				
Weighted-average common shares outstanding — basic	322,148	315,380	320,949	313,990
Dilutive securities	2,918	6,642	3,471	8,094
Weighted-average common shares outstanding — diluted	325,066	322,022	324,420	322,084
Net income per share — basic	$ 0.23	$ 0.12	$ 0.66	$ 0.43
Net income per share — diluted	$ 0.23	$ 0.12	$ 0.65	$ 0.42

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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Anti-dilutive securities and contingently issuable shares excluded	15,059	20,346	15,311	14,213

NOTE 10. COMMITMENTS AND CONTINGENCIES

Build-to-Suit Lease and Headquarters Lease

In April 2022, the office building (New Premises) associated with our October 2019 build-to-suit lease agreement (Build-to-Suit Lease) was substantially completed. The New Premises is 220,517 square feet and is in Alameda, California, adjacent to our existing corporate headquarters. The Build-to-Suit Lease term is 242 months, includes two five-year options to extend the term of the lease and a one-time option to terminate the lease after 180 months. In addition to the monthly lease payments, currently estimated at $0.7 million, subject to an annual increase of 3% during the Term, we are also

responsible for paying operating expenses related to the New Premises. On April 15, 2022, the lease commenced for the New Premises. We determined the classification of the lease was an operating lease. Upon commencement of the lease, we recognized a right-of-use asset of $160.9 million inclusive of $44.9 million for the cost of the tenant improvements in excess of the allowance provided by the lessor and an operating lease liability of $116.0 million discounted over 180 months using our estimated incremental borrowing rate of 4.9%.

In May 2022, we entered into the seventh amendment to the lease for our corporate headquarters located on Harbor Bay Parkway, Alameda, California (the Alameda Lease). The May 2022 amendment to the Alameda Lease (the Seventh Lease Amendment) provides, among other things, for the expansion of the premises under the Alameda Lease by 34,745 square feet of office facilities located at 1751 Harbor Bay Parkway, Alameda, California (the 1751 Expansion Space). The term for the 1751 Expansion Space will run coterminous with the term of the Alameda Lease for the existing space. In connection with the Seventh Lease Amendment, we remeasured our lease components under the Alameda Lease relating to the existing premises using an incremental borrowing rate of 5.0%. As of June 1, 2022, we have taken possession of the 1751 Expansion Space, and accordingly we have adjusted our right-of-use asset and liability by $4.3 million.

For more information about our Leases, see “Note 11. Commitments and Contingencies—Leases” of the “Notes to Consolidated Financial Statements” included in Part II, Item 8 of our Fiscal 2021 Form 10-K.

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 are seeking, 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 have 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 has, 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 a judgment is expected during the fourth quarter of 2022.

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. 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 remedies, equitable relief enjoining MSN from infringing this patent, as well as 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. 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.

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

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

NOTE 11. SUBSEQUENT EVENTS

Cybrexa Therapeutics, LLC (Cybrexa)

In November 2022, we entered into an agreement with Cybrexa Therapeutics, LLC (Cybrexa), which provides us the right to acquire CBX-12 (alphalex™ exatecan), a clinical-stage peptide-drug conjugate (PDC) that utilizes Cybrexa's proprietary alphalex technology to enhance delivery of exatecan to tumor cells. Under the terms of the agreement, we will pay an upfront fee of $60.0 million for a warrant entitling us to the right to acquire the Cybrexa affiliate that controls CBX-12 and related assets, and to fund certain development and manufacturing expenses incurred by Cybrexa to advance CBX-12 during the warrant period. Cybrexa will continue the development of CBX-12 according to an agreed development plan, including phase 1 studies, and may be eligible to receive up to $65.0 million in additional development milestone payments, during the warrant period. We may exercise the warrant for up to $300.0 million based upon our evaluation of a pre-specified clinical data package to be delivered by Cybrexa. Following exercise of the warrant, Cybrexa would be eligible to receive up to $277.5 million in additional payments upon achievement of further development, regulatory and commercial milestones.

Sairopa, B.V. (Sairopa)

In November 2022, we entered into an exclusive option and license agreement with Sairopa, B.V. (Sairopa). Under the terms of the agreement, we will make an upfront payment of $40.0 million for an option to obtain an exclusive, worldwide license to develop and commercialize ADU-1805 and other anti-SIRPα antibodies, and for certain expenses to be incurred by Sairopa in conducting phase 1 clinical studies of ADU-1805. Sairopa is eligible to receive additional development milestone payments during the option period totaling up to $97.5 million. Following the completion of the clinical studies, we may exercise the option for $225.0 million based upon our evaluation of a pre-specified clinical data package to be delivered by Sairopa. Following the exercise of the option, Sairopa would be eligible to receive up to $465.0 million in additional development, commercial, and net sales milestone payments, as well as tiered royalties on future net sales of products.

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, 2021, filed with the Securities and Exchange Commission (SEC) on February 18, 2022 (Fiscal 2021 Form 10-K).

Overview

We are an oncology-focused biotechnology company that strives to accelerate the discovery, development and commercialization of new medicines for patients with difficult-to-treat cancers. Using our considerable drug discovery, development and commercialization resources and capabilities, we have invented and brought to market innovative therapies that appropriately balance patient benefits and risks; we will continue to build on this foundation as we strive to provide cancer patients with new treatment options that improve upon current standards of care.

Today, four products that originated in Exelixis laboratories are available to be prescribed to patients. Sales related to our flagship molecule, cabozantinib, account for the large 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 62 other countries as: CABOMETYX® (cabozantinib) tablets approved 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, currently by the FDA and European Commission (EC), for previously treated, radioactive iodine (RAI)-refractory differentiated thyroid cancer (DTC); and COMETRIQ® (cabozantinib) capsules approved for progressive, metastatic medullary thyroid cancer (MTC). For physicians treating these types of cancer, cabozantinib has become or is becoming an important medicine in their selection of effective therapies.

The other two products resulting from our discovery efforts are: COTELLIC® (cobimetinib), an inhibitor of MEK, approved as part of multiple combination regimens to treat specific forms of advanced melanoma and marketed under a collaboration with Genentech, Inc., a member of the Roche Group (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).

Our plan is to utilize our operating cash flows and cash and investments to expand the cabozantinib franchise by potentially adding new indications in areas of unmet medical need. We will also leverage our operating cash flows to continue advancing our diverse small molecule and biotherapeutics programs, exploring multiple modalities and mechanisms of action to discover new oncology drugs. So far, these drug discovery and preclinical activities have resulted in four clinical-stage compounds: XL092, a next-generation oral tyrosine kinase inhibitor (TKI); XB002, an antibody drug conjugate (ADC) that targets tissue factor (TF); XL102, a potent, selective and orally bioavailable covalent inhibitor of cyclin-dependent kinase 7 (CDK7); and XL114, a novel anti-cancer compound that inhibits the CARD11-BCL10-MALT1 (CBM) complex.

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 and 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 (U.K.) 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. 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. (Ono), 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 continue to evaluate cabozantinib, both as a single agent and in combination with ICIs, in a broad development program comprising over 100 ongoing or planned clinical trials across multiple tumor types. We, along with our collaboration partners, sponsor some of the trials, and independent investigators conduct the remaining trials 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. The data from these third-party 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.

Building on preclinical and clinical observations that cabozantinib in combination with ICIs may promote a more immune-permissive tumor environment, we initiated numerous 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 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 (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, reducing the risk of disease progression or death compared with the doublet combination of nivolumab and ipilimumab (hazard ratio: 0.73; 95% confidence interval [CI]: 0.57-0.94; P=0.01). Median PFS for the triplet combination was not reached (95% CI: 14.0-not estimable) versus 11.3 months for the doublet combination of nivolumab and ipilimumab (95% CI: 7.7-18.2). 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. 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.

To expand our exploration of combinations with ICIs, we also initiated multiple trials evaluating cabozantinib in combination with F. Hoffmann-La Roche Ltd.'s (Roche) ICI, atezolizumab, beginning in 2017 with COSMIC-021, a broad phase 1b study evaluating the safety and tolerability of cabozantinib in combination with atezolizumab in patients with a wide variety of locally advanced or metastatic solid tumors. The data from COSMIC-021 have been instrumental in guiding our clinical development strategy for cabozantinib in combination with ICIs, including supporting the initiation of COSMIC-312, a phase 3 pivotal trial evaluating cabozantinib in combination with atezolizumab versus sorafenib in previously untreated advanced HCC, and three phase 3 pivotal trials in collaboration with Roche, CONTACT-01, CONTACT-02 and CONTACT-03, evaluating the combination of cabozantinib with atezolizumab in patients with metastatic non-small cell lung cancer (NSCLC), metastatic castration-resistant prostate cancer (mCRPC) and advanced RCC, respectively. CONTACT-01 and CONTACT-03 are sponsored by Roche and co-funded by us, and we announced the completion of enrollment for the two trials in November 2021 and January 2022, respectively. We expect to receive results from CONTACT-01 in the fourth quarter of 2022 and from CONTACT-03 in the first half of 2023. CONTACT-02 is sponsored by us and co-funded by Roche, and we anticipate completing enrollment in the first half of 2023.

Pipeline Activities

Our small molecule discovery programs are supported by a robust and expanding infrastructure, including a library of 4.6 million compounds. We have extensive experience in the identification and optimization of drug candidates against

multiple target classes for oncology, inflammation and metabolic diseases. The first compound to enter the clinic following our re-initiation of drug discovery activities in 2017 was XL092, a next-generation oral TKI that targets VEGF receptors, MET, AXL, MER and other kinases implicated in cancer's growth and spread. In designing XL092, 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 XL092: STELLAR-001 and STELLAR-002. STELLAR-001 is a phase 1b clinical trial evaluating XL092, both as a monotherapy and in combination with either atezolizumab or avelumab, an ICI developed by Merck KGaA Damstadt, Germany and Pfizer Inc. We have established a recommended dose of 100 mg for both single-agent XL092 and XL092 in combination with atezolizumab, and we have begun enrolling expansion cohorts for patients with clear cell RCC, non-clear cell RCC, hormone-receptor positive breast cancer, mCRPC and colorectal cancer (CRC); the dose-escalation stage for XL092 in combination with avelumab is ongoing, with expansion cohorts planned initially in urothelial carcinoma (UC). We presented data from STELLAR-001 during poster sessions at the 2022 ESMO Congress in September 2022, which showed XL092 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. STELLAR-002 is a phase 1b clinical trial evaluating XL092 in combination with either nivolumab, nivolumab and ipilimumab, or a fixed dose of nivolumab and relatlimab, a lymphocyte activation gene-3 (LAG-3)-blocking antibody developed by BMS (replacing Nektar Therapeutics' bempegaldesleukin in the original trial protocol following the expansion of our clinical trial collaboration and supply agreement with BMS, which we announced in October 2022). We are enrolling patients with advanced solid tumors in dose-escalation cohorts, and depending on the dose-escalation results, STELLAR-002 may enroll expansion cohorts for patients with clear cell and non-clear cell RCC, mCRPC, UC, CRC, HCC, NSCLC and head and neck squamous cell carcinoma. To better understand the individual contribution of the therapies, treatment arms in the expansion cohorts may include XL092 as a single-agent in addition to the ICI combination regimens. We also initiated STELLAR-303, the first global phase 3 pivotal trial for XL092, in June 2022, and we expect to initiate a second pivotal trial in late 2022 with others to follow in 2023. STELLAR-303 is evaluating XL092 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, and the trial aims to enroll approximately 600 patients worldwide with documented RAS status. 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 endpoint of STELLAR-303 is OS, and additional efficacy endpoints include PFS, objective response rate (ORR) and duration response (DOR) per Response Evaluation Criteria in Solid Tumors (RECIST) v. 1.1. as assessed by the investigator.

We augment our small molecule discovery activities through research collaborations and in-licensing arrangements with other companies. The most advanced compounds to emerge from these arrangements are XL102, the lead program targeting CDK7 under our collaboration with Aurigene Discovery Technologies Limited (Aurigene), and XL114, Aurigene's novel anti-cancer compound that inhibits the CBM complex. Based on encouraging preclinical data, we exercised our exclusive options to license XL102 and XL114 from Aurigene and initiated phase 1 clinical trials evaluating XL102 and XL114 in January 2021 and April 2022, respectively, and we expect to provide clinical updates from the phase 1 study of XL102 in the fourth quarter of 2022. Most recently, in November 2022, we entered into an agreement with Cybrexa Therapeutics, LLC (Cybrexa), which provides us the right to acquire CBX-12 (alphalex™ exatecan), a clinical-stage peptide-drug conjugate (PDC) that utilizes Cybrexa's proprietary alphalex technology to enhance delivery of exatecan to tumor cells.

Beyond small molecules, we have also launched rigorous efforts to discover and advance 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, and this biotherapeutic approach has been validated by multiple regulatory approvals for the commercial sale of ADCs in the past several years. To facilitate the growth of these 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. We have already made significant progress under these arrangements and expect we will continue to advance our biotherapeutics programs throughout the remainder of 2022 and in future years:

- *Sairopa.* We entered into a collaboration with Sairopa, B.V. (Sairopa) in November 2022, focused on the development of ADU-1805, a monoclonal antibody (mAb) that targets SIRPα. The collaboration is intended to expand our clinical pipeline with an IND filing for ADU-1805 anticipated in early 2023 to explore its applicability across multiple tumor types, as well as the potential to combine ADU-1805 with XL092 and approved ICIs.

- *Ryvu*. We entered into a collaboration with Ryvu Therapeutics S.A. (Ryvu) in July 2022, focused on the development of novel targeted therapies utilizing Ryvu's STING (STimulator of INterferon Genes) technology. The collaboration is intended to expand our portfolio of biotherapeutics by combining our tumor-specific targeting approaches with Ryvu's proprietary small molecule STING agonists and STING biology know-how.
- *BioInvent*. We entered into a collaboration with BioInvent International AB (BioInvent) in June 2022, focused on the identification and development of novel antibodies for use as oncology therapeutics. The collaboration 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.
- *GamaMabs.* We completed an asset purchase from GamaMabs Pharma SA (GamaMabs) in May 2022. In the transaction, we acquired all rights, title and interest in GamaMabs' antibody program directed at anti-M✔llerian hormone receptor 2 (AMHR2), a novel oncology target with relevance in multiple forms of cancer.
- *Iconic.* We in-licensed XB002, our lead TF-targeting ADC program, from Iconic, Inc. (Iconic) in December 2020 and initiated the JEWEL-101 phase 1 clinical trial in June 2021, and we presented promising initial dose-escalation results from the trial at the 34th EORTC-NCI-AACR (ENA) Symposium in October 2022. In December 2021, we amended our exclusive option and license agreement with Iconic to acquire broad rights to use the anti-TF antibody used in XB002 for any application, including conjugated to other payloads, as well as rights within oncology to a number of other anti-TF antibodies developed by Iconic, including for use in ADCs and multispecific biotherapeutics.
- *Invenra*. We have expanded our collaboration with Invenra, Inc. (Invenra) several times since our first engagement in 2018, most recently in August 2021 to include an additional 20 oncology targets.
- *WuXi Bio.* We expanded our access to antibodies through arrangements with WuXi Biologics Ireland Limited, a wholly owned subsidiary of WuXi Biologics (Cayman) Inc. (individually and collectively referred to as WuXi Bio) in March 2021. We are focused on leveraging WuXi Bio's panel of mAbs against an undisclosed target for the development of ADC, bispecific and certain other novel tumor-targeting biotherapeutics.
- *Adagene*. We entered into a collaboration with Adagene Inc. (Adagene) in February 2021, focused on using Adagene's SAFEbody® technology to develop novel masked ADCs or other innovative biotherapeutics, with the potential to develop ADCs or other biotherapeutics with improved therapeutic index.
- *NBE and Catalent*. We entered into collaborations with NBE-Therapeutics AG (NBE) and Catalent, Inc.'s wholly owned subsidiaries Redwood Bioscience, Inc., R.P. Scherer Technologies, LLC and Catalent Pharma Solutions, Inc. (individually and collectively referred to as Catalent) in September 2020. These platform collaborations allow us to utilize their site-specific conjugation technologies and payloads to construct ADCs using the antibodies we have sourced from our arrangements with WuXi Bio, GamaMabs and Invenra.

These arrangements have led directly to the advancement of two biotherapeutics development candidates, XB010 and XB014. XB010, our first ADC advanced internally, targets the tumor antigen 5T4 and incorporates antibodies sourced from Invenra. It was constructed using Catalent's SMARTag® site-specific bioconjugation platform. XB014 is our first bispecific antibody, which combines a PD-L1 targeting arm with a CD47 targeting arm to block a macrophage checkpoint, and was developed through our collaboration with Invenra.

As of the date of this Quarterly Report, we expect to advance multiple programs into preclinical development over the next six months. 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.

COVID-19 Update

As of the date of this Quarterly Report on Form 10-Q, the COVID-19 pandemic continues to have a modest impact on our business operations. While the pandemic has created operational difficulties and complexities, we have thus far been successful at devising solutions designed to mitigate its impact. We will continue to monitor new developments that could pose additional risks for us, including the spread of the Omicron variant and its subvariants in the U.S. and other countries, and the potential emergence of new SARS-CoV-2 variants that may prove especially contagious or virulent. Despite our COVID-19 pandemic mitigation efforts, we may experience delays or an inability to execute on our clinical and preclinical development plans, reduced revenues or other adverse impacts to our business as described in more detail in

"Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q. We recognize that this pandemic will continue to present unique challenges for us throughout the remainder of 2022, and potentially into 2023.

Third Quarter 2022 Business Updates and Financial Highlights

During the third quarter of 2022**,** we continued to execute on our business objectives, generating significant revenues from operations and enabling us to continue to seek to maximize the clinical and commercial potential of our products and expand our product pipeline. Significant business updates and financial highlights for the quarter and subsequent to quarter-end include:

Business Updates

- In July 2022, we announced an exclusive license agreement with Ryvu to develop novel targeted therapies utilizing Ryvu's STING technology.
- In July 2022, we announced results from the phase 3 COSMIC-313 trial, in which the triplet combination of cabozantinib, nivolumab and ipilimumab met its primary endpoint, demonstrating significant improvement in PFS versus the doublet combination of nivolumab and ipilimumab at the primary analysis. At a prespecified interim analysis for the secondary endpoint of OS, the triplet combination did not demonstrate a significant benefit, and therefore the trial will continue to the next analysis of OS.
- In July 2022, we filed a patent lawsuit in the United States District Court for the District of Delaware (the Delaware District Court) against MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. (individually and collectively referred to as MSN) asserting infringement of U.S. Patent No. 11,298,349 (pharmaceutical composition) arising from MSN's further amendment of its Abbreviated New Drug Application (ANDA), originally filed with the FDA in September 2019. This lawsuit, our fourth case against MSN, has been consolidated with the patent lawsuit we filed in February 2022 (collectively, MSN II) and involves an Exelixis patent that is different from those asserted previously in February 2022 and in the consolidated patent lawsuits that we filed in 2019 and 2020 (collectively, MSN I), for which a trial took place in May 2022. 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 the patents at issue in MSN II, the latest of which expires on February 10, 2032. For a more detailed discussion of this litigation matter, see "Legal Proceedings" in Part II, Item 1 of this Quarterly Report on Form 10-Q.
- In September 2022, we filed a patent lawsuit in the Delaware District Court against Teva Pharmaceutical Industries Limited, Teva Pharmaceuticals Development, Inc. and Teva Pharmaceuticals USA, Inc. (individually and collectively referred to as Teva), asserting infringement of U.S. Patent No. 11,298,349 arising from Teva's amendment of its ANDA, originally filed with the FDA in May 2021. This lawsuit, our second case against Teva, has been consolidated with the prior patent lawsuit we filed in June 2021 and involves an Exelixis patent that is different from those asserted previously in June 2021. We are seeking, among other relief, an order that the effective date of any FDA approval of Teva's ANDA would be a date no earlier than the expiration of the patents at issue in our consolidated patent lawsuits against Teva, the latest of which expires on July 9, 2033. All proceedings were stayed pursuant to an order of the Delaware District Court in October 2022. For a more detailed discussion of this litigation matter, see "Legal Proceedings" in Part II, Item 1 of this Quarterly Report on Form 10-Q.
- In September 2022, clinical data from COSMIC-313 were presented as part of Presidential Symposium III at the 2022 ESMO Congress. In addition, cabozantinib was the subject of multiple data presentations in RCC, DTC and advanced adrenocortical carcinoma, and we also presented phase 1b data from STELLAR-001, in which XL092 demonstrated preliminary clinical activity similar to that observed with cabozantinib in phase 1 across a range of solid tumors.
- In October 2022, we announced an expansion of our clinical trial collaboration and supply agreement with BMS to include the use of the fixed-dose combination of nivolumab and relatlimab in STELLAR-002, our ongoing phase 1b clinical trial evaluating XL092 in combination with multiple ICIs in advanced solid tumors.
- In October 2022, we announced promising initial dose-escalation results from JEWEL-101, the ongoing phase 1 trial evaluating XB002 in patients with advanced solid tumors, during the Antibody-drug Conjugates Poster Session at the 34th 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.
- In November 2022, we announced an agreement with Cybrexa that provides us the right to acquire CBX-12, a clinical-stage PDC that utilizes Cybrexa's proprietary alphalex technology to enhance delivery of exatecan to tumor cells.

- In November 2022, we announced an exclusive option and license agreement and clinical development collaboration with Sairopa to develop ADU-1805, a mAb that targets SIRPα.

Financial Highlights

- Net product revenues for the third quarter of 2022 were $366.5 million, as compared to $263.1 million for the third quarter of 2021.
- Total revenues for the third quarter of 2022 were $411.7 million, as compared to $328.4 million for the third quarter of 2021.
- Research and development expenses for the third quarter of 2022 were $198.8 million, as compared to $163.4 million for the third quarter of 2021.
- Selling, general and administrative expenses for the third quarter of 2022 were $115.0 million, as compared to $101.6 million for the third quarter of 2021.
- Provision for income taxes for the third quarter of 2022 was $18.8 million, as compared to $15.1 million for the third quarter of 2021.
- Net income for the third quarter of 2022 was $73.2 million, or $0.23 per share, basic and diluted, as compared to net income of $38.2 million, or $0.12 per share, basic and diluted, for the third quarter of 2021.

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 cabozantinib 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 NSCLC and mCRPC or evaluating XL092 in combination with an ICI in CRC, 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 and by Teva Pharmaceuticals Development, Inc. and Teva Pharmaceuticals USA, Inc. (individually and collectively referred to as Teva). The approval of either MSN's or Teva's ANDA 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. For a more detailed discussion of challenges and risks we face, see “Risk Factors” in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Fiscal Year Convention

We have adopted a 52- or 53-week fiscal year policy that generally ends on the Friday closest to December 31st. Fiscal year 2022, which is a 52-week fiscal year, will end on December 30, 2022 and fiscal year 2021, which was a 52-week fiscal year, ended on December 31, 2021. For convenience, references in this report as of and for the fiscal period ended October 1, 2021, and as of and for the fiscal year ending December 30, 2022 are indicated as being as of and for the period ended September 30, 2021, and the year ending December 31, 2022, respectively.

Results of Operations

Revenues

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

	Three Months Ended September 30,		Percent Change	Nine Months Ended September 30,		Percent Change
	2022	2021		2022	2021	
Net product revenues	$ 366,482	$ 263,117	39 %	$ 1,023,824	$ 774,577	32 %
License revenues	34,384	49,694	-31 %	123,977	116,862	6 %
Collaboration services revenues	10,872	15,612	-30 %	39,344	92,391	-57 %
Total revenues	$ 411,738	$ 328,423	25 %	$ 1,187,145	$ 983,830	21 %

Net Product Revenues

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

	Three Months Ended September 30,		Percent Change	Nine Months Ended September 30,		Percent Change
	2022	2021		2022	2021	
Gross product revenues	$ 496,141	$ 357,462	39 %	$ 1,427,451	$ 1,051,871	36 %
Discounts and allowances	(129,659)	(94,345)	37 %	(403,627)	(277,294)	46 %
Net product revenues	$ 366,482	$ 263,117	39 %	$ 1,023,824	$ 774,577	32 %

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

	Three Months Ended September 30,		Percent Change	Nine Months Ended September 30,		Percent Change
	2022	2021		2022	2021	
CABOMETYX	$ 361,385	$ 259,791	39 %	$ 1,003,356	$ 759,000	32 %
COMETRIQ	5,097	3,326	53 %	20,468	15,577	31 %
Net product revenues	$ 366,482	$ 263,117	39 %	$ 1,023,824	$ 774,577	32 %

The increases in net product revenues for the three and nine months ended September 30, 2022, as compared to the corresponding prior year periods, were primarily related to increases of 30% and 27%, respectively, in the number of units sold, and to a lesser extent 7% and 4% increases in the average net selling price of CABOMETYX for the three and nine months ended September 30, 2022, respectively, as compared to the corresponding prior year periods.

We project that our net product revenues may increase for the remainder of 2022, 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 2021 Form 10-K.

The increase in discounts and allowances for the three months ended September 30, 2022, as compared to the corresponding prior year period, was primarily the result of an increase in the dollar amount of chargebacks related to the government’s 340B Drug Pricing Program (the 340B Program), which mandates drug manufacturers offer discount drug pricing for certain eligible covered entities that meet 340B Program requirements. The increase in discounts and allowances for the nine months ended September 30, 2022, as compared to the corresponding prior year period, was primarily from higher utilization in the 340B Program.

Discounts and allowances as a percentage of gross revenues have increased over time as the number of patients participating in government programs, including the government-mandated 340B Program, as well as the discounts given and rebates paid to government payers, has also increased. We project this trend will continue and that our discounts and allowances as a percentage of gross revenues may increase during the remainder of 2022, as compared to the corresponding prior year period.

License Revenues

License revenues generally 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 the milestone would be achieved and a significant reversal of revenues would not occur; (b) royalty revenues; and (c) the profit on the U.S. commercialization of COTELLIC from Genentech.

Milestone revenues, which are allocated between license revenues and collaboration services revenues, were $1.7 million and $28.5 million for the three and nine months ended September 30, 2022, respectively, as compared to $19.7 million and $33.1 million for the corresponding prior year periods. Milestone revenues by period included the following:

- For the nine months ended September 30, 2022, $25.8 million in revenues was recognized in connection with two regulatory milestones totaling $27.0 million upon the approval by the European Commission and Health Canada, of cabozantinib as a monotherapy for the treatment of adult patients with locally advanced or metastatic DTC, refractory or not eligible to RAI who have progressed during or after prior systemic therapy.
- For the three and nine months ended September 30, 2021, $18.8 million in revenues was recognized in connection with a $20.0 million milestone we achieved following Takeda’s first commercial sale in Japan of CABOMETYX in combination with OPDIVO for the treatment of patients with unresectable or metastatic RCC.
- For the nine months ended September 30, 2021, $11.9 million in revenues was recognized in connection with a $12.5 million regulatory milestone we determined was probable of achievement. The milestone was achieved in the third quarter of 2021 upon Ipsen’s submission of a variation application to the EMA for CABOMETYX as a treatment for patients with previously treated, RAI-refractory DTC.

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 $27.6 million and $79.7 million for the three and nine months ended September 30, 2022, respectively, as compared to $25.1 million and $70.4 million for the corresponding prior year periods. Ipsen’s net sales of cabozantinib have continued to grow since Ipsen’s 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 and nine months ended September 30, 2022 also included $2.7 million and $7.8 million, respectively, related to Takeda’s net sales of CABOMETYX, as compared to $2.0 million and $5.4 million for the corresponding prior year periods. Takeda royalty revenues have continued to grow since Takeda’s first commercial sale of CABOMETYX in Japan in 2020. As of September 30, 2022, CABOMETYX is approved and is commercially available in 62 countries outside the U.S.

Our share of profits on the U.S. commercialization of COTELLIC under our collaboration agreement with Genentech was $1.5 million and $5.3 million for the three and nine months ended September 30, 2022, respectively, as compared to $1.7 million and $5.7 million for the corresponding prior year periods. We also earned royalties on ex-U.S. net sales of

COTELLIC by Genentech of $1.5 million and $4.0 million for the three and nine months ended September 30, 2022, respectively, as compared to $1.6 million and $3.3 million for the corresponding prior year periods.

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

Collaboration Services Revenues

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

Development cost reimbursements were $13.1 million and $47.7 million for the three and nine months ended September 30, 2022, respectively, as compared to $17.5 million and $98.4 million for the corresponding prior year periods. The decrease in development cost reimbursements for the three months ended September 30, 2022, as compared to the corresponding prior year period, was primarily attributable to decreases in spending on the COSMIC-021 and COSMIC-312 studies, which was partially offset by an increase in spending on the CONTACT-02 study. The decrease in development cost reimbursements for the nine months ended September 30, 2022, as compared to the corresponding prior year period was primarily due to Ipsen's decision to opt in and co-fund COSMIC-311 development costs in the second quarter of 2021, which included a cumulative catch up for Ipsen's share of global development costs incurred since the beginning of the study. To a lesser extent, the decrease was attributable to decreases in spending on the COSMIC-021 and COSMIC-312 studies, which was partially offset by an increase in spending on the CONTACT-02 study.

Collaboration services revenues were reduced by $3.9 million and $11.9 million for the three and nine months ended September 30, 2022, respectively, as compared to $3.7 million and $10.5 million for the corresponding prior year periods, 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 2022, as compared to the corresponding prior year period, primarily as a result of decreased development cost reimbursements related to Ipsen's opt-in and co-funding of COSMIC-311 and the related cumulative catch-up in development cost reimbursements recognized in 2021, for which no similar event is projected to occur in 2022.

Cost of Goods Sold

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

	Three Months Ended September 30,		Percent Change	Nine Months Ended September 30,		Percent Change
	2022	2021		2022	2021	
Cost of goods sold	$ 15,305	$ 11,874	29 %	$ 41,989	$ 39,956	5 %
Gross margin	96 %	95 %		96 %	95 %	

Cost of goods sold is related to our product revenues and consists primarily 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 increases in cost of goods sold for the three and nine months ended September 30, 2022, as compared to the corresponding prior year periods, were primarily due to an increase in royalties as a result of increased U.S. CABOMETYX sales, which were partially offset by lower period costs. We project our gross margin will not change significantly during the remainder of 2022.

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. 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. 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 in order to select development candidates with the best potential for further evaluation and advancement into clinical development.

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

	Three Months Ended September 30,		Percent Change	Nine Months Ended September 30,		Percent Change
	2022	2021		2022	2021	
Research and development expenses:						
Development:						
Clinical trial costs	$ 71,210	$ 55,376	29 %	$ 190,996	$ 165,635	15 %
Personnel expenses	33,262	26,918	24 %	104,841	84,977	23 %
Consulting and outside services	8,954	6,772	32 %	24,300	18,707	30 %
Other development costs[1]	(1,610)	18,690	-109 %	19,462	33,508	-42 %
Total development	111,816	107,756	4 %	339,599	302,827	12 %
Drug discovery:						
License and other collaboration costs[2]	24,268	21,387	13 %	67,077	73,291	-8 %
Other drug discovery costs[3]	24,806	13,067	90 %	64,246	36,078	78 %
Total drug discovery	49,074	34,454	42 %	131,323	109,369	20 %
Stock-based compensation	16,438	11,487	43 %	34,886	37,550	-7 %
Other research and development[4]	21,509	9,673	122 %	49,181	21,702	127 %
Total research and development expenses	$ 198,837	$ 163,370	22 %	$ 554,989	$ 471,448	18 %

(1) Primarily includes development milestone expenses related to our in-licensing collaboration agreements as well as other miscellaneous development costs.
(2) Primarily includes upfront license fees, research funding commitments and other payments associated with our in-licensing collaboration programs in preclinical development stage.
(3) Primarily includes personnel expenses, consulting and outside services and laboratory supplies.
(4) Includes the allocation of general corporate costs to research and development services, and development cost reimbursements in connection with our collaboration arrangement with Roche executed in December 2019.

The increases in research and development expenses for the three and nine months ended September 30, 2022, as compared to the corresponding prior year periods, were primarily related to increases in personnel expenses, clinical trial costs, and consulting and outside services, which were partially offset by a decrease in other development costs. Clinical trial costs, which include services performed by third-party contract research organizations and other vendors who support our clinical trials, increased primarily due to higher costs associated with the various XL092 and XB002 studies, as well as the CONTACT-02 cabozantinib study, which were partially offset by decreases in costs associated with the COSMIC-313, COSMIC-021, and COSMIC-312 cabozantinib studies. Personnel expenses increased primarily due to an increase in headcount to support our expanding discovery and development organization. Consulting and outside services expenses increased primarily as a result of the continued growth in our discovery and research activities. The reduction in other development costs is primarily due to the reversal of a development milestone in the third quarter of 2022, which was recorded in the third quarter of 2021. The compound has not progressed as expected and therefore we are no longer able to predict when the milestone will occur. License and other collaboration costs increased for the three months ended September 30, 2022, as compared to the corresponding prior year period, primarily due to an increase in development milestone payments, which was partially offset by a decrease in upfront license fees from business activities. License and other collaboration costs decreased during the nine months ended September 30, 2022, as compared to the corresponding prior period, primarily due to lower upfront license fees from business development activities. Stock-based compensation expense increased for the three months ended September 30, 2022, as compared to the corresponding prior year period, primarily due to the impact of modifying certain stock-based compensation awards during the three months ended September 30, 2022, which was partially offset by lower stock-based compensation expense associated with the

achievement of PSUs. Stock-based compensation expense decreased for the nine months ended September 30, 2022, as compared to the corresponding prior year period, primarily due to lower stock-based compensation expense associated with the achievement of PSUs.

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 indications, and 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 are focusing a significant amount of 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 continuing clinical development program of cabozantinib, which includes over 100 ongoing or planned clinical trials across multiple indications. Notable ongoing company-sponsored studies resulting from this program include: COSMIC-313, for which BMS is providing nivolumab and ipilimumab free of charge; and CONTACT-02, for which Roche is sharing the development costs and providing atezolizumab free of charge.

We are expanding our oncology product pipeline through drug discovery efforts, which encompass both small molecule and biotherapeutics 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 2022, as compared to the corresponding prior year period, primarily driven by our ongoing clinical evaluation of cabozantinib, the initiation of new clinical trials and expansion of ongoing clinical trials evaluating other product candidates in our pipeline, including STELLAR-303 and planned initiation of a second phase 3 pivotal trial for XL092, and also our current early-stage trials evaluating XL092, XB002, XL102 and XL114, as well as anticipated business development activities.

A discussion of the risks and uncertainties with respect to our research and development activities and the consequences to our business, financial position and growth prospects can be found in “Risk Factors” in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Selling, General and Administrative Expenses

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

	Three Months Ended September 30,		Percent Change	Nine Months Ended September 30,		Percent Change
	2022	2021		2022	2021	
Selling, general and administrative expenses	$ 94,084	$ 79,079	19 %	$ 293,773	$ 243,300	21 %
Stock-based compensation	20,899	22,479	-7 %	46,832	$ 59,104	-21 %
Total selling, general and administrative expenses	$ 114,983	$ 101,558	13 %	$ 340,605	$ 302,404	13 %

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

The increases in selling, general and administrative expenses for the three and nine months ended September 30, 2022, as compared to the corresponding prior year periods, were primarily related to increases in personnel expenses, marketing costs, business technology initiatives, and rent and utilities expenses, partially offset by a decrease in stock-based compensation expense.

Personnel expenses increased primarily due to an increase in administrative headcount to support our commercial and research and development organizations. Marketing costs increased primarily due to increased spending in support of the commercialization of the combination therapy of CABOMETYX and OPDIVO for the treatment of advanced RCC. Business technology initiatives increased primarily to support productivity and efficiency in our organization. Rent and

utilities expenses increased primarily related to the commencement of our Alameda built-to-suit lease in the second quarter of 2022. Stock-based compensation expense decreased primarily due to lower compensation expense associated with the achievement of PSUs and fewer stock options granted, which was partially offset by an increase in the number of RSUs granted.

We project our selling, general and administrative expenses may increase for the remainder of 2022, 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 September 30,		Percent Change	Nine Months Ended September 30,		Percent Change
	2022	2021		2022	2021	
Interest income	$ 9,498	$ 1,658	473 %	$ 16,077	$ 6,231	158 %
Other income (expense), net	(69)	(19)	263 %	140	(120)	n/a
Non-operating income	$ 9,429	$ 1,639	475 %	$ 16,217	$ 6,111	165 %

The increases in non-operating income for the three and nine months ended September 30, 2022, as compared to the corresponding prior year periods, were primarily the result of increases 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 September 30,		Percent Change	Nine Months Ended September 30,		Percent Change
	2022	2021		2022	2021	
Provision for income taxes	$ 18,832	$ 15,056	25 %	$ 53,324	$ 40,236	33 %
Effective tax rate	20.5 %	28.3 %		20.1 %	22.8 %	

The effective tax rates for the three and nine months ended September 30, 2022, differed from the U.S. federal statutory 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, which were partially offset by state taxes.

The effective tax rates for the three and nine months ended September 30, 2021 differed from the U.S. federal statutory rate of 21% primarily due to non-deductible executive compensation, partially offset by excess tax benefits related to the exercise of certain stock options during the periods and the generation of federal tax credits.

Liquidity and Capital Resources

As of September 30, 2022, we had $2.1 billion in cash, cash equivalents, restricted cash equivalents and investments, as compared to $1.9 billion as of December 31, 2021. 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 a period of at least 12 months following the filing date of this report.

Our primary cash requirements for operating activities, which we project will increase for the remainder of 2022, as compared to the corresponding period in 2021, are for: employee related expenditures; costs related to our development and discovery programs; income tax payments; cash payments for inventory; 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. In general, research and development expenditures are no longer deductible in the current period 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 2022 and have paid higher estimated federal taxes. 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 2022, as compared to the corresponding period in 2021; cash collections related to royalties earned from our commercial collaboration arrangements with Ipsen, Takeda and others and cash collections upon achievement of certain development, regulatory and commercial milestones; and cash collections for cost reimbursements under certain of our development programs. 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 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 laboratory facilities and equipment. We project that we may continue to spend significant amounts of cash to fund the continued development and commercialization of cabozantinib. 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, regulatory and commercial expertise. 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 with combined credit limits of $1.5 million and $16.7 million as of September 30, 2022 and December 31, 2021, respectively.

The standby letter of credit entered in January 2021, as a guarantee of our obligation to fund our portion of the tenant improvements related to our Alameda build-to-suit lease was terminated and the related collateral was returned in the third quarter of 2022, following the substantial completion of the building and the commencement of the lease.

Sources and Uses of Cash (in thousands):

	September 30, 2022	December 31, 2021	Percent Change
Working capital	$ 1,539,888	$ 1,497,157	3 %
Cash, cash equivalents, restricted cash equivalents, and investments	$ 2,100,209	$ 1,854,908	13 %

Working capital: The increase in working capital as of September 30, 2022, as compared to December 31, 2021, was primarily due to the favorable impacts to our net current assets resulting from our net income during the nine months ended September 30, 2022, which was partially offset by purchases of long-term investments and estimated tax payments made that are classified as long-term. In the future, our working capital may be impacted by one of these factors or other factors, the amounts and timing of which are variable.

Cash, cash equivalents, restricted cash equivalents and investments: Cash and cash equivalents primarily consist of cash deposits held at major banks, commercial paper and other securities with original maturities 90 days or less. Restricted cash equivalents and investments relate to our standby letter of credit agreements and are invested in short-term marketable securities. 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 September 30, 2022, as compared to December 31, 2021, was primarily due to cash inflows generated by our operations, including collections of amounts due from customers, and collection of a $100.0 million milestone payment from Ipsen, 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):

	Nine Months Ended September 30,	
	2022	2021
Net cash provided by operating activities	$ 288,920	$ 304,352
Net cash used in investing activities	$ (278,632)	$ (29,829)
Net cash provided by financing activities	$ 2,589	$ 3,193

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 nine months ended September 30, 2022 decreased, as compared to the corresponding prior year period, primarily due to an increase in cash paid for certain operating expenses resulting in net unfavorable changes in operating assets and liabilities, which was partially offset by an increase in cash received on sales of our products and from our commercial collaboration arrangements, including collection of a $100.0 million milestone payment from Ipsen.

Investing Activities

The changes in cash flows from investing activities primarily relates to the timing of marketable securities investment activity 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 nine months ended September 30, 2022 increased, as compared to the corresponding prior year period, primarily due to a decrease in cash proceeds from maturities and sales of investments, and an increase in purchases of investments, which were partially offset by a decrease in capital expenditures.

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 nine months ended September 30, 2022 decreased, as compared to the corresponding prior year period, primarily due to an increase in withholding taxes remitted to the government related to net share settlements of equity awards, which was partially offset by an increase in proceeds received from the issuance of common stock under our equity incentive plans.

Contractual Obligations

In May 2022, we entered into the seventh amendment to the lease for our corporate headquarters located on Harbor Bay Parkway, Alameda, California (the Alameda Lease) for the expansion of the premises by 34,745 square feet of office facilities located at 1751 Harbor Bay Parkway, Alameda, California (the 1751 Expansion Space). The term of the 1751 Expansion Space is coterminous with the term of the Alameda Lease for the existing space.

In April 2022, the office building (New Premises) associated with our October 2019 build-to-suit lease agreement (Build-to-Suit Lease) was substantially completed. The New Premises is 220,517 square feet and is in Alameda, California, adjacent to our existing corporate headquarters. The Build-to-Suit Lease term is 242 months, includes two five-year options to extend the term of the lease and a one-time option to terminate the lease after 180 months. In addition to the lease payments, we are also responsible for paying operating expenses related to the New Premises.

There were no material changes outside of the ordinary course of business in our contractual obligations as of September 30, 2022 from those disclosed in our Fiscal 2021 Form 10-K. For more information about our Build-to-Suit Lease, 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 2021 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 nine months ended September 30, 2022, 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 2021 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 September 30, 2022 have not changed significantly from those described in Item 7A of our Fiscal 2021 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 Approved Drug Products with Therapeutic Equivalence Evaluations, also referred to as the Orange Book, for CABOMETYX. MSN's initial notice letter did not provide a Paragraph IV certification against U.S. Patents No. 7,579,473 (composition of matter) or 8,497,284 (methods of treatment), each of which is listed in the Orange Book. On October 29, 2019, we filed a complaint in the Delaware District Court for patent infringement against MSN asserting infringement of U.S. Patent No. 8,877,776 arising from MSN's ANDA filing with the FDA. On November 20, 2019, MSN filed its response to the complaint, alleging that the asserted claims of U.S. Patent No. 8,877,776 are invalid and not infringed. On May 5, 2020, we received notice from MSN that it had amended its ANDA to include additional Paragraph IV certifications. In particular, the May 5, 2020 amended ANDA requested approval to market a generic version of CABOMETYX tablets prior to expiration of two previously unasserted CABOMETYX patents: U.S. Patents No. 7,579,473 and 8,497,284. On May 11, 2020, we filed a complaint in the Delaware District Court for patent infringement against MSN asserting infringement of U.S. Patents No. 7,579,473 and 8,497,284 arising from MSN's amended ANDA filing with the FDA. Neither of our complaints have alleged infringement of U.S. Patents No. 9,724,342, 10,034,873 and 10,039,757. On May 22, 2020, MSN filed its response to the complaint, alleging that the asserted claims of U.S. Patents No. 7,579,473 and 8,497,284 are invalid and not infringed. On March 23, 2021, MSN filed its First Amended Answer and Counterclaims (amending its prior filing from May 22, 2020), seeking, among other things, a declaratory judgment that U.S. Patent No. 9,809,549 (salt and polymorphic forms) is invalid and would not be infringed by MSN if its generic version of CABOMETYX tablets were approved by the FDA. U.S. Patent No. 9,809,549 is not listed in the Orange Book. On April 7, 2021, we filed our response to MSN's First Amended Answer and Counterclaims, denying, among other things, that U.S. Patent No. 9,809,549 is invalid or would not be infringed. The two lawsuits comprising 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 are seeking, 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 have 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 has, 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 a judgment is expected during the fourth quarter of 2022.

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. 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 remedies, equitable relief enjoining MSN from infringing this patent, as well as 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. 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.

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 risks discussed elsewhere in this report, the following are important factors that make an investment in our securities speculative or risky, and that could cause actual results or events to differ materially from those contained in any forward-looking statements made by us or on our behalf. The risks and uncertainties described 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. If any of the following risks or such other risks actually occur, our business and the value of your investment in our company could be harmed.

Risk Factor Summary

- *Our ability to grow our company is dependent upon the commercial success of CABOMETYX in its approved indications and the continued clinical development, regulatory approval, clinical acceptance and commercial success of the cabozantinib franchise in additional indications.*
- *If we are unable to obtain or maintain coverage and reimbursement for our products from third-party payers, our business will suffer.*
- *Pricing for pharmaceutical products, both in the U.S. and in foreign countries, has come under increasing attention and scrutiny by federal, state and foreign national 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.*
- *The timing of the entrance of generic competitors to CABOMETYX and legislative and regulatory action designed to reduce the barriers to the development, approval and adoption of generic drugs in the U.S. could limit the revenue we derive from our products, most notably CABOMETYX, which could have a material adverse impact on our business, financial condition and results of operations.*
- *We are subject to healthcare laws, regulations and enforcement, as well as laws and regulations relating to privacy, data collection and processing of personal data; our failure to comply with those laws could have a material adverse impact on our business, financial condition and results of operations.*
- *Clinical testing of cabozantinib for new indications, or of new product candidates, is a lengthy, costly, complex and uncertain process that may fail ultimately to demonstrate safety and efficacy data for those products sufficiently differentiated to compete in our highly competitive market environment.*
- *The regulatory approval processes of the U.S. Food and Drug Administration and comparable foreign regulatory authorities are lengthy, uncertain and subject to change, and may not result in regulatory approvals for additional cabozantinib indications or for our other product candidates, which could have a material adverse impact on our business, financial condition and results of operations.*
- *We may be unable to expand our discovery and development pipeline, which could limit our growth and revenue potential.*
- *Our profitability could be negatively impacted if expenses associated with our extensive clinical development, business development and commercialization activities, both for the cabozantinib franchise and our other product candidates, grow more quickly than the revenues we generate.*
- *Our clinical, regulatory and commercial collaborations with major companies make us reliant on those companies for their continued performance and investments, which subjects us to a number of risks. For example, we rely on Ipsen and Takeda for the commercial success of CABOMETYX in its approved indications outside of the U.S., and we are unable to control the amount or timing of resources expended by these collaboration partners in the commercialization of CABOMETYX in its approved indications outside of the U.S. In addition, our growth potential is dependent in part upon companies with which we have entered into research collaborations, in-licensing arrangements and similar business development relationships.*
- *Data breaches, cyber-attacks and other failures in our information technology operations and infrastructure could compromise our intellectual property or other sensitive information, damage our operations and cause significant harm to our business and reputation.*
- *If we are unable to adequately protect our intellectual property, third parties may be able to use our technology, which could adversely affect our ability to compete in the market.*
- *If the COVID-19 pandemic is further prolonged or becomes more severe, our business operations and corresponding financial results could suffer, which could have a material adverse impact on our financial condition and prospects for growth.*
- *The loss of key personnel or the inability to retain and, where necessary, attract additional personnel could impair our ability to operate and expand our operations.*

Risks Related to the Commercialization of Our Products

Our ability to grow our company is dependent upon the commercial success of CABOMETYX in its approved indications and the continued clinical development, regulatory approval, clinical acceptance and commercial success of the cabozantinib franchise in additional indications.

We anticipate that for the foreseeable future, our ability to maintain or meaningfully increase 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. In this regard, part of our strategy is to pursue additional indications for CABOMETYX and increase the number of cancer patients who could potentially benefit from this medicine. 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 cabozantinib for additional indications are achieved, we and our collaboration partners may not be able to commercialize CABOMETYX effectively and successfully in these additional indications. If revenue from CABOMETYX decreases or remains flat, or if we are unable to expand the number of labeled indications for which CABOMETYX is approved, or if we or our collaboration partners fail to achieve anticipated product royalties and collaboration milestones, we may need to reduce our operating expenses, access other sources of cash or otherwise modify our business plans, which could have a material adverse impact on our business, financial condition and results of operations.

Our ability to grow revenues from sales of CABOMETYX depends upon the degree of market acceptance among physicians, patients, healthcare payers, and the medical community.

Our ability to increase or maintain revenues from sales of CABOMETYX for its approved indications is, and if approved for additional indications will be, highly dependent upon the extent of market acceptance of CABOMETYX among physicians, patients, foreign and U.S. government healthcare payers such as Medicare and Medicaid, commercial healthcare plans and the medical community. Market acceptance for CABOMETYX could be impacted by numerous factors, including the effectiveness and safety profile, or the perceived effectiveness and safety profile, of CABOMETYX compared to competing products, the strength of CABOMETYX sales and marketing efforts and changes in pricing and reimbursement for CABOMETYX. If CABOMETYX does not continue to be prescribed broadly for the treatment of patients in its approved indications, our product revenues could flatten or decrease, which could have a material adverse impact on our business, financial condition and results of operations.

Our competitors may develop products and technologies that impair the relative value of our marketed products and any current and future product candidates.

The biopharmaceutical industry is competitive and characterized by constant technological change and diverse offerings of products, particularly in the area of oncology therapies. Many of our competitors have greater capital resources, larger research and development staff and facilities, deeper regulatory expertise and more extensive product manufacturing and commercial capabilities than we do, which may afford them a competitive advantage. Further, our competitors may be more effective at in-licensing and developing new commercial products that could render our products, and those of our collaboration partners, obsolete and noncompetitive. We face, and will continue to face, intense competition from biopharmaceutical companies, as well as academic research institutions, clinical reference laboratories and government agencies that are pursuing scientific and clinical research activities similar to ours.

Furthermore, the specific indications for which CABOMETYX is currently or may be approved, based on the results from clinical trials currently evaluating cabozantinib, are highly competitive. Several novel therapies and combinations of therapies have been approved, are in advanced stages of clinical development or are under expedited regulatory review in these indications, and these other therapies are currently competing or are expected to compete with CABOMETYX. Even if our current and future clinical trials, including those evaluating cabozantinib in combination with an ICI in NSCLC and mCRPC or evaluating XL092 in combination with an ICI in CRC, 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.

If we are unable to maintain or increase our sales, marketing, market access and product distribution capabilities for our products, we may be unable to maximize product revenues, which could have a material adverse impact on our business, financial condition and results of operations.

Maintaining our sales, marketing, market access and product distribution capabilities requires significant resources, and there are numerous risks involved with maintaining and continuously improving our commercial organization, including our potential inability to successfully recruit, train, retain and incentivize adequate numbers of qualified and effective sales and marketing personnel. We are competing for talent with numerous commercial- and precommercial-stage, oncology-focused biopharmaceutical companies seeking to build out and maintain their commercial organizations, as well as larger biopharmaceutical organizations that have extensive, well-funded and more experienced sales and marketing operations, and we may be unable to maintain or adequately scale our commercial organization as a result of such competition. Also, to the extent that the commercial opportunities for CABOMETYX grow over time, we may not properly scale the size and experience of our commercialization teams to market and sell CABOMETYX successfully in an expanded number of indications. If we are unable to maintain or scale our commercial function appropriately, we may not be able to maximize product revenues, which could have a material adverse impact on our business, financial condition and results of operations.

If we are unable to obtain or maintain coverage and reimbursement for our products from third-party payers, our business will suffer.

Our ability to commercialize our products successfully is highly dependent on the extent to which health insurance coverage and reimbursement is, and will be, available from third-party payers, including foreign and U.S. governmental payers, such as Medicare and Medicaid, and private health insurers. Third-party payers continue to scrutinize and manage access to pharmaceutical products and services and may limit reimbursement for newly approved products and indications. Patients are generally not capable of paying for CABOMETYX or COMETRIQ themselves and rely on third-party payers to pay for, or subsidize, the costs of their medications, among other medical costs. Accordingly, market acceptance of CABOMETYX and COMETRIQ is dependent on the extent to which coverage and reimbursement is available from third-party payers. These entities could refuse, limit or condition coverage for our products, such as by using tiered reimbursement or pressing for new forms of contracting, or alternatively for patients who rely on our co-pay assistance program, implement co-pay accumulators or maximizers that exempt such co-pay assistance from patient deductibles, which has increased and could further increase the costs of our co-pay assistance program or cause patients to abandon CABOMETYX or COMETRIQ therapy due to higher out-of-pocket costs. If third-party payers do not provide or increase limitations on coverage or reimbursement for CABOMETYX or COMETRIQ, our revenues and results of operations may suffer. In addition, even if third-party payers provide some coverage or reimbursement for CABOMETYX or COMETRIQ, the availability of such coverage or reimbursement for prescription drugs under private health insurance and managed care plans, which often varies based on the type of contract or plan purchased, may not be sufficient for patients to afford CABOMETYX or COMETRIQ.

Current healthcare laws and regulations in the U.S. and future legislative or regulatory reforms to the U.S. healthcare system may affect our ability to commercialize our marketed products profitably.

Federal and state governments in the U.S. are considering legislative and regulatory proposals to change the U.S. healthcare system in ways that could affect our ability to continue to commercialize CABOMETYX and COMETRIQ profitably. Similarly, among policy makers and payers, there is significant interest in promoting such changes with the stated goals of containing healthcare costs and expanding patient access. The life sciences industry and specifically the market for the sale, insurance coverage and distribution of pharmaceuticals has been a particular focus of these efforts and would likely be significantly affected by any major legislative or regulatory initiatives. For instance, efforts to repeal, substantially modify or invalidate some or all of the provisions of the Patient Protection and Affordable Care Act of 2010, as amended (PPACA), some of which have been successful, create considerable uncertainties for all businesses involved in healthcare, including our own.

In addition, there have been, and may in the future be, initiatives at both the federal and state level that could significantly modify the terms and scope of government-provided health insurance coverage, ranging from establishing a single-payer, national health insurance system to more limited “buy-in” options to existing public health insurance programs, each of which could have a significant impact on the healthcare industry. Although such attempts to reform the U.S. healthcare system have not significantly impacted our business to date, it is possible that additional legislative, executive and judicial activities in the future could have a material adverse impact on our business, financial condition and results of operations.

Furthermore, because we participate in the 340B Program to sell a portion of our marketed products, changes in the administration of the program could have a material adverse impact on our revenues. Some manufacturers are currently involved in ongoing litigation regarding the legality of contract pharmacy arrangements under the 340B Program, which may affect the way in which manufacturers are required to extend discounts to covered entities through contract pharmacies. Effective July 2022, we implemented a 340B Program "integrity initiative," pursuant to which we request all hospital covered entities (i.e., hospitals that participate in the 340B Program) to provide claims-level data for CABOMETYX and COMETRIQ dispensed by contract pharmacies. A covered entity that elects not to provide this limited claims data and that does not have an in-house pharmacy may designate a single contract pharmacy location within our authorized specialty pharmacy network. We believe this initiative will provide much-needed transparency and promote compliance with program requirements, and at the same time, should not restrict patient access to our medicines. The U.S. Department of Health and Human Services (HHS) has notified us that it is reviewing our policy, and we have responded to HHS' request for information. Since 2021, numerous manufacturers that previously implemented similar contract pharmacy integrity programs have received enforcement letters from HHS stating that those manufacturers' actions restricted contract pharmacy transactions in violation of the 340B Program statute, which may subject them to repayment of overcharges and civil monetary penalties. As mentioned above, certain of these manufacturers are now in litigation with the government over the legality of these programs, and depending on the outcome of such litigation, we may be required to modify or suspend our 340B Program integrity initiative program. Further, it is possible that HHS could seek to implement administrative proceedings to recover overcharges and/or impose civil monetary penalties against us regarding our 340B Program integrity initiative. If such proceedings were implemented against us, a negative ruling could have a material adverse effect on our business, financial condition and results of operations. Due to general uncertainty with respect to this litigation and in the current regulatory and healthcare policy environment, and specifically regarding positions that the Biden Administration may take with respect to these issues, we are unable to predict the impact of any legislative, regulatory, third-party payer or policy actions, including potential cost containment and healthcare reform measures. If enacted, we and any third parties we may engage may be unable to adapt to any changes implemented as a result of such measures, and we may have difficulties in maintaining or increasing profitability or otherwise experience a material adverse impact on our business, financial condition and results of operations.

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: 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; 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; and revise the rebate methodology under the Medicaid Drug Rebate Program. For instance in August 2022, President Biden signed the Inflation Reduction Act, which among other things: allows for the Centers for Medicare and Medicaid Services (CMS) to impose price controls for certain single-source drugs and biotherapeutics reimbursed under Medicare Part B and Part D; subjects drug manufacturers to civil monetary penalties and a potential excise tax for offering a price that is not equal to or less than the government-imposed "maximum fair price" under the law and imposes additional rebates for price increases that exceed 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 will take effect incrementally starting in 2023 and may be subject to various legal challenges. Although public rulemaking and related agency guidance for the Inflation Reduction Act has yet to be issued and it is uncertain what impact the Inflation Reduction Act will ultimately have upon our business, over time 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. 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.

Lengthy regulatory pricing and reimbursement procedures and cost control initiatives imposed by governments outside the U.S. could delay the marketing of and/or result in downward pressure on the price of our approved products, resulting in a decrease in revenue.

Outside the U.S., including major markets in the EU and Japan, the pricing and reimbursement of prescription pharmaceuticals is generally subject to governmental control. In these countries, pricing and reimbursement negotiations with governmental authorities or payers can take six to 12 months or longer after the initial marketing authorization is granted for a product, or after the marketing authorization for a new indication is granted. This can substantially delay broad availability of the product. To obtain reimbursement and/or pricing approval in some countries, our collaboration partners Ipsen and Takeda may also be required to conduct a study or otherwise provide data that seeks to establish the cost effectiveness of CABOMETYX compared with other available established therapies. The conduct of such a study could also result in delays in the commercialization of CABOMETYX.

Additionally, cost-control initiatives, increasingly based on affordability and accessibility, as well as post-marketing assessments of the added value of CABOMETYX and COMETRIQ as compared to existing treatments, could influence the prices paid for and net revenues we realize from CABOMETYX and COMETRIQ, or the indications for which we are able to obtain reimbursement, which would result in lower license revenues to us. Upcoming legislative and policy changes in the EU are aimed at increasing cooperation between the EU Member States. Such initiatives, particularly the Regulation on Health Technology Assessment adopted in December 2021, may further impact the price and reimbursement status of CABOMETYX and COMETRIQ in the future.

The timing of the entrance of generic competitors to CABOMETYX and legislative and regulatory action designed to reduce barriers to the development, approval and adoption of generic drugs in the U.S. could limit the revenue we derive from our products, most notably CABOMETYX, which could have a material adverse impact on our business, financial condition and results of operations.

Under the Federal Food, Drug and Cosmetic Act (FDCA), the FDA can approve an ANDA for a generic version of a branded drug without the applicant undertaking the human clinical testing necessary to obtain approval to market a new drug. The FDA can also approve a New Drug Application (NDA) under section 505(b)(2) of the FDCA that relies in part on the agency's findings of safety and/or effectiveness for a previously approved drug, where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use. Both the ANDA and 505(b)(2) NDA processes are discussed in more detail in "Item 1. Business—Government Regulation—FDA Review and Approval—Abbreviated FDA Approval Pathways and Generic Products" in our Fiscal 2021 Form 10-K. In either case, if an ANDA or 505(b)(2) NDA applicant submits an application referencing one of our marketed products prior to the expiry of one or more our Orange Book-listed patents for the applicable product, we may litigate with the potential generic competitor to protect our patent rights, which would result in substantial costs, divert the attention of management, and could have an adverse impact on our stock price. For example, MSN and Teva have separately submitted ANDAs to the FDA requesting approval to market their respective generic versions of CABOMETYX tablets, and we have subsequently filed patent lawsuits against both companies. For a more detailed discussion of these litigation matters, see "Legal Proceedings" in Part II, Item 1 of this Quarterly Report on Form 10-Q. It is possible that MSN, Teva or other companies, following FDA approval of an ANDA or 505(b)(2) NDA, could introduce generic or otherwise competitor versions of our marketed products before our patents expire if they do not infringe our patents or if it is determined that our patents are invalid or unenforceable, and we expect that generic cabozantinib products would be offered at a significantly lower price compared to our marketed cabozantinib products. Therefore, regardless of the regulatory approach, the introduction of a generic version of cabozantinib would likely decrease our revenues derived from the U.S. sales of CABOMETYX and thereby materially harm our business, financial condition and

results of operations. There are also equivalent procedures in the EU permitting authorization of generic versions and biosimilars of medicinal products authorized in the EU once related data and market exclusivity periods have expired.

The U.S. federal government has also taken numerous legislative and regulatory actions to expedite the development and approval of generic drugs and biosimilars. Both Congress and the FDA are considering, and have enacted, various legislative and regulatory proposals focused on drug competition, including legislation focused on drug patenting and provision of drug to generic applicants for testing. For example, the Ensuring Innovation Act, enacted in April 2021, amended the FDA's statutory authority for granting new chemical entity (NCE) exclusivity to reflect the agency's existing regulations and longstanding interpretation that award NCE exclusivity based on a drug's active moiety, as opposed to its active ingredient, which is intended to limit the applicability of NCE exclusivity, thereby potentially facilitating generic competition. The FDA has also released a Drug Competition Action Plan, which proposes actions to broaden access to generic drugs and lower consumers' healthcare costs by, among other things, improving the efficiency of the generic drug approval process and supporting the development of complex generic drugs. In addition, the Further Consolidated Appropriations Act, 2020, which incorporated the framework from the Creating and Restoring Equal Access To Equivalent Samples (CREATES) legislation, purports to promote competition in the market for drugs and biotherapeutic products by facilitating the timely entry of lower-cost generic and biosimilar versions of those drugs and biotherapeutic products, including by allowing ANDA, 505(b)(2) NDA or biosimilar developers to obtain access to branded drug and biotherapeutic product samples. While the full impact of these provisions is unclear at this time, its provisions do have the potential to facilitate the development and future approval of generic versions of our products, introducing generic competition that could have a material adverse impact on our business, financial condition and results of operations.

Risks Related to Healthcare Regulatory and Other Legal Compliance Matters

We are subject to healthcare laws, regulations and enforcement; our failure to comply with those laws could have a material adverse impact on our business, financial condition and results of operations.

We are subject to federal and state healthcare laws and regulations, which laws and regulations are enforced by the federal government and the states in which we conduct our business. Should our compliance controls prove ineffective at preventing or mitigating the risk and impact of improper business conduct or inaccurate reporting, we could be subject to enforcement of the following, including, without limitation:

- the federal AKS;
- the FDCA and its implementing regulations;
- federal civil and criminal false claims laws, including the civil False Claims Act, and the Civil Monetary Penalties Law;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations, as amended;
- state law equivalents of each of the above federal laws;
- the Open Payments program of the PPACA;
- state and local laws and regulations that require drug manufacturers to file reports relating to marketing activities, payments and other remuneration and items of value provided to healthcare professionals and entities; and
- state and federal pharmaceutical price and price reporting laws and regulations.

In addition, we may be subject to the Foreign Corrupt Practices Act, a U.S. law which regulates certain financial relationships with foreign government officials (which could include, for example, medical professionals employed by national healthcare programs) and its foreign equivalents, as well as federal and state consumer protection and unfair competition laws.

These federal and state healthcare laws and regulations govern drug marketing practices, including off-label promotion, and also impact our current and future business arrangements with third parties, including various healthcare entities. If our operations are found, or even alleged, to be in violation of the laws described above or other governmental regulations that apply to us, we, or our officers or employees, may be subject to significant penalties, including administrative civil and criminal penalties, damages, fines, regulatory penalties, the curtailment or restructuring of our operations, exclusion from participation in Medicare, Medicaid and other federal and state healthcare programs, imprisonment, reputational harm, additional reporting requirements and oversight through a Corporate Integrity

Agreement or other monitoring agreement, any of which would adversely affect our ability to sell our products and operate our business and also adversely affect our financial results. Furthermore, responding to any such allegation or investigation and/or defending against any such enforcement actions can be time-consuming and would require significant financial and personnel resources. Therefore, if any state or the federal government initiates an enforcement action against us, our business may be impaired, and even if we are ultimately successful in our defense, litigating these actions could result in substantial costs and divert the attention of management.

Enhanced governmental and private scrutiny over, or investigations or litigation involving, pharmaceutical manufacturer patient assistance programs and donations to patient assistance foundations created by charitable organizations could negatively impact our business practices, harm our reputation, divert the attention of management and increase our expenses.

To help patients afford our products, we have a patient assistance program and also occasionally make donations to independent charitable foundations that help financially needy patients. These types of programs designed to assist patients with affording pharmaceuticals have become the subject of Congressional interest and enhanced government scrutiny. The HHS Office of Inspector General established guidelines permitting pharmaceutical manufacturers to make donations to charitable organizations that provide co-pay assistance to Medicare patients, provided that manufacturers meet certain specified compliance requirements. In the event we make such donations but are found not to have complied with these guidelines and other laws or regulations respecting the operation of these programs, we could be subject to significant damages, fines, penalties or other criminal, civil or administrative sanctions or enforcement actions. Moreover, in December 2020, the CMS finalized changes to Medicaid Drug Rebate Program pricing calculations regarding the provision of co-payment assistance to patients that may be impacted by private insurer accumulator programs. The portion of this rule dealing with manufacturer co-payment assistance (and related support programs) was struck down by the U.S. District Court for the District of Columbia in May 2022 (and the deadline for an appeal has lapsed). Consequently, while this rule has been vacated, it is also possible that CMS could issue new rulemaking or guidance on this topic that would affect the amount of rebates owed under the Medicaid program or otherwise limit our ability to support our patient co-pay assistance program. We also rely on a third-party hub provider and exercise oversight to monitor patient assistance program activities. Hub providers are generally hired by manufacturers to assist patients with insurance coverage, financial assistance and treatment support after the patients receive a prescription from their healthcare professional. For manufacturers of specialty pharmaceuticals (including our marketed products), the ability to have a single point of contact for their therapies helps ensure efficient medication distribution to patients. Accordingly, our hub activities are also subject to scrutiny and may create risk for us if not conducted appropriately. A variety of entities, including independent charitable foundations and pharmaceutical manufacturers, but not including our company, have received subpoenas from the U.S. Department of Justice (DOJ) and other enforcement authorities seeking information related to their patient assistance programs and support, and certain of these entities have entered into costly civil settlement agreements with DOJ and other enforcement authorities that include requirements to maintain complex corporate integrity agreements that impose significant reporting and other requirements. Should we or our hub providers receive a subpoena or other process, regardless of whether we are ultimately found to have complied with the regulations governing patient assistance programs, this type of government investigation could negatively impact our business practices, harm our reputation, divert the attention of management and increase our expenses.

We are subject to laws and regulations relating to privacy, data protection and the collection and processing of personal data. Failure to maintain compliance with these regulations could create additional liabilities for us.

The legislative and regulatory landscape for privacy and data protection continues to evolve in the U.S. and other jurisdictions around the world. For example, the California Consumer Privacy Act of 2018 (CCPA) went into operation in 2020 and affords California residents expanded privacy rights and protections, including civil penalties for violations and statutory damages under a private right of action for data security breaches. These protections will be expanded by the California Privacy Rights Act (CPRA), which will be operational in most key respects on January 1, 2023. Similar legislative proposals have passed or are being advanced in other states, and Congress is also considering additional federal privacy legislation. In addition, most healthcare professionals and facilities are subject to privacy and security requirements under HIPAA with respect to our clinical and commercial activities. Although we are not considered to be a covered entity or business associate under HIPAA, we could be subject to penalties if we use or disclose individually identifiable health information in a manner not authorized or permitted by HIPAA. Other countries also have, or are developing, laws governing the collection, use and transmission of personal information. For example, in the EU, the EU General Data Protection Regulation 2016/679 (GDPR) regulates the processing of personal data of individuals within the EU, even if, under certain circumstances, that processing occurs outside the EU, and also places restrictions on transfers of such data to countries outside of the EU, including the U.S. Should we fail to provide adequate privacy or data security protections or

maintain compliance with these laws and regulations, including the CCPA, CPRA and GDPR, we could be subject to sanctions or other penalties, litigation, an increase in our cost of doing business and questions concerning the validity of our data processing activities, including clinical trials.

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

Clinical testing of cabozantinib for new indications, or of new product candidates, is a lengthy, costly, complex and uncertain process that may fail ultimately to demonstrate safety and efficacy data for those products sufficiently differentiated to compete in our highly competitive market environment.

Clinical trials are inherently risky and may reveal that cabozantinib, despite its approval for certain indications, or a new product candidate, is ineffective or has an unacceptable safety profile with respect to an intended use. Such results may significantly decrease the likelihood of regulatory approval of a product candidate or of an approved product for a new indication. Moreover, the results of preliminary studies do not necessarily predict clinical or commercial success, and late-stage or other potentially label-enabling clinical trials may fail to confirm the results observed in early-stage trials or preliminary studies. Although we have established timelines for manufacturing and clinical development of cabozantinib and our other product candidates based on existing knowledge of our compounds in development and industry metrics, we may not be able to meet those timelines.

We may experience numerous unforeseen events, during or as a result of clinical investigations, that could delay or prevent commercialization of cabozantinib in new indications or of XL092 or other new product candidates. These events may include:

- lack of acceptable efficacy or a tolerable safety profile;
- negative or inconclusive clinical trial results that require us to conduct further testing or to abandon projects;
- discovery or commercialization by our competitors of other compounds or therapies that show significantly improved safety or efficacy compared to cabozantinib or our other product candidates;
- our inability to identify and maintain a sufficient number of clinical trial sites;
- lower-than-anticipated patient registration or enrollment in our clinical testing;
- additional complexities posed by clinical trials evaluating cabozantinib, XL092 or our other product candidates in combination with other therapies, including extended timelines to provide for collaboration on clinical development planning, the failure by our collaboration partners to provide us with an adequate and timely supply of product that complies with the applicable quality and regulatory requirements for a combination trial
- reduced staffing or shortages in laboratory supplies and other resources necessary to complete the trials;
- failure of our third-party contract research organizations or investigators to satisfy their contractual obligations, including deviating from any trial protocols; and
- withholding of authorization from regulators or institutional review boards to commence or conduct clinical trials or delays, variations, suspensions or terminations of clinical research for various reasons, including noncompliance with regulatory requirements or a determination by these regulators and institutional review boards that participating patients are being exposed to unacceptable health risks.

The ongoing Russo-Ukrainian War has had a modest impact on our clinical development operations, particularly with respect to patient recruitment, potentially delaying our ability to complete enrollment in a timely manner. In addition, this conflict has had and may continue to have an adverse impact on the ability of clinical sites and their patients to adhere to trial protocols for in-office clinical visits and other procedures, our ability to supply clinical sites with cabozantinib or other study drugs and to pay clinical sites and investigators for work performed, as well as our ability to collect data and conduct site monitoring visits, all of which could undermine the data quality for patients enrolled at these clinical sites. The need to shift enrollment of patients away from these clinical sites or close certain sites entirely, or to replace patients in affected territories should investigators be unable to continue treating and monitoring them, could further impact our anticipated timelines for completing the trials and achieving clinical endpoints, as well as increase our clinical development expenses.

If there are further delays in or termination of the clinical testing of cabozantinib, XL092 or our other product candidates due to any of the events described above or otherwise, our expenses could increase and our ability to generate revenues could be impaired, either of which could adversely impact our financial results. Furthermore, we rely on our collaboration partners to fund a significant portion of our clinical development programs. Should one or all of our collaboration partners decline to support future planned clinical trials, we will be entirely responsible for financing the

further development of the cabozantinib franchise, XL092 or our other product candidates and, as a result, we may be unable to execute our current business plans, which could have a material adverse impact on our business, financial condition and results of operations.

We may not be able to pursue the further development of the cabozantinib franchise, XL092 or our other product candidates or meet current or future requirements of the FDA or regulatory authorities in other jurisdictions in accordance with our stated timelines or at all. Our planned clinical trials may not begin on time, or at all, may not be completed on schedule, or at all, may not be sufficient for registration of our product candidates or otherwise may not result in an approvable product. The duration and the cost of clinical trials vary significantly as a result of factors relating to a particular clinical trial, including, among others: the characteristics of the product candidate under investigation; the number of patients who ultimately participate in the clinical trial; the duration of patient follow-up; the number of clinical sites included in the trial; and the length of time required to enroll eligible patients. Any delay could limit our ability to generate revenues, cause us to incur additional expense and cause the market price of our common stock to decline significantly.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, uncertain and subject to change, and may not result in regulatory approvals for additional cabozantinib indications or for our other product candidates, 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, XL092 and our other product candidates are subject to extensive regulation by the FDA and other regulatory agencies in the U.S., as well as by comparable regulatory authorities in other territories. The processes of obtaining regulatory approvals in the U.S. and other foreign jurisdictions 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 EMA or any application or submission to comparable regulatory authorities in other jurisdictions, the product candidate must undergo extensive clinical trials, which can take many years and require substantial expenditures.

Any clinical trial may fail to produce results satisfactory to the FDA or regulatory authorities in other jurisdictions. The FDA has substantial discretion in the approval process and may refuse to approve any NDA or sNDA or 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 XL092 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. Recently, in part due to questions raised by the process underlying the approval of the Alzheimer's disease drug Aduhelm®, government authorities and other stakeholders have been scrutinizing the accelerated approval pathway, with some stakeholders advocating for reforms. Even prior to the Aduhelm approval, 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. Moreover, also spurred by the Aduhelm controversy, the HHS Office of Inspector General has initiated an assessment of how the FDA implements the accelerated approval pathway. In addition, members of Congress have introduced proposed legislation to revise the statutory accelerated approval pathway, including with respect to the FDA's ability to rapidly withdraw products and indications for which effectiveness is not confirmed in post-marketing studies. At this time, it is not clear what impact, if any, these developments may have on the statutory accelerated approval pathway or 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 XL092, 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,

XL092 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, XL092 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.

We may be unable to expand our discovery and development pipeline, which could limit our growth and revenue potential.

Our business is focused on the discovery, development and commercialization of new medicines for difficult-to-treat cancers. In this regard, we have invested in substantial technical, financial and human resources toward drug discovery activities with the goal of identifying new product candidates to advance into clinical trials. Notwithstanding this investment, many programs that initially show promise will ultimately fail to yield product candidates for multiple reasons. For example, product candidates may, on further study, be shown to have inadequate efficacy, harmful side effects, suboptimal pharmaceutical profiles or other characteristics suggesting that they are unlikely to be commercially viable products.

Apart from our drug discovery efforts, our strategy to expand our development pipeline is also dependent on our ability to successfully identify and acquire or in-license relevant product candidates and technologies. However, the in-licensing and acquisition of product candidates and technologies is a highly competitive area, and many other companies are pursuing the same or similar product candidates and technologies to those that we may consider attractive. In particular, larger companies with more capital resources and more extensive clinical development and commercialization capabilities may have a competitive advantage over us. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We may also be unable to in-license or acquire additional product candidates and technologies on acceptable terms that would allow us to realize an appropriate return on our investment. Even if we succeed in our efforts to obtain rights to suitable product candidates and technologies, the competitive business environment may result in higher acquisition or licensing costs, and our investment in these potential products and technologies will remain subject to the inherent risks associated with the development and commercialization of new medicines. In certain circumstances, we may also be reliant on the licensor for the continued development of the in-licensed technology and their efforts to safeguard their underlying intellectual property.

With respect to acquisitions, we may not be able to integrate the target company successfully into our existing business, maintain the key business relationships of the target company, or retain key personnel of the acquired business. Furthermore, we could assume unknown or contingent liabilities or otherwise incur unanticipated expenses. Any acquisitions or investments made by us also could result in our spending significant amounts, issuing dilutive securities, assuming or incurring significant debt obligations and contingent liabilities, incurring large one-time expenses and acquiring intangible assets that could result in significant future amortization expense and significant write-offs, any of which could harm our financial condition and results of operations. If our drug discovery efforts, including research collaborations, in-licensing arrangements and other business development activities, do not result in suitable product candidates, our business and prospects for growth could suffer.

Risks Related to Financial Matters and Capital Requirements

Our profitability could be negatively impacted if expenses associated with our extensive clinical development, business development and commercialization activities, both for the cabozantinib franchise and our other product candidates, grow more quickly than the revenues we generate.

Although we reported net income of $73.2 million and $212.5 million for the three and nine months ended September 30, 2022, respectively, and $231.1 million for the fiscal year ended December 31, 2021, we may not be able to maintain or increase profitability on a quarterly or annual basis, and we are unable to predict the extent of future profits or losses. The amount of our net profits or losses will depend, in part, on: the level of sales of CABOMETYX and COMETRIQ in the U.S.; our achievement of development, regulatory and commercial milestones, if any, under our collaboration agreements; the amount of royalties from sales of CABOMETYX and COMETRIQ outside of the U.S. under our collaboration agreements; other collaboration revenues; and the level of our expenses, including those associated with our extensive drug discovery, clinical development and business development activities, both for the cabozantinib franchise and our other product candidates, as well as our general business expansion plans. Our expected future expenses in particular may also be

increased by inflationary pressures, whether resulting from the effects of the ongoing Russo-Ukrainian War or the COVID-19 pandemic or otherwise, which could increase the costs of outside services, labor, raw materials and finished drug product. We expect to continue to spend substantial amounts to fund the continued development of the cabozantinib franchise for additional indications and of our other product candidates, as well as the commercialization of our approved products. In addition, we intend to continue to expand our oncology product pipeline through our drug discovery efforts, including research collaborations, in-licensing arrangements and other strategic transactions that align with our oncology drug development, regulatory and commercial expertise, which efforts could involve substantial costs. To offset these costs in the future, we will need to generate substantial revenues. If these costs exceed our current expectations, or we fail to achieve anticipated revenue targets, the market value of our common stock may decline.

If additional capital is not available to us when we need it, we may be unable to expand our product offerings and maintain business growth.

Our commitment of cash resources to CABOMETYX and the reinvestment in our product pipeline through the continued development of the cabozantinib franchise and our other product candidates, and increasing drug discovery activities, as well as through the execution of business development transactions, could require us to obtain additional capital. We may seek such additional capital through some or all of the following methods: corporate collaborations; licensing arrangements; and public or private debt or equity financings. Our ability to obtain additional capital may depend on prevailing macroeconomic conditions and financial, business and other factors beyond our control. We do not know whether additional capital will be available when needed, or that, if available, we will obtain additional capital on terms favorable to us or our stockholders. If we are unable to raise additional funds when we need them, we may be unable to expand our product offerings and maintain business growth, which could have a material adverse impact on our business, financial condition and results of operations.

Risks Related to Our Relationships with Third Parties

We rely on Ipsen and Takeda for the commercial success of CABOMETYX in its approved indications outside of the U.S., and we are unable to control the amount or timing of resources expended by these collaboration partners in the commercialization of CABOMETYX in its approved indications outside of the U.S.

We rely upon the regulatory, commercial, medical affairs, market access and other expertise and resources of our collaboration partners, Ipsen and Takeda, for commercialization of CABOMETYX in their respective territories outside of the U.S. We cannot control the amount and timing of resources that our collaboration partners dedicate to the commercialization of CABOMETYX, or to its marketing and distribution, and our ability to generate revenues from the commercialization of CABOMETYX by our collaboration partners depends on their ability to obtain and maintain regulatory approvals for, achieve market acceptance of, and to otherwise effectively market, CABOMETYX in its approved indications in their respective territories. If our collaboration partners are unable or unwilling to invest the resources necessary to commercialize CABOMETYX successfully in the EU, Japan and other international territories where it has been approved, this could reduce the amount of revenue we are due to receive under these collaboration agreements, thus resulting in harm to our business and operations.

Our clinical, regulatory and commercial collaborations with major companies make us reliant on those companies for their continued performance and investments, which subjects us to a number of risks.

We have established clinical and commercial collaborations with leading biopharmaceutical companies for the development and commercialization of our products, and our dependence on these collaboration partners subjects us to a number of risks, including, but not limited to:

- our collaboration partners' decision to terminate our collaboration, or their failure to comply with the terms of our collaboration agreements and related ancillary agreements, either intentionally or as a result of negligence or other insufficient performance;
- our inability to control the amount and timing of resources that our collaboration partners devote to the development or commercialization of our products;
- the possibility that our collaboration partners may stop or delay clinical trials, fail to supply us on a timely basis with product required for a combination trial, or deliver product that fails to meet appropriate quality and regulatory standards;

- disputes that may arise between us and our collaboration partners that result in the delay or termination of the development or commercialization of our drug candidates, or that diminish or delay receipt of the economic benefits we are entitled to receive under the collaboration, or that result in costly litigation or arbitration;
- the possibility that our collaboration partners may experience financial difficulties that prevent them from fulfilling their obligations under our agreements;
- our collaboration partners' inability to obtain regulatory approvals in a timely manner, or at all;
- our collaboration partners' failure to comply with legal and regulatory requirements relevant to the authorization, marketing, distribution and supply of our marketed products in the territories outside the U.S. where they are approved; and
- our collaboration partners' failure to properly maintain or defend our intellectual property rights or their use of our intellectual property rights or proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential litigation.

If any of these risks materialize, we may not receive collaboration revenues or otherwise realize anticipated benefits from such collaborations, and our product development efforts and prospects for growth could be delayed or disrupted, all of which could have a material adverse impact on our business, financial condition and results of operations.

Our growth potential is dependent in part upon companies with which we have entered into research collaborations, in-licensing arrangements and similar business development relationships.

To expand our early-stage product pipeline, we have augmented our drug discovery activities with multiple research collaborations and in-licensing arrangements with other companies. Our dependence on our relationships with these research and in-licensing partners subjects us to numerous risks, including, but not limited to:

- our research and in-licensing partners' decision to terminate our relationship, or their failure to comply with the terms of our agreements, either intentionally or as a result of negligent performance;
- disputes that may arise between us and our research and in-licensing partners that result in the delay or termination of research activities with respect to any in-licensed assets or supporting technology platforms;
- the possibility that our research and in-licensing partners may experience financial difficulties that prevent them from fulfilling their obligations under our agreements;
- our research and in-licensing partners' failure to properly maintain or defend their intellectual property rights or their use of third-party intellectual property rights or proprietary information in such a way as to invite litigation that could jeopardize or invalidate our license to develop these assets or utilize technology platforms;
- laws, regulations or practices imposed by countries outside the U.S. that could impact or inhibit scientific research or the development of healthcare products by foreign competitors or otherwise disadvantage healthcare products made by foreign competitors, as well as general political or economic instability in those countries, any of which could complicate, interfere with or impede our relationships with our ex-U.S. research, development and in-licensing partners; and
- our research and in-licensing partners' failure to comply with applicable healthcare laws, as well as established guidelines, laws and regulations related to Good Manufacturing Practice and Good Laboratory Practice.

If any of these risks materialize, we may not be able to expand our product pipeline or otherwise realize a return on the resources we will have invested to develop these early-stage assets, which could have a material adverse impact on our financial condition and prospects for growth.

If third parties upon which we rely to perform clinical trials for cabozantinib in new indications or for new product candidates do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize cabozantinib or other product candidates beyond currently approved indications.

We do not have the ability to conduct clinical trials for cabozantinib or for new potential product candidates independently, so we rely on independent third parties for the performance of these trials, such as the U.S. federal government, third-party contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, or if the third parties must be replaced or if the quality or accuracy of the data they generate or provide is compromised due to their failure to adhere to our clinical trial or data security protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for or commercialize

cabozantinib beyond currently approved indications or obtain regulatory approval for XL092 or our other product candidates. In addition, due to the complexity of our research initiatives, we may be unable to engage with third-party contract research organizations that have the necessary experience and sophistication to help advance our drug discovery efforts, which would impede our ability to identify, develop and commercialize our potential product candidates.

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 own or operate manufacturing or distribution facilities for chemistry, manufacturing and control development activities, preclinical, clinical or commercial production and distribution for our current products and new product candidates. Instead, we 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 continue to expand our supply chain through secondary 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). If our third-party contract manufacturers or data service providers fail to support our efforts to continue to comply with DSCSA and any future federal or state electronic pedigree requirements, we may face legal penalties or be restricted from selling our products.

If third-party scientific advisors and contractors we rely on to assist with our drug discovery efforts do not perform as expected, the expansion of our product pipeline may be delayed.

We work with scientific advisors at academic and other institutions, as well as third-party contractors in various locations throughout the world, that assist us in our research and development efforts, including in drug discovery and preclinical development strategy. These third parties are not our employees and may have other commitments or contractual obligations that limit their availability to us. Although these third-party scientific advisors and contractors generally agree not to do competing work, if a conflict of interest between their work for us and their work for another entity arises, we may lose their services. There has also been increased scrutiny surrounding the disclosures of payments made to medical researchers from companies in the pharmaceutical industry, and it is possible that the academic and other institutions that employ these medical researchers may prevent us from engaging them as scientific advisors and contractors or otherwise limit our access to these experts, or that the scientific advisors themselves may now be more reluctant to work with industry partners. Even if these scientific advisors and contractors with whom we have engaged intend to meet their contractual obligations, their ability to perform services may be impacted by increased demand for such services from other companies or by other external factors, such as reduced capacity to perform services, as we experienced in the early stages of the COVID-19 pandemic. If we experience additional delays in the receipt of services, lose work performed by these scientific advisors and contractors or are unable to engage them in the first place, our discovery and development efforts with respect to the matters on which they were working or would work in the future may be significantly delayed or otherwise adversely affected.

Risks Related to Our Information Technology and Intellectual Property

Data breaches, cyber-attacks and other failures in our information technology operations and infrastructure could compromise our intellectual property or other sensitive information, damage our operations and cause significant harm to our business and reputation.

In the ordinary course of our business, we and our third-party service providers, such as contract research organizations, collect, maintain and transmit sensitive data on our networks and systems, including our intellectual property and proprietary or confidential business information (such as research data and personal information) and confidential information with respect to our customers, clinical trial patients and our collaboration partners. We have also outsourced significant elements of our information technology infrastructure to third parties and, as a result, such third parties may or could have access to our confidential information. The secure maintenance of this information is critical to our business and reputation, and while we have enhanced and are continuing to enhance our cybersecurity efforts commensurate with the growth and complexity of our business, our systems and those of third-party service providers may be vulnerable to a cyber-attack. In addition, we are heavily dependent on the functioning of our information technology infrastructure to carry out our business processes, such as external and internal communications or access to clinical data and other key business information. Accordingly, both inadvertent disruptions to this infrastructure and cyber-attacks could cause us to incur significant remediation or litigation costs, result in product development delays, disrupt critical business operations, expend key information technology resources and divert the attention of management.

Although the aggregate impact of cyber-attacks on our operations and financial condition has not been material to date, we and our third-party service providers have frequently been the target of threats of this nature and expect them to continue. Any future data breach and/or unauthorized access or disclosure of our information or intellectual property could compromise our intellectual property and expose our sensitive business information or sensitive business information of our collaboration partners, which may lead to significant liability for us. A data security breach could also lead to public exposure of personal information of our clinical trial patients, employees or others and result in harm to our reputation and business, compel us to comply with federal and/or state breach notification laws and foreign law equivalents including the GDPR, subject us to investigations and mandatory corrective action, or otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could disrupt our business, result in increased costs or loss of revenue, and/or result in significant financial exposure. Furthermore, the costs of maintaining or upgrading our cybersecurity systems (including the recruitment and retention of experienced information technology professionals, who are in high demand) at the level necessary to keep up with our expanding operations and prevent against potential attacks are increasing, and despite our best efforts, our network security and data recovery measures and those of our third-party service providers may still not be adequate to protect against such security breaches and disruptions, which could cause material harm to our business, financial condition and results of operations.

If we are unable to adequately protect our intellectual property, third parties may be able to use our technology, which could adversely affect our ability to compete in the market.

Our success will depend in part upon our ability to obtain patents and maintain adequate protection of the intellectual property related to our technologies and products. The patent positions of biopharmaceutical companies, including our patent position, are generally uncertain and involve complex legal and factual questions. We will be able to protect our intellectual property rights from unauthorized use by third parties only to the extent that our technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. We will continue to apply for patents covering our technologies and products as, where and when we deem lawful and appropriate. However, these applications may be challenged or may fail to result in issued patents. Our issued patents have been and may in the future be challenged by third parties as invalid or unenforceable under U.S. or foreign laws, or they may be infringed by third parties, and we are from time to time involved in the defense and enforcement of our patents or other intellectual property rights in a court of law, U.S. Patent and Trademark Office *inter partes* review or reexamination proceeding, foreign opposition proceeding or related legal and administrative proceeding in the U.S. and elsewhere. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings and litigation can be substantial and the outcome can be uncertain. An adverse outcome may allow third parties to use our intellectual property without a license and/or allow third parties to introduce generic and other competing products, any of which would negatively impact our business. Third parties may also attempt to invalidate or design around our patents, or assert that they are invalid or otherwise unenforceable, and seek to introduce generic versions of cabozantinib. For example, we received Paragraph IV certification notice letters from MSN and Teva concerning the respective ANDAs that each had filed with the FDA seeking approval to market their respective generic versions of CABOMETYX tablets. Should MSN, Teva or any other third parties receive FDA approval of an ANDA or a 505(b)(2) NDA with respect to cabozantinib, it is possible that such company or

companies could introduce generic versions of our marketed products before our patents expire if they do not infringe our patents or if it is determined that our patents are invalid or unenforceable, and the resulting generic competition could have a material adverse impact on our business, financial condition and results of operations.

In addition, because patent applications can take many years to issue, third parties may have pending applications, unknown to us, which may later result in issued patents that cover the production, manufacture, commercialization or use of our product candidates. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. They may also be negatively impacted by the decisions of foreign courts, which could limit the protection contemplated by the original regulatory approval and our ability to thwart the development of competing products that might otherwise have been determined to infringe our intellectual property rights. Furthermore, others may independently develop similar or alternative technologies or design around our patents. In addition, our patents may be challenged or invalidated or may fail to provide us with any competitive advantages, if, for example, others were the first to invent or to file patent applications for closely related inventions.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the U.S., and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. Many countries, including certain countries in the EU, have compulsory licensing laws based on related EU rules, under which a patent owner may be compelled to grant licenses to third parties (for example, the patent owner has failed to “work” the invention in that country or the third party has patented improvements). In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. Initiatives seeking compulsory licensing of life-saving drugs are also becoming increasingly prevalent in developing countries either through direct legislation or international initiatives. Governments in those developing countries could require that we grant compulsory licenses to allow competitors to manufacture and sell their own versions of our products or product candidates, thereby reducing our product sales. Moreover, the Russian Federation has and may further limit protections on patents originating from “unfriendly countries” (including the U.S.) in response to sanctions relating to the ongoing Russo-Ukrainian War, and in general, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patent and other intellectual property protection, which makes it difficult to stop infringement. We also rely on trade secret protection for some of our confidential and proprietary information, and we are taking security measures to protect our proprietary information and trade secrets, particularly in light of recent instances of data loss and misappropriation of intellectual property in the biopharmaceutical industry. However, these measures may not provide adequate protection, and while we seek to protect our proprietary information by entering into confidentiality agreements with employees, partners and consultants, as well as maintain cybersecurity protocols within our information technology infrastructure, we cannot provide assurance that our proprietary information will not be disclosed, or that we can meaningfully protect our trade secrets. In addition, our competitors may independently develop substantially equivalent proprietary information or may otherwise gain access to our trade secrets.

Litigation or third-party claims of intellectual property infringement could require us to spend substantial time and money and adversely affect our ability to develop and commercialize products.

Our commercial success depends in part upon our ability to avoid infringing patents and proprietary rights of third parties and not to breach any licenses that we have entered into with regard to our technologies and the technologies of third parties. Other parties have filed, and in the future are likely to file, patent applications covering products and technologies that we have developed or intend to develop. If patents covering technologies required by our operations are issued to others, we may have to obtain licenses from third parties, which may not be available on commercially reasonable terms, or at all, and may require us to pay substantial royalties, grant a cross-license to some of our patents to another patent holder or redesign the formulation of a product candidate so that we do not infringe third-party patents, which may be impossible to accomplish or could require substantial time and expense. In addition, we may be subject to claims that our employees or independent contractors have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that they used or sought to use patent inventions belonging to their former employers. Furthermore, third parties may obtain patents that relate to our technologies and claim that use of such technologies infringes on their patents or otherwise employs their proprietary technology without authorization. Regardless of their merit, such claims could require us to incur substantial costs and divert the attention of management and key technical personnel in defending ourselves against any such claims or enforcing our own patents. In the event of any third party’s successful claim of patent infringement or misappropriation of trade secrets, we may lose valuable intellectual property rights or personnel, which could impede or prevent the achievement of our product development goals, or we may be required to pay damages and obtain one or more licenses from these third parties, subjecting us to substantial

royalty payment obligations. We may not be able to obtain these licenses on commercially reasonable terms, or at all. Defense of any lawsuit or failure to obtain any of these licenses could adversely affect our ability to develop and commercialize products.

Risks Related to Our Operations, Managing Our Growth and Employee Matters

If the COVID-19 pandemic is further prolonged or becomes more severe, our business operations and corresponding financial results could suffer, which could have a material adverse impact on our financial condition and prospects for growth.

To date, the COVID-19 pandemic has had a modest impact on our business operations, in particular with respect to our clinical trial, drug discovery and commercial activities. For example, to varying degrees and at different rates across our clinical trials, we experienced declines in screening and enrollment activity during the early days of the COVID-19 pandemic, as well as delays in new site activations and restrictions on the access to treatment sites that is necessary to monitor clinical study progress and administration. As the COVID-19 pandemic continues to have a significant presence in various parts of the world, particularly with the potential emergence of new variants that may prove especially contagious or virulent, the impact on our clinical development operations could continue or grow more severe. We anticipate that a further prolonged, or more severe, global public health crisis could limit our ability to identify and work with clinical investigators at clinical trial sites globally to enroll, initiate and maintain treatment per protocol of patients for our ongoing clinical trials. Disruptions to medical and administrative operations at clinical trial sites, including staffing and materials shortages and the implementation of crisis management initiatives, have and may continue to reduce personnel and other resources necessary to conduct our clinical trials, which could further delay some of our clinical trial plans or may require certain trials to be temporarily suspended. In addition, increased costs connected with our efforts to mitigate the adverse impacts resulting from the COVID-19 pandemic on our clinical trials could cause the expenses we incur in conducting those clinical trials to increase considerably. Depending upon the duration and severity of the COVID-19 pandemic, we could also experience delays in planning and conducting new clinical trials of the investigative product candidates entering and advancing through our development pipeline, which could increase the operating expenses associated with these trials and adversely affect their timelines for completion and ultimately our ability to obtain regulatory approvals.

Both drug discovery work in our laboratories and outsourced drug discovery activities have fully resumed following temporary suspensions during the early days of the COVID-19 pandemic; however, we may be unable to maximize the potential of these programs due to the imposition of increased safety protocols, and should the effects of the COVID-19 pandemic become more severe, we may have to again scale back or suspend activities in the future. We are also reliant on laboratory materials manufactured and distributed from areas impacted by both the COVID-19 pandemic and other natural disasters, for which supply has become limited. If we are unable to obtain the requisite materials to conduct our planned drug discovery activities, we may be required to redirect the focus of, or even suspend, such activities. Should the COVID-19 pandemic be further prolonged or grow in severity, we may ultimately be unable to achieve our drug discovery and preclinical development objectives within the previously disclosed timelines, which could have a material adverse impact on our prospects for growth.

In addition, it remains possible that the evolving dynamics of the COVID-19 pandemic may require further modifications to our standard sales and marketing practices, including shifts from in-person back to primarily telephonic and virtual interactions with healthcare professionals. Such changes in our commercial operations could negatively impact the flow of important information regarding our medicines, which along with obstacles to patient access to healthcare professionals, could diminish sales of our marketed products.

These continuing or future effects of the COVID-19 pandemic could materially and adversely affect our business, financial condition, results of operations and growth prospects, and exacerbate the other risks and uncertainties described elsewhere in this ‘‘Risk Factors’’ section.

If we are unable to manage our growth, there could be a material adverse impact on our business, financial condition and results of operations, and our prospects may be adversely affected.

We have experienced and expect to continue to experience growth in the number of our employees and in the scope of our operations, in particular as we continue to expand the cabozantinib franchise into new indications and grow our pipeline of product candidates. This growth places significant demands on our management and resources, and our current and planned personnel and operating practices may not be adequate to support our growth. To effectively manage our growth, we must continue to improve existing, and implement new, facilities, operational and financial systems, and procedures and controls, as well as expand, train and manage our growing employee base, and there can be no assurance

that we will effectively manage our growth without experiencing operating inefficiencies or control deficiencies. We continue to increase our management personnel to oversee our expanding operations, and recruiting and retaining qualified individuals is difficult. If we are unable to manage our growth effectively, or we are unsuccessful in recruiting qualified management personnel, there could be a material adverse impact on our business, financial condition and results of operations.

The loss of key personnel or the inability to retain and, where necessary, attract additional personnel could impair our ability to operate and expand our operations.

We are highly dependent upon the principal members of our management, as well as clinical, commercial and scientific staff, the loss of whose services might adversely impact the achievement of our objectives. Also, we may not have sufficient personnel to execute our business plans. Retaining and, where necessary, recruiting qualified clinical, commercial, scientific and pharmaceutical operations personnel will be critical to support activities related to advancing the development programs for the cabozantinib franchise and our other product candidates, successfully executing upon our commercialization plan for the cabozantinib franchise and our proprietary research and development efforts. Competition is intense for experienced clinical, commercial, scientific and pharmaceutical operations personnel, and we may be unable to retain or recruit such personnel with the expertise or experience necessary to allow us to successfully develop and commercialize our products. Further, all of our employees are employed “at will” and, therefore, may leave our employment at any time.

Risks Related to Environmental and Product Liability

We use hazardous chemicals and biological materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our research and development processes involve the controlled use of hazardous materials, including chemicals and biological materials, and our operations can produce hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge, or any resultant injury from these materials, and we may face liability under applicable laws for any injury or contamination that results from our use or the use by our collaboration partners or other third parties of these materials. Such liability may exceed our insurance coverage and our total assets, and in addition, we may be required to indemnify our collaboration partners against all damages and other liabilities arising out of our development activities or products produced in connection with our collaborations with them. Moreover, our continued compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development and production efforts.

We face potential product liability exposure far in excess of our limited insurance coverage.

We may be held liable if any product we or our collaboration partners develop or commercialize causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing or sale. Regardless of merit or eventual outcome, product liability claims could result in decreased demand for our products and product candidates, injury to our reputation, withdrawal of patients from our clinical trials, product recall, substantial monetary awards to third parties and the inability to commercialize any products that we may develop in the future. We maintain limited product liability insurance coverage for our clinical trials and commercial activities for cabozantinib. However, our insurance may not be sufficient to reimburse us for expenses or losses we may suffer. Moreover, if insurance coverage becomes more expensive, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability.

Risks Related to Our Common Stock

Our stock price has been and may in the future be highly volatile.

The trading price of our common stock has been highly volatile, and it may remain highly volatile or fluctuate substantially due to factors such as the following, many of which we cannot control:

- the announcement of FDA or other regulatory approval or non-approval, or delays in the FDA or other regulatory review process with respect to cabozantinib, XL092 or our other product candidates, our collaboration partners’ product candidates being developed in combination with either cabozantinib, XL092 or our other product candidates, or our competitors’ product candidates;
- the commercial performance of both CABOMETYX and COMETRIQ and the revenues we generate from those approved products, including royalties paid under our collaboration and license agreements;

- adverse or inconclusive results or announcements related to our or our collaboration partners' clinical trials or delays in those clinical trials;
- the timing of achievement of our clinical, regulatory, partnering, commercial and other milestones for the cabozantinib franchise, XL092 or any of our other product candidates or programs;
- our ability to make future investments in the expansion of our pipeline through drug discovery, including future research collaborations, in-licensing arrangements and other strategic transactions;
- our ability to obtain the materials and services, including an adequate product supply for any approved drug product, from our third-party vendors or do so at acceptable prices;
- the timing and amount of expenses incurred for clinical development and manufacturing of cabozantinib, XL092 and our other product candidates;
- actions taken by regulatory agencies, both in the U.S. and abroad, with respect to cabozantinib or our clinical trials for cabozantinib, XL092 or our other product candidates;
- unanticipated regulatory actions taken by the FDA as a result of changing FDA standards and practices concerning the review of product candidates, including approvals at earlier stages of clinical development or with lesser developed data sets and expedited reviews;
- the announcement of new products or clinical trial data by our competitors;
- the announcement of regulatory applications, such as MSN's and Teva's respective ANDAs, seeking approval of generic versions of our marketed products;
- quarterly variations in our or our competitors' results of operations;
- changes in our relationships with our collaboration partners, including the termination or modification of our agreements, or other events or conflicts that may affect our collaboration partners' timing and willingness to develop, or if approved, commercialize our products and product candidates out-licensed to them;
- the announcement of an in-licensed product candidate or strategic acquisition;
- litigation, including intellectual property infringement and product liability lawsuits, involving us;
- changes in earnings estimates or recommendations by securities analysts, or financial guidance from our management team, and any failure to achieve the operating results projected by securities analysts or by our management team;
- the entry into new financing arrangements;
- developments in the biopharmaceutical industry;
- sales of large blocks of our common stock or sales of our common stock by our executive officers, directors and significant stockholders;
- additions and departures of key personnel or board members;
- the disposition of any of our technologies or compounds; and
- general market, macroeconomic and political conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

These and other factors could have material adverse impact on the market price of our common stock. In addition, the stock markets in general, and the markets for biotechnology and pharmaceutical stocks in particular, have historically experienced significant volatility that has often been unrelated or disproportionate to the operating performance of particular companies. Likewise, as a result of significant changes in U.S. or global political and macroeconomic conditions, including historically high inflation, as well as policies governing foreign trade and healthcare spending and delivery, or the ongoing Russo-Ukrainian War, the financial markets could continue to experience significant volatility that could also continue to negatively impact the markets for biotechnology and pharmaceutical stocks. These broad market fluctuations have adversely affected and may in the future adversely affect the trading price of our common stock. Excessive volatility may continue for an extended period of time following the date of this report.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been initiated. A securities class action suit against us could result in substantial costs and divert the attention of management, which could have a material adverse impact on our business, financial condition and results of operations.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent or deter attempts by our stockholders to replace or remove our current management, which could cause the market price of our common stock to decline.

Provisions in our corporate charter and bylaws may discourage, delay or prevent an acquisition of us, a change in control, or attempts by our stockholders to replace or remove members of our current Board of Directors. Because our Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include:

- a prohibition on actions by our stockholders by written consent;
- the ability of our Board of Directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our Board of Directors; and
- advance notice requirements for director nominations and stockholder proposals.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

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

		Incorporation by Reference				
Exhibit Number	**Exhibit Description**	**Form**	**File Number**	**Exhibit/ Appendix Reference**	**Filing Date**	**Filed Herewith**
3.1	Restated Certificate of Incorporation of Exelixis, Inc.	10-Q	000-30235	3.1	8/5/2021	
3.2	Amended and Restated Bylaws of Exelixis, Inc.	8-K	000-30235	3.1	3/3/2021	
10.1	Cash Compensation Information for Non-Employee Directors					X
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

Exhibit Number	Exhibit Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit/ Appendix Reference	Filing Date	
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.

November 1, 2022
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 10.1

CASH COMPENSATION INFORMATION FOR NON-EMPLOYEE DIRECTORS

Exelixis, Inc.
Cash Compensation for Non-Employee Directors

Board of Directors	Retainer Fee	$55,000
	Additional Chair Retainer Fee	$31,000
	Meeting Fee[12]	$2,500
Audit Committee	Retainer Fee	$12,000
	Additional Chair Retainer Fee	$13,000
	Meeting Fee[13]	$1,000
Compensation Committee	Retainer Fee	$10,000
	Additional Chair Retainer Fee	$10,000
	Meeting Fee[13]	$1,000
Nominating and Corporate Governance Committee	Retainer Fee	$5,000
	Additional Chair Retainer Fee	$10,000
	Meeting Fee[14]	$1,000
Research & Development Committee	Retainer Fee	$5,000
	Additional Chair Retainer Fee	$10,000
	Meeting Fee[14]	$1,000
Risk Committee	Retainer Fee	$5,000
	Additional Chair Retainer Fee	$10,000
	Meeting Fee[14]	$1,000

[1]Meetings for which minutes are generated count toward the meeting threshold to determine when Meeting Fees are to be paid.
[2]Meeting Fee paid for all meetings in excess of eight meetings.
[3]Meeting Fee paid for all meetings in excess of seven meetings.
[4]Meeting Fee paid for all meetings in excess of four meetings.

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: November 1, 2022

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: November 1, 2022

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 September 30, 2022, 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 1st day of November 2022.

/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)