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 October 2, 2020

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 26, 2020, there were 310,243,961 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	3
	Condensed Consolidated Statements of Income (Loss)	4
	Condensed Consolidated Statements of Comprehensive Income (Loss)	4
	Condensed Consolidated Statements of Stockholders' Equity	5
	Condensed Consolidated Statements of Cash Flows	7
	Notes to Condensed Consolidated Financial Statements	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	36
Item 4.	Controls and Procedures	36
	PART II - OTHER INFORMATION	
Item 1.	Legal Proceedings	37
Item 1A.	Risk Factors	37
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, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 334,046	$ 266,501
Short-term investments	853,835	585,742
Trade receivables, net	166,138	119,073
Inventory	19,319	12,886
Prepaid expenses and other current assets	34,470	26,988
Total current assets	1,407,808	1,011,190
Long-term investments	358,079	536,385
Property and equipment, net	56,385	48,892
Deferred tax assets, net	155,678	172,374
Goodwill	63,684	63,684
Other long-term assets	69,409	53,145
Total assets	$ 2,111,043	$ 1,885,670
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 47,927	$ 11,581
Accrued compensation and benefits	40,782	37,364
Accrued clinical trial liabilities	47,074	38,777
Rebates and fees due to customers	19,129	18,719
Accrued collaboration liabilities	11,102	11,856
Other current liabilities	35,329	24,449
Total current liabilities	201,343	142,746
Long-term portion of deferred revenues	9,322	6,596
Long-term portion of operating lease liabilities	47,626	48,011
Other long-term liabilities	721	2,347
Total liabilities	259,012	199,700
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: 309,402 and 304,831 at September 30, 2020 and December 31, 2019, respectively	309	305
Additional paid-in capital	2,321,441	2,241,947
Accumulated other comprehensive income	6,239	3,069
Accumulated deficit	(475,958)	(559,351)
Total stockholders' equity	1,852,031	1,685,970
Total liabilities and stockholders' equity	$ 2,111,043	$ 1,885,670

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues:				
Net product revenues	$ 168,587	$ 191,768	$ 541,197	$ 565,024
License revenues	33,205	69,137	113,318	132,443
Collaboration services revenues	29,300	10,798	62,971	29,998
Total revenues	231,092	271,703	717,486	727,465
Operating expenses:				
Cost of goods sold	8,725	7,537	27,235	22,577
Research and development	176,762	97,295	393,572	242,516
Selling, general and administrative	88,185	51,265	210,916	170,218
Total operating expenses	273,672	156,097	631,723	435,311
Income (loss) from operations	(42,580)	115,606	85,763	292,154
Interest income	3,994	7,191	16,376	20,253
Other income (expense), net	565	(140)	571	688
Income (loss) before income taxes	(38,021)	122,657	102,710	313,095
Provision for (benefit from) income taxes	(5,981)	25,205	19,317	60,826
Net income (loss)	$ (32,040)	$ 97,452	$ 83,393	$ 252,269
Net income (loss) per share:				
Basic	$ (0.10)	$ 0.32	$ 0.27	$ 0.84
Diluted	$ (0.10)	$ 0.31	$ 0.26	$ 0.80
Weighted-average common shares outstanding:				
Basic	309,116	303,268	307,437	301,999
Diluted	309,116	315,453	317,495	315,046

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net income (loss)	$ (32,040)	$ 97,452	$ 83,393	$ 252,269
Other comprehensive income (loss):				
Net unrealized gains (losses) on available-for-sale debt securities, net of tax impact of $453, $(129), $(893) and $(936), respectively	(1,601)	461	3,170	3,369
Comprehensive income (loss)	$ (33,641)	$ 97,913	$ 86,563	$ 255,638

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, 2020					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at June 30, 2020	308,886	$ 309	$2,269,093	$ 7,840	$ (443,918)	$ 1,833,324
Net loss	—	—	—	—	(32,040)	(32,040)
Other comprehensive loss	—	—	—	(1,601)	—	(1,601)
Issuance of common stock under equity incentive and stock purchase plans	516	—	1,872	—	—	1,872
Stock transactions associated with taxes withheld on equity awards	—	—	(5,179)	—	—	(5,179)
Stock-based compensation	—	—	55,655	—	—	55,655
Balance at September 30, 2020	309,402	$ 309	$2,321,441	$ 6,239	$ (475,958)	$ 1,852,031

	Three Months Ended September 30, 2019					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at June 30, 2019	302,785	$ 303	$2,211,668	$ 2,207	$ (725,546)	$ 1,488,632
Net income	—	—	—	—	97,452	97,452
Other comprehensive income	—	—	—	461	—	461
Issuance of common stock under equity incentive and stock purchase plans	991	1	4,967	—	—	4,968
Stock transactions associated with taxes withheld on equity awards	—	—	(935)	—	—	(935)
Stock-based compensation	—	—	13,139	—	—	13,139
Balance at September 30, 2019	303,776	$ 304	$2,228,839	$ 2,668	$ (628,094)	$ 1,603,717

Continued on next page

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

	Nine Months Ended September 30, 2020					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2019	304,831	$ 305	$2,241,947	$ 3,069	$ (559,351)	$ 1,685,970
Net income	—	—	—	—	83,393	83,393
Other comprehensive income	—	—	—	3,170	—	3,170
Issuance of common stock under equity incentive and stock purchase plans	4,571	4	19,823	—	—	19,827
Stock transactions associated with taxes withheld on equity awards	—	—	(26,120)	—	—	(26,120)
Stock-based compensation	—	—	85,791	—	—	85,791
Balance at September 30, 2020	309,402	$ 309	$2,321,441	$ 6,239	$ (475,958)	$ 1,852,031

	Nine Months Ended September 30, 2019					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2018	299,876	$ 300	$2,168,217	$ (701)	$ (880,363)	$ 1,287,453
Net income	—	—	—	—	252,269	252,269
Other comprehensive income	—	—	—	3,369	—	3,369
Issuance of common stock under equity incentive and stock purchase plans	3,900	4	23,244	—	—	23,248
Stock transactions associated with taxes withheld on equity awards	—	—	(3,369)	—	—	(3,369)
Stock-based compensation	—	—	40,747	—	—	40,747
Balance at September 30, 2019	303,776	$ 304	$2,228,839	$ 2,668	$ (628,094)	$ 1,603,717

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,	
	2020	**2019**
Net income	$ 83,393	$ 252,269
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	6,731	6,088
Stock-based compensation	85,791	40,747
Non-cash lease expense	3,607	1,803
Deferred taxes	15,803	56,339
Other, net	1,609	(621)
Changes in operating assets and liabilities:		
Trade receivables, net	(47,074)	(7,017)
Inventory	(13,466)	(3,528)
Prepaid expenses and other assets	(15,868)	(14,108)
Deferred revenue	4,012	3,592
Accounts payable and other liabilities	51,151	33,371
Net cash provided by operating activities	175,689	368,935
Cash flows from investing activities:		
Purchases of property, equipment and other	(16,055)	(5,575)
Purchases of investments	(866,975)	(887,698)
Proceeds from maturities and sales of investments	781,324	436,227
Net cash used in investing activities	(101,706)	(457,046)
Cash flows from financing activities:		
Proceeds from issuance of common stock under equity incentive and stock purchase plans	19,682	18,956
Taxes paid related to net share settlement of equity awards	(26,120)	(3,369)
Other, net	—	(34)
Net cash (used in) provided by financing activities	(6,438)	15,553
Net increase (decrease) in cash, cash equivalents and restricted cash	67,545	(72,558)
Cash, cash equivalents and restricted cash at beginning of period	268,137	315,875
Cash, cash equivalents and restricted cash at end of period	$ 335,682	$ 243,317
Supplemental cash flow disclosures:		
Right-of-use assets obtained in exchange for lease obligations	$ 1,824	$ 12,944
Unpaid liabilities incurred for purchases of property and equipment	$ 843	$ 159
Unpaid liabilities incurred to acquire investments	$ —	$ 8,961

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 difficult-to-treat cancers. Our drug discovery and development capabilities and commercialization platform are the foundations upon which we intend to bring to market novel, effective and tolerable therapies to provide cancer patients with additional treatment options.

Since we were founded in 1994, four products resulting from our discovery efforts have progressed through clinical development, received regulatory approval and established a commercial presence in various geographies around the world. Two are derived from cabozantinib, our flagship molecule, an inhibitor of multiple tyrosine kinases including MET, AXL, VEGF receptors and RET. Our cabozantinib products are: CABOMETYX® (cabozantinib) tablets approved for advanced renal cell carcinoma (RCC) and previously treated hepatocellular carcinoma; and COMETRIQ® (cabozantinib) capsules approved for progressive, metastatic medullary thyroid cancer. For these types of cancer, cabozantinib has become or is becoming a standard of care. Beyond these approved indications, cabozantinib is currently the focus of a broad clinical development program and is being investigated both alone and in combination with other therapies in a wide variety of cancers.

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).

We also remain committed to building our product pipeline by discovering and developing new therapies for cancer patients. Using our in-house drug discovery expertise, specifically in medicinal chemistry, tumor biology and pharmacology, we are advancing small molecule drug candidates toward and through preclinical development. In addition, we have augmented our internal drug discovery activities with multiple partnerships, including several that enable us to discover and advance various biologics, such as bispecific antibodies and antibody-drug conjugates (ADCs), and we continue to engage in business development initiatives aimed at identifying and in-licensing promising, early-stage oncology assets, which we can further develop utilizing our established clinical development infrastructure.

Basis of Presentation

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

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the U.S. for interim financial information and pursuant to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (SEC). Accordingly, they do not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements. In our opinion, all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation of our financial statements for the periods presented have been included. Operating results for the three and nine months ended September 30, 2020 are not necessarily indicative of the results that may be expected for the year ending December 31, 2020 or for any future period. The accompanying Condensed Consolidated Financial Statements and Notes thereto should be read in conjunction with our Consolidated Financial Statements and Notes thereto for the year ended December 31, 2019, included in our Annual Report on Form 10-K filed with the SEC on February 25, 2020.

We have adopted a 52- or 53-week fiscal year policy that generally ends on the Friday closest to December 31st. Fiscal year 2020, which is a 52-week fiscal year, will end on January 1, 2021 and fiscal year 2019, which was a 53-week fiscal year, ended on January 3, 2020. For convenience, references in this report as of and for the fiscal periods ended October 2, 2020 and September 27, 2019, and as of and for the fiscal years ending January 1, 2021, and ended January 3, 2020, are indicated as being as of and for the fiscal periods ended September 30, 2020 and September 30, 2019 and the years ending

December 31, 2020 and ended December 31, 2019, respectively. Similarly, references in this report to the first day of the fiscal year ending January 1, 2021 are indicated as being as of January 1, 2020.

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.

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. 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.

In March 2020, we received the Preliminary Calculation of our Branded Prescription Drug Fee for 2020, and in August 2020, the Final Calculation of our Branded Prescription Drug Fee for 2020 from the Internal Revenue Service for the 2018 sales year, which resulted in an increase in our estimate of such fees for the 2018 and 2019 sales years. Accordingly, we recorded an adjustment to increase selling, general and administrative expenses and our accrual for these fees by $5.1 million during the nine months ended September 30, 2020. This adjustment resulted in a $0.02 decrease in basic and diluted earnings per share for the nine months ended September 30, 2020.

Recently Adopted Accounting Pronouncements

On January 1, 2020, we adopted Accounting Standards Update (ASU) No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606* (ASU 2018-18). ASU 2018-18 clarifies that certain transactions between collaborative arrangement participants should be accounted for as part of revenues under Accounting Standards Codification (ASC) Topic 606, *Revenue from Contracts with Customers* (Topic 606) when the counterparty is a customer for a distinct good or service (i.e. a unit of account). For units of account that are in the scope of Topic 606, all of the guidance in Topic 606 should be applied, including the guidance on recognition, measurement, presentation and disclosure. ASU 2018-18 precludes entities from presenting amounts related to transactions with a counterparty in a collaborative arrangement that is not a customer together with revenue from contracts with customers. If a portion of a distinct bundle of goods or services within an arrangement is not with a customer, then the unit of account is not within the scope of Topic 606, and the recognition and measurement of that unit of account shall be based on analogy to authoritative accounting literature or, if there is no appropriate analogy, a reasonable, rational, and consistently applied accounting policy election. Upon adoption of ASU 2018-18, we have presented revenues from performance obligations associated with our collaboration arrangements that are within the scope of Topic 606 (license revenues) separately from revenues from performance obligations that are not subject to Topic 606 (collaboration services revenues). The adoption of ASU 2018-18 was applied retrospectively, and prior periods have been restated to conform to the presentation prescribed by ASU 2018-18. The adoption of ASU 2018-18 did not impact total revenues for the prior period presented in the accompanying Condensed Consolidated Statements of Income.

On January 1, 2020, we adopted ASU No. 2017-04, *Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment* (ASU 2017-04). ASU 2017-04 simplifies goodwill impairment testing by eliminating the second

step of the impairment test. The amended guidance requires an impairment charge to be recognized for the amount by which the carrying amount of a reporting unit exceeds its fair value under a one-step impairment test. The adoption of ASU 2017-04 did not impact the accompanying Condensed Consolidated Financial Statements.

On January 1, 2020, we adopted ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326)* (ASU 2016-13). ASU 2016-13 implements an impairment model, known as the current expected credit loss model, that is based on expected losses rather than incurred losses. Under the new guidance, we will recognize our estimate of current expected credit losses as an allowance on financial assets measured at amortized cost, including accounts receivable, unbilled collaboration revenues, and investments classified as available for sale. Current expected credit losses were immaterial as of the date of adoption, and the adoption of ASU 2016-13 did not have a significant impact on the accompanying Condensed Consolidated Financial Statements.

Investment Impairment

Quarterly, we assess each of our investments in debt securities available-for-sale whose fair value is below its cost basis to determine if the investment's impairment is due to credit-related factors or noncredit-related factors. Factors considered in determining whether an impairment is credit-related include the extent to which the investment's fair value is less than its cost basis, declines in published credit ratings, issuer default on interest or principal payments, and declines in the financial condition and near-term prospects of the issuer. If we determine a credit-related impairment exists, we will measure the credit loss based on a discounted cash flows model. Credit-related impairments on debt securities available-for-sale are recognized as an allowance for credit losses with a corresponding adjustment to other income, net in the accompanying Condensed Consolidated Statements of Income. The portion of the impairment that is not credit-related is recorded, net of applicable taxes, as a reduction of other comprehensive income.

We have elected to exclude accrued interest from both the fair value and the amortized cost basis of debt securities available-for-sale for the purposes of identifying and measuring an impairment. We write-off accrued interest as a reduction of interest income when an issuer has defaulted on interest payments due on a security.

Accounts Receivable

Trade receivables, net contain amounts billed to our customers for product sales, and amounts billed to our collaboration partners for development, regulatory and sales-based milestone payments, royalties on the sale of licensed products, profit-sharing arrangements, development cost reimbursements, and payments for product supply services. Our customers are primarily pharmaceutical and biotechnology companies that are located in the U.S., and collaboration partners that are located in Europe and Japan. As of September 30, 2020 and December 31, 2019, 47% and 38%, respectively, of our trade receivables were from our collaboration partner Ipsen Pharma SAS (Ipsen), and 12% and 14% were from affiliates of McKesson Corporation. We record trade receivables net of allowances for credit losses and chargebacks, and cash discounts for prompt payment. We apply an aging method to estimate credit losses and consider our historical loss information, adjusted to account for current conditions, and reasonable and supportable forecasts of future economic conditions affecting our customers.

Goodwill

We recorded goodwill amounts as the excess purchase price over tangible assets, liabilities and intangible assets acquired based on their estimated fair value. We review the carrying amount of goodwill for impairment annually and whenever events or changes in circumstance indicate that the carrying value may not be recoverable. We perform our annual assessment of the recoverability of our goodwill as of the first day of our fourth quarter. The assessment of recoverability may first consider qualitative factors to determine whether the existence of events or circumstances leads to a determination that it is more likely than not that the fair value of a reporting unit is less than its carrying amount. We perform a quantitative assessment if the qualitative assessment results in a more likely than not determination or if a qualitative assessment is not performed. The quantitative assessment determines whether the carrying amount of a reporting unit exceeds its fair value, in which case an impairment charge is recognized for the amount by which the carrying amount of a reporting unit exceeds its fair value, limited to the goodwill balance. We operate in one business segment, which is also considered to be our sole reporting unit and therefore, goodwill is tested for impairment at the enterprise level. We did not recognize any impairment charges in any of the periods presented.

Collaboration Agreements

We assess whether our collaboration agreements are subject to ASC Topic 808, *Collaborative Arrangements* (Topic 808) based on whether they involve joint operating activities and whether both parties have active participation in the arrangement and are exposed to significant risks and rewards. To the extent that the arrangement falls within the scope of Topic 808, we apply by analogy the unit of account guidance under Topic 606 to identify distinct performance obligations, and then determine whether a customer relationship exists for each distinct performance obligation. If we determine a performance obligation within the arrangement is with a customer, we apply the guidance in Topic 606. If a portion of a distinct bundle of goods or services within an arrangement is not with a customer, then the unit of account is not within the scope of Topic 606, and the recognition and measurement of that unit of account shall be based on analogy to authoritative accounting literature or, if there is no appropriate analogy, a reasonable, rational, and consistently applied accounting policy election.

We enter into collaboration arrangements, under which we license certain rights to our intellectual property to third parties. The terms of these arrangements typically include payments to us for one or more of the following: nonrefundable up-front license fees; development, regulatory and sales-based milestone payments; product supply services; development cost reimbursements; profit-sharing arrangements; and royalties on net sales of licensed products. As part of the accounting for these arrangements, we develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. These key assumptions may include forecasted revenues, clinical development timelines and costs, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

Up-front License Fees: If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from nonrefundable up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license, which generally occurs at or near the inception of the contract. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenues from nonrefundable up-front fees. We evaluate the measure of progress at the end of each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Regulatory and Development Milestone Payments: At the inception of each arrangement that includes development milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until uncertainty associated with the approvals has been resolved. The transaction price is then allocated to each performance obligation, on a relative standalone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achieving such development and regulatory milestones and any related variable consideration constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis.

Product Supply Services: Arrangements that include a promise for the future supply of drug product for either clinical development or commercial supply at the licensee's discretion are generally considered as options. We assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations.

Development Cost Reimbursements: Our collaboration arrangements may include promises of future clinical development and drug safety services, as well as participation on certain joint committees. When such services are provided to a customer, and they are distinct from the licenses provided to our collaboration partners, these promises are accounted for as a separate performance obligation which we estimate using internal development costs incurred and projections through the term of the arrangements. We record revenues for these services as the performance obligations are satisfied over time based on measure of progress. However, if we conclude that our collaboration partner is not a customer for those collaborative research and development activities, we present such payments as a reduction of research and development expenses.

Profit-sharing Arrangements: Under the terms of our collaboration agreement with Genentech for cobimetinib, we are entitled to a share of U.S. profits and losses received in connection with the commercialization of cobimetinib. We

account for this arrangement in accordance with Topic 606. We have determined that we are an agent under the agreement and therefore revenues are recorded net of costs incurred. We record revenues for the variable consideration associated with the profits and losses under the collaboration agreement when it is probable that a significant reversal in the amount of cumulative revenues recognized will not occur.

Royalty and Sales-based Milestone Payments: For arrangements that include royalties and sales-based milestone payments, including milestone payments earned for the first commercial sale of a product, the license is deemed to be the predominant item to which such payments relate and we recognize revenues at the later of when the related sales occur or when the performance obligation to which the royalty has been allocated has been satisfied.

Recent Accounting Pronouncements Not Yet Adopted

In December 2019, the Financial Accounting Standards Board issued ASU 2019-12, *Income Taxes (Topic 740)-Simplifying the Accounting for Income Taxes* (ASU 2019-12). ASU 2019-12 simplifies the accounting for income taxes by removing certain exceptions to the general principles in ASC Topic 740, *Income Taxes* and clarifying and amending existing guidance. ASU 2019-12 will be effective for us in the first quarter of 2021 with early adoption permitted. We are currently assessing the impact of ASU 2019-12 on our financial statements.

NOTE 2. REVENUES

Revenues consisted of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Product revenues:				
Gross product revenues	$ 220,401	$ 239,916	$ 702,865	$ 704,084
Discounts and allowances	(51,814)	(48,148)	(161,668)	(139,060)
Net product revenues	168,587	191,768	541,197	565,024
Collaboration revenues:				
License revenues	33,205	69,137	113,318	132,443
Collaboration services revenues	29,300	10,798	62,971	29,998
Total collaboration revenues	62,505	79,935	176,289	162,441
Total revenues	$ 231,092	$ 271,703	$ 717,486	$ 727,465

Net product revenues and license revenues are recorded in accordance with Topic 606. License revenues include the recognition of the portion of milestones 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 Topic 808 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 to GlaxoSmithKline (GSK) 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,	
	2020	2019	2020	2019
CABOMETYX	$ 159,555	$ 187,410	$ 522,381	$ 552,315
COMETRIQ	9,032	4,358	18,816	12,709
Net product revenues	$ 168,587	$ 191,768	$ 541,197	$ 565,024

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,	
	2020	2019	2020	2019
Ipsen	16 %	28 %	16 %	17 %
Affiliates of CVS Health Corporation	14 %	13 %	15 %	15 %
Affiliates of McKesson Corporation	12 %	12 %	13 %	12 %
Affiliates of AmerisourceBergen Corporation	11 %	9 %	11 %	10 %
Affiliates of Optum Specialty Pharmacy	10 %	7 %	11 %	8 %
Takeda Pharmaceutical Company Limited (Takeda)	10 %	0 %	7 %	2 %

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
U.S.	$ 171,552	$ 194,484	$ 549,379	$ 572,957
Europe	36,006	76,017	117,959	120,134
Japan	23,534	1,202	50,148	34,374
Total revenues	$ 231,092	$ 271,703	$ 717,486	$ 727,465

Net product revenues are attributed to geographic region based on the ship-to location. License and collaboration services revenues are attributed to geographic region based on the location of our collaboration partners' headquarters.

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 and Discounts for Prompt Payment	Other Customer Credits/Fees and Co-pay Assistance	Rebates	Total
Balance at December 31, 2019	$ 7,514	$ 3,497	$ 15,222	$ 26,233
Provision related to sales made in:				
Current period	108,166	11,718	41,351	161,235
Prior periods	33	(352)	752	433
Payments and customer credits issued	(107,118)	(11,513)	(41,546)	(160,177)
Balance at September 30, 2020	$ 8,595	$ 3,350	$ 15,779	$ 27,724

The allowance for chargebacks and discounts for prompt payment is 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 revenues in advance of the contractual billing schedule and such amounts are recorded, net of any allowance for credit losses, as a contract asset when recognized. Contract assets, which are presented in prepaid expenses and other current assets in the accompanying Condensed Consolidated Balance Sheets, were $0 and $1.1 million as of September 30, 2020 and December 31, 2019, respectively. We may be required to defer recognition of revenues for upfront and milestone payments until we perform our obligations under these arrangements, and such amounts are recorded as deferred revenues upon receipt or when due. Contract liabilities were $10.6 million and $6.6 million as of September 30, 2020 and

December 31, 2019, respectively. The current portion of the contract liabilities totaling $1.3 million and $0 as of September 30, 2020 and December 31, 2019, respectively, are presented in other current liabilities and the remainder of the contract liabilities are presented in long-term portion of deferred revenues as of those dates in the accompanying Condensed Consolidated Balance Sheets. For those contracts that have multiple performance obligations, contract assets and liabilities are reported on a net basis at the contract level.

Significant changes in contract assets during the nine months ended September 30, 2020 include the impact of a $20.0 million development milestone from Ipsen we determined was probable of achievement, which was offset by the impact of a $10.0 million milestone from Takeda which was recognized as revenues during the year ended December 31, 2019 and was achieved, invoiced and collected in the first quarter of 2020.

During the nine months ended September 30, 2020 and 2019, we recognized $6.8 million and $2.7 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, 2020, we recognized $33.1 million and $115.3 million, respectively, in revenues for performance obligations satisfied in previous periods as compared to $67.7 million and $129.0 million during the comparable periods in 2019. Such revenues primarily related to milestone and royalty payments allocated to the license performance obligations for our collaborations with Ipsen, Takeda, Daiichi Sankyo and Genentech.

As of September 30, 2020, $88.9 million of the combined transaction prices for our Ipsen and Takeda collaborations were allocated to performance obligations that had not yet been satisfied. See “Note 3. Collaboration Agreements - Cabozantinib Commercial Collaborations - Performance Obligations and Transaction Prices for our Ipsen and Takeda Collaborations” to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2019 for information about the expected timing to satisfy these performance obligations.

NOTE 3. COLLABORATION AGREEMENTS

We have established multiple collaborations with leading pharmaceutical companies for the commercialization and further development of cabozantinib. Additionally, consistent with our business strategy prior to the commercialization of cabozantinib, we entered into other collaborations with leading pharmaceutical companies for other compounds and programs in our portfolio. Under these collaborations, we are generally entitled to receive milestone and royalty payments, and for certain collaborations receive payments for product supply services, development cost reimbursements, and/or profit-sharing payments. See “Note 2. Revenues” for additional information on revenues recognized under our collaboration agreements.

We have also established multiple collaborations with smaller, discovery-focused biotechnology companies to expand our product pipeline. Under these collaborations, we may be required to make milestone and royalty payments, and for certain collaborations make payments for development cost reimbursements and/or option exercise fees.

See “Note 3. Collaboration Agreements” to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2019, or as further described below, for a description of each of our collaboration agreements.

Cabozantinib 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. During the second quarter of 2020, Ipsen opted into and is now co-funding the development costs for CONTACT-01 and CONTACT-02, two phase 3 pivotal trials of cabozantinib in combination with atezolizumab in patients with previously treated, metastatic non-small cell lung cancer and metastatic castration-resistant prostate cancer, respectively, and the four remaining cohorts of COSMIC-021 it had not previously opted into. COSMIC-021 is a broad phase 1b study evaluating the safety and tolerability of cabozantinib in combination with atezolizumab in patients with locally advanced or metastatic solid tumors.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
License revenues	$ 19,910	$ 66,409	$ 71,456	$ 95,318
Collaboration services revenues	16,096	9,607	46,503	24,815
Total	$ 36,006	$ 76,016	$ 117,959	$ 120,133

At September 30, 2020, we are eligible to receive additional regulatory and development milestone payments from Ipsen totaling an aggregate of $59.0 million, as well as sales-based milestones, including milestone payments earned for the first commercial sale of a product, of up to $469.9 million. We excluded these milestones from the transaction price as of September 30, 2020 because we determined such payments to be fully constrained under Topic 606 due to the fact that it was not probable that a significant reversal of cumulative revenue would not occur, given the inherent uncertainty of success with these milestones. We will re-evaluate the transaction price at each reporting period and as uncertain events are resolved or other changes in circumstances occur.

As of September 30, 2020, $42.6 million of the transaction price was allocated to our research and development services performance obligation that has not yet been satisfied.

Takeda Collaboration

In January 2017, we entered into a collaboration agreement with Takeda. Under this collaboration 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,	
	2020	2019	2020	2019
License revenues	$ 9,780	$ —	$ 32,726	$ 9,056
Collaboration services revenues	13,204	1,187	16,468	5,189
Total	$ 22,984	$ 1,187	$ 49,194	$ 14,245

Milestone revenues for the three and nine months ended September 30, 2020 included $9.2 million in revenues recognized in connection with a $10.0 million milestone we expect to achieve upon Takeda's and Ono Pharmaceutical Co., Ltd.'s supplemental application to the Japanese Ministry of Health, Labour and Welfare for Manufacturing and Marketing Approval of CABOMETYX in combination with Opdivo for the treatment of patients with unresectable, advanced or metastatic RCC. At September 30, 2020, we have not yet received this milestone payment.

During the third quarter of 2020, Takeda opted into and is now co-funding the development costs for CONTACT-01, CONTACT-02 and certain cohorts of COSMIC-021. Concurrently, we entered into the third amendment to the collaboration agreement with Takeda (the Amendment), which modified certain cost sharing obligations related to the Japan-specific development costs associated with CONTACT-01 and CONTACT-02. We determined the Amendment represented a contract modification that was treated as a termination of an existing contract and the creation of a new contract under Topic 606. As a result, we allocated the remaining transaction price to the performance obligations identified in the contract. The two remaining performance obligations are the research and development services associated with committed studies described in "Note 3. Collaboration Agreements" of the Notes to Consolidated Financial Statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, and the research and development services associated with CONTACT-01, CONTACT-02, and certain cohorts of COSMIC-021 studies. In allocating the transaction price for the modified contract we estimated the standalone selling price for the performance obligations. We utilized development costs incurred for these obligations in process and the projections of costs through the term of the arrangement. Revenue is recognized when, or as, we satisfy our performance obligations by transferring the promised services to Takeda. Revenue is being recognized using the cost proportional performance method, based on costs incurred to perform the research and development services, since the level of costs incurred over time is thought to best reflect the transfer of services to Takeda.

We are eligible to receive additional regulatory and development milestone payments, without contractual limit, for additional potential future indications. We are further eligible to receive sales-based milestones, including milestone payments earned for the first commercial sale of a product, of up to $124.0 million. We excluded these milestones from the transaction price as of September 30, 2020 because we determined such payments to be fully constrained under Topic 606 due to the fact that it was not probable that a significant reversal of cumulative revenue would not occur, given the inherent uncertainty of success with these milestones. We will re-evaluate the transaction price at each reporting period and as uncertain events are resolved or other changes in circumstances occur.

As of September 30, 2020, $46.3 million of the transaction price was allocated to our research and development services performance obligations that has not yet been satisfied.

GSK

In October 2002, we established a product development and commercialization collaboration agreement with GSK. We are required to pay a 3% royalty to GSK on the net sales of any product incorporating cabozantinib by us and our collaboration partners. Royalties earned by GSK in connection with the sales of cabozantinib are included in cost of goods sold for sales by us and as a reduction of collaboration services revenues for sales by our collaboration partners. Such royalties were $7.9 million and $23.7 million during the three and nine months ended September 30, 2020, respectively, as compared to $8.0 million and $23.1 million during the comparable periods in 2019.

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 U.S. Food and Drug Administration (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,	
	2020	2019	2020	2019
Profits on U.S. commercialization	$ 1,595	$ 1,102	$ 4,378	$ 3,507
Royalty revenues on ex-U.S. sales	$ 1,370	$ 1,614	$ 3,804	$ 4,426

In-Licensing Collaborations

Redwood Bioscience, Inc., R.P. Scherer Technologies, LLC, Catalent Pharma Solution LLC Collaboration

In September 2020, we entered into a collaboration and license agreement with 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). Under the terms of the agreement, we made an upfront payment of $10.0 million in exchange to nominate and have the exclusive option to license four targets using Catalent's ADC platform over a three-year period. In addition, we have a right to extend the target selection term to five years and nominate up to two additional targets for an additional payment of $4.0 million. We will also contribute research funding to Catalent for discovery and preclinical development work. For each option we decide to exercise, we will pay an exercise fee of $2.0 million, and would assume responsibilities for all subsequent clinical development, commercialization and global manufacturing of that program. Catalent would then become eligible to receive up to $44.0 million per compound in potential development milestone payments, $60.0 million per product in potential commercial milestone payments, as well as royalties on potential sales.

NBE Therapeutics AG (NBE) Collaboration

In September 2020, we entered into a collaboration and license agreement with NBE. Under the terms of the agreement, we made an upfront payment of $25.0 million in exchange for exclusive options to nominate four targets using NBE's ADC platform over a two-year period. In addition, within the first eighteen months of the agreement, we also have a right to extend the target selection term to three years for an additional payment of $2.0 million. We will also contribute research funding to NBE for discovery and preclinical development work. For each option we decide to exercise, we will be

required to pay an exercise fee of $10.0 million, and would assume responsibilities for all subsequent clinical development, commercialization and global manufacturing of that program. NBE would then become eligible to receive up to $90.0 million per program in potential development milestone payments, $135.0 million per program in potential commercial milestone payments, as well as royalties on potential 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, 2020	December 31, 2019
Cash and cash equivalents	$ 334,046	$ 266,501
Restricted cash equivalents included in long-term investments	1,636	1,636
Cash, cash equivalents, and restricted cash equivalents as reported in the accompanying Condensed Consolidated Statements of Cash Flows	$ 335,682	$ 268,137

Restricted cash equivalents consisted of certificates of deposit with original maturities of 90 days or less used to collateralize letters of credit. The long-term classification of restricted cash equivalents is based upon the remaining term of the underlying restriction.

Cash and Investments

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

	September 30, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Debt securities available-for-sale:				
Commercial paper	$ 466,141	$ 225	$ —	$ 466,366
Corporate bonds	629,309	7,526	(20)	636,815
U.S. Treasury and government-sponsored enterprises	213,449	354	(10)	213,793
Municipal bonds	20,326	105	—	20,431
Total debt securities available-for-sale	1,329,225	8,210	(30)	1,337,405
Cash	55,979	—	—	55,979
Money market funds	96,992	—	—	96,992
Certificates of deposit	55,583	1	—	55,584
Total cash and investments	$ 1,537,779	$ 8,211	$ (30)	$ 1,545,960

	December 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Debt securities available-for-sale:				
Commercial paper	$ 389,573	$ —	$ —	$ 389,573
Corporate bonds	752,295	3,934	(3)	756,226
U.S. Treasury and government-sponsored enterprises	166,483	187	(5)	166,665
Total debt securities available-for-sale	1,308,351	4,121	(8)	1,312,464
Cash	40,964	—	—	40,964
Money market funds	2,467	—	—	2,467
Certificates of deposit	32,728	5	—	32,733
Total cash and investments	$ 1,384,510	$ 4,126	$ (8)	$ 1,388,628

Interest receivable was $4.5 million and $6.2 million as of September 30, 2020 and December 31, 2019, 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, 2020 and 2019.

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, 2020	
	Fair Value	Gross Unrealized Losses
Corporate bonds	$ 29,627	$ (20)
U.S. Treasury and government-sponsored enterprises	70,465	(10)
Total	$ 100,092	$ (30)

	December 31, 2019	
	Fair Value	Gross Unrealized Losses
Corporate bonds	$ 14,529	$ (3)
U.S. Treasury and government-sponsored enterprises	2,848	(5)
Total	$ 17,377	$ (8)

All securities presented have been in an unrealized loss position less than 12 months. There were 16 and 9 investments in an unrealized loss position as of September 30, 2020 and December 31, 2019, respectively. During the nine months ended September 30, 2020 and 2019, 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, 2020	December 31, 2019
Maturing in one year or less	$ 993,211	$ 789,913
Maturing after one year through five years	344,194	522,551
Total debt securities available-for-sale	$ 1,337,405	$ 1,312,464

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;
- 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, 2020		
	Level 1	Level 2	Total
Commercial paper	$ —	$ 466,366	$ 466,366
Corporate bonds	—	636,815	636,815
U.S. Treasury and government-sponsored enterprises	—	213,793	213,793
Municipal bonds	—	20,431	20,431
Total debt securities available-for-sale	—	1,337,405	1,337,405
Money market funds	96,992	—	96,992
Certificates of deposit	—	55,584	55,584
Total financial assets carried at fair value	$ 96,992	$ 1,392,989	$ 1,489,981

	December 31, 2019		
	Level 1	Level 2	Total
Commercial paper	$ —	$ 389,573	$ 389,573
Corporate bonds	—	756,226	756,226
U.S. Treasury and government-sponsored enterprises	—	166,665	166,665
Total debt securities available-for-sale	—	1,312,464	1,312,464
Money market funds	2,467	—	2,467
Certificates of deposit	—	32,733	32,733
Total financial assets carried at fair value	$ 2,467	$ 1,345,197	$ 1,347,664

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.

NOTE 6. INVENTORY

Inventory consisted of the following (in thousands):

	September 30, 2020	December 31, 2019
Raw materials	$ 5,298	$ 2,709
Work in process	17,911	9,447
Finished goods	4,535	4,367
Total	$ 27,744	$ 16,523
Balance Sheet classification:		
Current portion included in inventory	$ 19,319	$ 12,886
Long-term portion included in other long-term assets	8,425	3,637
Total	$ 27,744	$ 16,523

Write-downs related to excess and expiring inventory were $2.2 million and $0.4 million for the nine months ended September 30, 2020 and 2019, respectively.

NOTE 7. STOCK-BASED COMPENSATION

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and development	$ 18,936	$ 4,301	$ 30,134	$ 13,745
Selling, general and administrative	36,719	8,838	55,657	27,002
Total stock-based compensation	$ 55,655	$ 13,139	$ 85,791	$ 40,747

As of September 30, 2020, 16,900,406 shares were available for grant under the Exelixis, Inc. 2017 Equity Incentive Plan (as amended and restated, the 2017 Plan). The share reserve is reduced by 1 share for each share issued pursuant to a stock option or stock appreciation award and 1.5 shares for full value awards granted in the form of restricted stock units (RSUs). On May 20, 2020, at our 2020 Annual Meeting of Stockholders, our stockholders approved the amendment and restatement of the 2017 Plan. The amendment and restatement increased the share reserve under the 2017 Plan by 21,000,000 shares, subject to adjustment for certain changes in our capitalization, which became effective immediately upon stockholder approval.

During the nine months ended September 30, 2020, we granted 1,189,888 stock options with a weighted average exercise price of $21.84 per share and a weighted average grant date fair value of $9.61 per share. As of September 30, 2020, there were 16,219,326 stock options outstanding and $28.4 million unrecognized compensation expense.

During the nine months ended September 30, 2020, we granted 2,813,888 service-based RSUs with a weighted average grant date fair value of $23.56 per share. As of September 30, 2020, there were 6,554,909 RSUs outstanding and $111.9 million unrecognized compensation expense.

Stock options and RSUs granted to employees during the nine months ended September 30, 2020 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 our Annual Report on Form 10-K for the fiscal year ended December 31, 2019.

During the year ended December 31, 2018, in connection with our long-term incentive compensation program, we granted 308,365 performance-based stock options (PSOs) to our President and Chief Executive Officer. In addition to the standard service-based vesting conditions included in our other stock options, these PSOs contain a market vesting condition such that they may not be exercised until, at any time after the grant date, the closing market price of our Common Stock is equal to or greater than 125% of the per share exercise price of the PSOs over a period of at least 30 consecutive calendar days. This market vesting condition was achieved during the three months ended June 30, 2020. The stock-based compensation expense for the PSOs is being recognized on an accelerated basis over the service period of the award, which commenced on the date of grant. The achievement of the market vesting condition did not impact the compensation expense recognized during the period.

As of September 30, 2020, there were 8,186,977 performance-based restricted stock units (PSUs) outstanding with $129.7 million in related unrecognized compensation expense. Expense recognition for PSUs commences when it is determined that achievement of the performance target is probable. Of the outstanding PSUs, 188,624 relate to awards for which we achieved the performance target during 2019 or had determined during 2019 that it was probable that we would achieve the performance target during 2020. During 2020, we determined that it had become probable that we would achieve additional performance targets for 2,947,563 additional PSUs granted during 2018 and 2019. Total stock-based compensation expense for PSUs was $41.2 million and $43.2 million during the three and nine months ended September 30, 2020, respectively. For more information about our PSUs, see “Note 8. Employee Benefit Plans” of the Notes to Consolidated Financial Statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019.

In September 2020, in connection with our long-term incentive compensation program, we awarded 1,951,830 PSUs (the target amount) that will vest upon the achievement of certain performance targets related to clinical trial positive top-line results and product approvals by the FDA (the 2020 PSUs). Employees may earn up to 200% of the target amount or 3,903,660 shares, depending on the volume and the timing of achievement of the performance targets. The 2020 PSUs

were designed to drive the performance of our management team and employees toward the achievement of key corporate objectives and will be forfeited if the performance targets are not met by December 31, 2024.

NOTE 8. INCOME TAXES

Our effective income tax rate was 15.7% and 18.8% during the three and nine months ended September 30, 2020, respectively, as compared to 20.5% and 19.4% for the comparable periods in 2019. The effective tax rate for the three and nine months ended September 30, 2020 differed from U.S. federal statutory tax rate of 21% primarily due to excess tax benefits related to the exercise of certain stock options and federal tax credits, offset by the non-deductible executive compensation during the periods. The effective tax rate for the three and nine months ended September 30, 2019 differed from the U.S. federal statutory rate of 21% primarily due to excess tax benefits related to the exercise of certain stock options and federal tax credits during the periods.

NOTE 9. NET INCOME (LOSS) PER SHARE

Net income (loss) 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,	
	2020	2019	2020	2019
Numerator:				
Net income (loss)	$ (32,040)	$ 97,452	$ 83,393	$ 252,269
Denominator:				
Weighted-average common shares outstanding — basic	309,116	303,268	307,437	301,999
Dilutive securities	—	12,185	10,058	13,047
Weighted-average common shares outstanding — diluted	309,116	315,453	317,495	315,046
Net income (loss) per share — basic	$ (0.10)	$ 0.32	$ 0.27	$ 0.84
Net income (loss) per share — diluted	$ (0.10)	$ 0.31	$ 0.26	$ 0.80

Dilutive securities included stock options, RSUs, PSUs, PSOs 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 for which the contingent vesting condition had not been achieved. 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,	
	2020	2019	2020	2019
Anti-dilutive securities and contingently issuable shares excluded	27,033	6,153	10,224	5,740

NOTE 10. COMMITMENTS AND CONTINGENCIES

In September 2019, we received a notice letter regarding an Abbreviated New Drug Application (ANDA) submitted to the FDA by MSN Pharmaceuticals, Inc. (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. Patent Nos. 8,877,776, 9,724,342, 10,034,873 and 10,039,757, which are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations, also referred to as the *Orange Book.* MSN's initial notice letter did not provide a Paragraph IV certification against U.S. Patent No. 7,579,473, the composition of matter patent, or U.S. Patent No. 8,497,284, a method of use patent. On October 29, 2019, we filed a complaint in the United States District Court for the District of Delaware for patent infringement against MSN asserting 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 U.S. Patent No. 8,877,776 is invalid and not infringed. On May 5, 2020, we received notice from MSN that it had amended its ANDA to assert additional Paragraph IV certifications. The ANDA now requests approval to market a generic version of CABOMETYX tablets prior to expiration of the two previously-unasserted CABOMETYX patents: U.S. Patent No. 7,579,473 and U.S. Patent No. 8,497,284. On May 11, 2020, we

filed a complaint in the United States District Court for the District of Delaware for patent infringement against MSN asserting U.S. Patent No. 7,579,473 and U.S. Patent No. 8,497,284 arising from MSN's amended ANDA filing with the FDA. On May 22, 2020, MSN filed its response to the complaint, alleging that each of U.S. Patent No. 7,579,473 and U.S. Patent No. 8,497,284 is invalid and not infringed. Neither of our complaints alleges infringement of U.S. Patent Nos. 9,724,342, 10,034,873 and 10,039,757. In our complaints, we are seeking, among other relief, an order that the effective date of any FDA approval of the ANDA would be a date no earlier than the expiration of all of U.S. Patent No. 7,579,473, U.S. Patent No. 8,497,284 and U.S. Patent No. 8,877,776, the latest of which expires on October 8, 2030, and equitable relief enjoining MSN from infringing these patents. These two lawsuits against MSN have been consolidated, and a bench trial has been scheduled for May 2022. The sale of a generic version of CABOMETYX earlier than its patent expiration could significantly decrease our revenues and thereby materially harm our business, financial condition and results of operations. It is not possible at this time to determine the likelihood of an unfavorable outcome or estimate of the amount or range of any potential loss.

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

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

This Quarterly Report on Form 10-Q contains forward-looking statements. These statements are based on Exelixis, Inc.'s (Exelixis, we, our or us) current expectations, assumptions, estimates and projections about our business and our industry and involve known and unknown risks, uncertainties and other factors that may cause our company's or our industry's results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied in, or contemplated by, the forward-looking statements. Our actual results and the timing of events may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such a difference include those discussed in "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q, as well as those discussed elsewhere in this report. These and many other factors could affect our future financial and operating results. We undertake no obligation to update any forward-looking statement to reflect events after the date of this report.

This discussion and analysis should be read in conjunction with our condensed consolidated financial statements and accompanying notes included in this report and the consolidated financial statements and accompanying notes thereto included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019 filed with the Securities and Exchange Commission (SEC) on February 25, 2020.

Overview

We are an oncology-focused biotechnology company that strives to accelerate the discovery, development and commercialization of new medicines for difficult-to-treat cancers. Since we were founded in 1994, four products resulting from our discovery efforts have progressed through clinical development, received regulatory approval and established a commercial presence in various geographies around the world. Two are derived from cabozantinib, our flagship molecule, an inhibitor of multiple tyrosine kinases including MET, AXL, VEGF receptors and RET. Our cabozantinib products are: CABOMETYX® (cabozantinib) tablets approved for advanced renal cell carcinoma (RCC) and previously treated hepatocellular carcinoma (HCC); and COMETRIQ® (cabozantinib) capsules approved for progressive, metastatic medullary thyroid cancer (MTC). For these types of cancer, cabozantinib has become or is becoming a standard of care. 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).

The U.S. Food and Drug Administration (FDA) first approved CABOMETYX for previously treated patients with advanced RCC in April 2016, and in December 2017 the FDA expanded CABOMETYX's approval to include previously untreated patients with advanced RCC. Additionally, in January 2019, the FDA approved CABOMETYX for the treatment of patients with HCC who have been previously treated with sorafenib. Most recently on August 24, 2020, we announced a significant milestone for our program combining cabozantinib with immune checkpoint inhibitors (ICIs) with the submission a supplemental New Drug Application (sNDA) for CABOMETYX in combination with Bristol-Myers Squibb Company's (BMS) Opdivo as a treatment of patients with advanced RCC to the FDA, and on October 19, 2020, we and BMS announced that

the FDA had accepted our sNDA and BMS' supplemental Biologics License Application (sBLA), granted Priority Review to both applications and assigned a Prescription Drug User Fee Act (PDUFA) goal date, or target action date, of February 20, 2021.

To develop and commercialize CABOMETYX and COMETRIQ outside the U.S., we have entered into license agreements with Ipsen Pharma SAS (Ipsen) and Takeda Pharmaceutical Company Limited (Takeda). We granted to Ipsen the rights to develop and commercialize cabozantinib outside of the U.S. and Japan, and to Takeda 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 cabozantinib in other potential indications, and we continue to 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) and Canada, as a treatment for advanced RCC and for HCC in adults who have previously been treated with sorafenib. In addition, in September 2020, Ipsen and BMS submitted type II variation applications to the European Medicines Agency (EMA) to approve the combination of CABOMETYX and Opdivo as a treatment for advanced RCC, with the EMA validating the type II variations and beginning its centralized review process, and both Ipsen and BMS plan to submit applications to approve the combination in other territories beyond the EU. With respect to the Japanese market, Takeda has achieved important milestones in 2020, including receipt of Manufacturing and Marketing Approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) and first commercial sales of CABOMETYX as a treatment of patients with curatively unresectable or metastatic RCC. Takeda also submitted an application to the Japanese MHLW for Manufacturing and Marketing Approval of CABOMETYX as a treatment of patients with unresectable HCC who progressed after prior systemic therapy, and most recently in October 2020, Takeda and Ono Pharmaceutical Co., Ltd. (Ono), BMS' development and commercialization partner in Japan, submitted a supplemental application to the Japanese MHLW for Manufacturing and Marketing Approval of CABOMETYX in combination with Opdivo for the treatment of patients with unresectable, advanced 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 benefit from this medicine. We are evaluating cabozantinib, both as a single agent and in combination with other therapies, in a broad development program comprising over 100 ongoing or planned clinical trials across multiple indications. 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 program. Informed by the available data from these clinical trials, we continue to advance cabozantinib's development program with potentially label-enabling trials. One pivotal trial that has resulted from this effort is COSMIC-311, our ongoing phase 3 pivotal trial evaluating cabozantinib versus placebo in patients with radioiodine (RAI)-refractory differentiated thyroid cancer (DTC) who have progressed after up to two VEGF receptor-targeted therapies. We plan to conduct an analysis among the first 100 patients randomized in COSMIC-311 for the co-primary endpoint of objective response rate (ORR), and an interim analysis of progression-free survival (PFS) before the end of 2020.

We are particularly interested in continuing to evaluate cabozantinib's potential in combination with ICIs to determine if these combinations further improve outcomes for patients. Building on preclinical and clinical observations that cabozantinib may promote a more immune-permissive tumor environment potentially resulting in cooperative activity of cabozantinib in combination with these products, we are evaluating cabozantinib in combination with a variety of ICIs. CheckMate -9ER, a phase 3 pivotal trial evaluating the combination of cabozantinib and nivolumab compared to sunitinib in previously untreated advanced or metastatic RCC, for which we and our collaboration partner BMS announced positive top-line results in April 2020, is reflective of this strategy. The trial met its primary endpoint of PFS at final analysis, as well as the secondary endpoints of overall survival (OS) at a pre-specified interim analysis and ORR, and showed that the combination of cabozantinib with nivolumab significantly reduced the risk of disease progression or death compared with sunitinib (hazard ratio [HR]=0.51; 95% confidence interval [CI]: 0.41 to 0.64; $p<0.0001$) and also significantly improved OS, reducing the risk of death by 40% compared with sunitinib (HR=0.60; 98.89% CI: 0.40 to 0.89; $p<0.0010$), as well as demonstrated a superior ORR of 56% versus 27% for sunitinib. Data from CheckMate -9ER were presented at Presidential Symposium I at the European Society for Medical Oncology (ESMO) Virtual Congress 2020 in September 2020 and served as the basis for the submission of our sNDA to the FDA for CABOMETYX in combination with Opdivo as a treatment of patients with advanced RCC. We have also collaborated with BMS on CheckMate -040, a multi-cohort phase 1/2 trial evaluating cabozantinib in combination with nivolumab and in combination with both nivolumab and ipilimumab in patients with previously treated or previously untreated advanced HCC, for which initial clinically meaningful results were presented at

American Society of Clinical Oncology's (ASCO's) Gastrointestinal Cancers Symposium in January 2020, and 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 expect to complete enrollment for COSMIC-313 in early 2021 and to report top-line results of the event-driven analyses from the trial in the 2022 time frame.

In an effort to diversify our exploration of combinations with ICIs, we have also initiated multiple trials evaluating cabozantinib in combination with F. Hoffmann-La Roche Ltd.'s (Roche's) ICI, atezolizumab, including COSMIC-312, a phase 3 pivotal trial evaluating cabozantinib in combination with atezolizumab versus sorafenib in previously untreated advanced HCC, for which we announced in August 2020 that enrollment was completed, and COSMIC-021, a broad phase 1b study evaluating the safety and tolerability of cabozantinib in combination with atezolizumab in patients with locally advanced or metastatic solid tumors. COSMIC-021 is divided into two parts: a dose-escalation phase, which was completed in 2018; and an expansion phase, which is ongoing. Findings from the dose-escalation stage of COSMIC-021 demonstrated that the combination was well-tolerated and showed encouraging anti-tumor activity in patients with advanced RCC. The expansion phase of COSMIC-021 comprises 24 total cohorts, with 20 cohorts evaluating the combination of cabozantinib and atezolizumab and four cohorts evaluating cabozantinib or atezolizumab as single-agent therapies. Based on continuing encouraging efficacy and safety data certain cohorts have been or may be further expanded, including the cohorts of patients with non-small cell lung cancer (NSCLC) who have been previously treated with an ICI and metastatic castration-resistant prostate cancer (mCRPC) who have been previously treated with enzalutamide and/or abiraterone acetate and experienced radiographic disease progression in soft tissue. We anticipate enrolling up to 1,732 patients in the trial in early 2021, although both the timing and final number of patients are subject to the initiation of additional cohorts or expansion of selected existing cohorts, as well as any further delays resulting from the COVID-19 pandemic. Since its initiation, data from COSMIC-021 have been instrumental in guiding our clinical development strategy for cabozantinib in combination with ICIs, including supporting the recent initiation of three phase 3 pivotal trials in collaboration with Roche evaluating the combination of cabozantinib with atezolizumab. The first, CONTACT-01, focuses on patients with metastatic NSCLC who have been previously treated with an ICI and platinum-containing chemotherapy; the second, CONTACT-02, focuses on patients with mCRPC who have been previously treated with one novel hormonal therapy; and the third, CONTACT-03, focuses on patients with inoperable, locally advanced or metastatic RCC who have progressed during or following treatment with an ICI as the immediate preceding therapy. Encouraging results from interim analyses of the mCRPC and NSCLC cohorts of COSMIC-021 were presented at ASCO's Genitourinary Cancer Symposium in February 2020 and the 2020 ASCO Virtual Scientific Program in May 2020, respectively, and positive results from two RCC cohorts of COSMIC-021 were presented at the ESMO Virtual Congress 2020 in September 2020. Based on regulatory feedback from the FDA, and if supported by the clinical data, we intend to file with the FDA for accelerated approval in an mCRPC indication as early as 2021.

We also remain committed to building our product pipeline by discovering and developing new therapies for cancer patients. Using our in-house drug discovery expertise, specifically in medicinal chemistry, tumor biology and pharmacology, we are advancing small molecule drug candidates toward and through preclinical development. Notably, these efforts are led by some of the same experienced scientists that led the efforts to discover cabozantinib, cobimetinib and esaxerenone, which have been approved for commercialization. In addition, we have augmented our internal drug discovery activities with multiple partnerships, including several that enable us to discover and advance various biologics, such as bispecific antibodies and antibody-drug conjugates (ADCs), and we continue to engage in business development initiatives aimed at identifying and in-licensing promising, early-stage oncology assets, which we can further develop utilizing our established clinical development infrastructure. In total, we are advancing drug candidates across approximately 20 ongoing discovery programs toward and through preclinical development, with plans for up to four new compounds to reach Investigational New Drug (IND) filing status by the end of the second quarter of 2021.

The first compounds to advance from our recent internal drug discovery efforts include XL092, a next-generation oral tyrosine kinase inhibitor that is currently in a phase 1 clinical trial in patients with advanced solid malignancies for which dose-escalation cohorts evaluating XL092, both as a single agent and in combination with atezolizumab, are currently enrolling. We presented data that support the ongoing clinical development of XL092 at the 32nd EORTC-NCI-AACR (ENA) Symposium in October 2020, and we expect that once recommended doses of both single-agent XL092 and XL092 in combination with atezolizumab are established, the trial will begin to enroll expansion cohorts for patients with clear cell and non-clear cell RCC, hormone-receptor positive breast cancer and mCRPC. In addition, we anticipate filing an IND for XL265, a TAM kinase-focused kinase inhibitor, in the first quarter of 2021.

In furtherance of our business development strategy, in 2019, we entered into collaboration and license agreements with Aurigene Discovery Technologies Limited (Aurigene), which is focused on the discovery and development of novel small molecules as therapies for cancer, and Iconic Therapeutics, Inc. (Iconic), which is focused on the

advancement of a next-generation ADC program targeting tissue factor in solid tumors. In September 2020, we presented preclinical data that support the continued development of ICON-2, Iconic's ADC comprised of an anti-tissue factor antibody and a proprietary linker-payload developed by Zymeworks Inc., at the World ADC Digital Conference, and in October 2020, we presented preclinical data that support the continued development of AUR102, the lead Aurigene program targeting cyclin-dependent kinase 7 (CDK7), at the 32nd ENA Symposium. Both ICON-2 and AUR102 continue to progress through preclinical development and could result in IND filings in the fourth quarter of 2020. We have also made progress under our other collaborations with Invenra, Inc. (Invenra), which is focused on the discovery and development of multispecific antibodies for the treatment of cancer, and StemSynergy Therapeutics, Inc. (StemSynergy), which is focused on the discovery and development of novel oncology compounds aimed to inhibit tumor growth by targeting Casein Kinase 1 alpha. Most recently, in September 2020, we entered into additional collaboration agreements to develop multiple ADCs with 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), and with NBE-Therapeutics AG (NBE). To further enhance our early-stage pipeline, we expect to enter into additional, external collaborative relationships around assets and technologies that complement our internal drug discovery and development efforts.

COVID-19 Update

As of the date of this Quarterly Report, the COVID-19 pandemic continues to have a modest impact on our business operations, in particular on our clinical trial, drug discovery and commercial activities. We have and continue to undertake considerable efforts to mitigate the various problems presented by this crisis, including as described below:

Clinical Trials. To varying degrees and at different rates across our clinical trials being conducted in regions impacted by COVID-19, we have experienced declines in screening and enrollment activity, delays in new site activations, and restrictions on the access to treatment sites that is necessary to monitor clinical study progress and administration. However, beginning with the second quarter of 2020, we experienced an increase in screening and enrollment activity, and overall, we and our collaboration partners, including principal investigators and personnel at clinical trial sites, have been successful in preventing material delays to our ongoing and planned clinical trials. We have done this through ongoing assessment of the pandemic's impact and, wherever possible, taking proactive steps in compliance with guidance issued by the FDA, EMA and other regulatory agencies to support the safety of our patients and their access to treatment, as well as to maintain the high quality of our clinical trials. We recognize, however, that we may have to make further operational adjustments to our ongoing and planned clinical trials and that patient enrollment, and new clinical trial site initiations may be further slowed due to the COVID-19 pandemic, especially if it is further prolonged or grows in severity.

Drug Discovery and Preclinical Development. We have partially resumed internal drug discovery in our laboratories following a temporary suspension of these activities while we observed the shelter in place orders issued by the State of California and Alameda County. While this temporary suspension did not result in any significant changes to the timelines for our late-stage discovery work, we did experience modest delays in the advancement of certain of our early-stage programs. We also experienced some modest delays with respect to the portion of drug discovery work outsourced to third-party contractors in regions first impacted by COVID-19. However, those service providers have resumed discovery work and are meeting their contractual obligations in accordance with planned timelines. Prior to the COVID-19 pandemic, we largely outsourced preclinical development work to third-party contractors, and that work has continued without substantial delay or interference resulting from the COVID-19 pandemic. While we continue to utilize our resources effectively to move new product candidates toward the clinic, we may ultimately be unable to achieve our drug discovery and preclinical development objectives within the previously disclosed timelines due to the COVID-19 pandemic, especially if it is further prolonged or grows in severity.

Commercial Activities. Although our field employees have limited their in-person promotional activities, they remain engaged with healthcare professionals and are available to them as an informational resource. Nevertheless, with healthcare professionals acutely focused on the COVID-19 pandemic and patient access to healthcare professionals limited due to shelter in place orders, we experienced a decrease in prescriptions for CABOMETYX during the second and third quarters of 2020, which we believe was, at least in part, attributable to the COVID-19 pandemic with respect to the second quarter of 2020. We also observed fluctuations in CABOMETYX ordering, and we believe that this effect could continue depending on developments related to the COVID-19 pandemic. Overall, despite the challenges posed by the pandemic, our commercial business has only experienced a modest impact. We believe this is the case largely because of the gravity of the cancer conditions that our products are indicated to treat and the fact that CABOMETYX has been available as an orally administrable cancer treatment in the U.S. since 2016, thereby establishing a safety and efficacy profile that is well known to healthcare

professionals. It remains possible, however, that over a longer period, changes to our standard sales and marketing practices resulting from the COVID-19 pandemic, including the shift from in-person to primarily telephonic and virtual interactions with healthcare professionals, along with obstacles to patient access to healthcare professionals, could diminish sales of our marketed products.

Supply Chain. We have not experienced production delays or seen any significant impact to our clinical or commercial supply chain as a result of the COVID-19 pandemic. In addition, we continue to maintain substantial safety stock inventories for our commercial drug substance and drug products, which should be sufficient to maintain robust long-term supply. We continue to work closely with our third-party contract manufacturers, suppliers, comparator drug sourcing vendors and collaboration partners to safeguard both the timely production and delivery of our products. If the COVID-19 pandemic is further prolonged or becomes more severe, however, we are prepared to modify our manufacturing and supply chain operations as appropriate in response.

General Business Operations. We have taken numerous temporary precautions to help mitigate the risk of transmission of the virus, including reducing the number of our employees working on-site at our Alameda headquarters under enhanced safety and social distancing protocols. Although having most of our employees continue to work remotely has required that we devise new ways of working and collaborating, to date we have not experienced any material reduction in productivity or interruptions in our general business operations. If the COVID-19 pandemic is further prolonged or becomes more severe, however, we may find it more challenging to maintain that level of productivity, to grow the company as we have anticipated, and to execute on our long-term business plans.

The circumstances surrounding the COVID-19 pandemic are volatile and subject to rapid change. Despite our 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, which are 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 2020, and potentially in future years should the adverse effects of the COVID-19 pandemic continue indefinitely.

Third Quarter 2020 Business Updates and Financial Highlights

During the third quarter of 2020, 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 2020, we announced the initiation of CONTACT-03, a global phase 3 pivotal trial evaluating cabozantinib in combination with atezolizumab in patients with inoperable, locally advanced or metastatic RCC who progressed during or following treatment with an ICI as the immediate preceding therapy. The co-primary endpoints of the trial are PFS per Response Evaluation Criteria in Solid Tumors (RECIST) v. 1.1 as assessed by independent review and OS, and the secondary endpoints include PFS, ORR and duration of response as assessed by the investigators.
- In July 2020, the FDA approved the sBLA submitted by Genentech for atezolizumab plus cobimetinib and vemurafenib for the treatment of BRAF V600 mutation-positive advanced melanoma in previously untreated patients. The approval is based on positive results from IMspire150, a phase 3 pivotal trial that demonstrated that adding atezolizumab to cobimetinib and vemurafenib helped to reduce the risk of disease worsening or death, compared to placebo plus cobimetinib and vemurafenib. This is the second FDA approval for a regimen including cobimetinib, which we discovered and is now being developed by Genentech as part of a worldwide collaboration agreement between the two companies.
- In August 2020, we announced the completion of patient enrollment in COSMIC-312, a global phase 3 pivotal trial evaluating cabozantinib in combination with atezolizumab versus sorafenib as a treatment of patients with previously untreated advanced HCC, providing the requisite patient population to conduct the event-driven analyses of the trial’s endpoints. Separately, patient enrollment remains open in China in order to enroll a sufficient number of patients to enable local registration, if supported by the clinical data. The co-primary endpoints of the trial are PFS and OS. Based on current event rates, we anticipate announcing top-line results in the first half of 2021.
- In August 2020, we announced the completion of patient enrollment in EXAMINER, the phase 4 trial evaluating the safety and efficacy of the 60 mg tablet formulation of cabozantinib compared with the 140 mg capsule

formulation, which is marketed as COMETRIQ, for the treatment of patients with progressive, metastatic MTC. EXAMINER is a post-marketing requirement from the FDA and the European Commission. The trial was designed to enroll up to 250 patients, and top-line results from the trial are anticipated later in 2020.

- In September 2020, we announced a collaboration and license agreement with Catalent to develop multiple ADCs using Catalent's proprietary SMARTag® site-specific bioconjugation technology.
- In September 2020, we announced a collaboration and license agreement with NBE to discover and develop multiple ADCs for oncology applications by leveraging NBE's unique expertise and proprietary platforms in ADC discovery, including NBE's SMAC-Technology™ (a site-specific conjugation technology) and novel payloads.
- In September 2020, we and Iconic announced preclinical data that support the continued development of ICON-2 for the treatment of diverse solid tumors. The data, which demonstrate the superior tolerability and exposure of ICON-2 compared with a monomethyl auristatin E anti-tissue factor ADC, were presented at the World ADC Digital Conference.
- In September 2020, clinical data from CheckMate -9ER, a phase 3 pivotal trial evaluating the combination of cabozantinib and nivolumab compared to sunitinib in previously untreated advanced or metastatic RCC, were presented as part of Presidential Symposium I at the ESMO Virtual Congress 2020. In addition, clinical data from the clear cell RCC and non-clear cell RCC cohorts of COSMIC-021, a phase 1b trial of cabozantinib in combination with atezolizumab in patients with locally advanced or metastatic solid tumors, were presented as part of the GU Proffered Paper Session and as part of a poster presentation, respectively, at the ESMO Virtual Congress.
- In September 2020, we announced that our collaboration partners Ipsen and BMS each submitted and received validation from the EMA for their type II variation applications for the combination of CABOMETYX and Opdivo as a treatment for advanced RCC.
- In October 2020, we announced data that support the ongoing clinical development of XL092. The data, which suggest XL092 has a desirable therapeutic profile that pairs the potential for significant anti-tumor activity with a much shorter clinical pharmacokinetic half-life than cabozantinib, as well as a potential synergistic effect in combination with ICIs, were presented at the 32nd ENA Symposium. Later in October 2020, we announced enrollment of the first patient into the dose-escalation cohort of the combination arm of the phase 1 trial evaluating the safety, tolerability, pharmacokinetics and preliminary anti-tumor activity of XL092 alone and in combination with atezolizumab in patients with advanced solid tumors.
- In October 2020, we and Aurigene announced preclinical data that support the continued development of AUR102. The data, which demonstrate that AUR102 effectively engages CDK7 and inhibits a key mediator of the cell cycle and transcription, were presented at the 32nd ENA Symposium.
- In October 2020, we and BMS announced that the FDA had accepted our sNDA and BMS' sBLA, respectively, for CABOMETYX in combination with Opdivo for the treatment of patients with advanced RCC, granted Priority Review to both applications and assigned a PDUFA goal date of February 20, 2021.
- In October 2020, our collaboration partner Takeda, along with Ono, submitted a supplemental application to the Japanese MHLW for Manufacturing and Marketing Approval of CABOMETYX in combination with Opdivo for the treatment of patients with unresectable, advanced or metastatic RCC.

Financial Highlights

- Net product revenues for the third quarter of 2020 were $168.6 million, compared to $191.8 million for the third quarter of 2019.
- Total revenues for the third quarter of 2020 were $231.1 million, compared to $271.7 million for the third quarter of 2019.
- Research and development expenses for the third quarter of 2020 were $176.8 million, compared to $97.3 million for the third quarter of 2019.
- Selling, general and administrative expenses for the third quarter of 2020 were $88.2 million, compared to $51.3 million for the third quarter of 2019.
- Provision for (benefit from) income taxes for the third quarter of 2020 was $(6.0) million, compared to $25.2 million for the third quarter of 2019.
- Net loss for the third quarter of 2020 was $(32.0) million, or $(0.10) per share, basic and diluted, compared to net income of $97.5 million, or $0.32 per share, basic and $0.31 per share diluted, for the third quarter of 2019.
- Cash and investments were $1.5 billion as of September 30, 2020, compared to $1.4 billion as of December 31, 2019.

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

Challenges and Risks

In addition to the challenges and risks imposed by the COVID-19 pandemic and described under "—COVID-19 Update" above, we will also continue to face challenges and risks that may impact our ability to execute on our remaining 2020 business objectives, and some of these risks to our business have been or may be exacerbated by the COVID-19 pandemic. 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 or 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 has been or 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 currently conducting, or may conduct in the future, 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 we and our collaboration partners receive the required regulatory approvals to market cabozantinib for additional indications, 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. However, 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, because of growing concerns over healthcare cost containment and corresponding policy initiatives and activities aimed at limiting access to, and restricting the prices of, pharmaceuticals.

Achievement of our remaining 2020 business objectives and the continued success of CABOMETYX will also depend on the success of our development and commercialization strategies to navigate increased competition, including that from, but not limited to, the use of therapies that combine an ICI with another targeted agent to treat cancer. In the longer term, we may eventually face competition from potential manufacturers of generic versions of our marketed products, including the proposed generic version of CABOMETYX tablets that is the subject of an Abbreviated New Drug Application (ANDA) submitted to the FDA by MSN Pharmaceuticals, Inc. (MSN), which if approved, could result in significant decreases in the revenue derived from the U.S. sales of CABOMETYX and thereby materially harm our business and financial condition. 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 internal drug discovery operations, all of which may be increased as a result of the COVID-19 pandemic. 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, and others are common to companies in the biotechnology, biopharmaceutical and pharmaceutical industries with development and commercial operations. Moreover, as described under "—COVID-19 Update" above, these risks have been or may be exacerbated by the COVID-19 pandemic. For a more detailed discussion of challenges and risks we face, including those relating to the COVID-19 pandemic, 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 2020, which is a 52-week fiscal year, will end on January 1, 2021 and fiscal year 2019, which was a 53-week fiscal year, ended on January 3, 2020. For convenience, references in this report as of and for the three months ended October 2, 2020 and September 27, 2019, and as of and for the fiscal years ending January 1, 2021, and ended January 3, 2020, are indicated as being as of and for the three months ended September 30, 2020 and September 30, 2019 and the years ending December 31, 2020 and ended December 31, 2019, 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
	2020	2019		2020	2019	
Net product revenues	$ 168,587	$ 191,768	(12 %)	$ 541,197	$ 565,024	(4 %)
License revenues	33,205	69,137	(52 %)	113,318	132,443	(14 %)
Collaboration services revenues	29,300	10,798	171 %	62,971	29,998	110 %
Total revenues	$ 231,092	$ 271,703	(15 %)	$ 717,486	$ 727,465	(1 %)

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
	2020	2019		2020	2019	
Gross product revenues	$ 220,401	$ 239,916	(8 %)	$ 702,865	$ 704,084	0 %
Discounts and allowances	(51,814)	(48,148)	8 %	(161,668)	(139,060)	16 %
Net product revenues	$ 168,587	$ 191,768	(12 %)	$ 541,197	$ 565,024	(4 %)

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
	2020	2019		2020	2019	
CABOMETYX	$ 159,555	$ 187,410	(15 %)	$ 522,381	$ 552,315	(5 %)
COMETRIQ	9,032	4,358	107 %	18,816	12,709	48 %
Net product revenues	$ 168,587	$ 191,768	(12 %)	$ 541,197	$ 565,024	(4 %)

The decreases in product revenues for CABOMETYX for the three and nine months ended September 30, 2020, as compared to the comparable periods in 2019, were due to a decrease in sales volumes driven by decreases in prescriptions and lower customer inventory. The increases in product revenues for COMETRIQ for the three and nine months ended September 30, 2020, as compared to the comparable periods in 2019, were due to increases in the number of units of COMETRIQ sold, due to a comparator purchase of the product for use in a clinical trial.

We expect our net product revenues to modestly decrease in 2020, as compared to fiscal 2019.

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 our Annual Report on Form 10-K for the year ended December 31, 2019. The 8% increase in discounts and allowances for the three months ended September 30, 2020, as compared to the comparable period in 2019, was primarily the result of an increase in the dollar amount of chargebacks related to Public Health Service hospitals, and to a lesser extent, an increase in Medicaid utilization and the dollar amount of the related Medicaid rebates. The 16% increase in discounts and allowances for the nine months ended September 30, 2020, as compared to the comparable period in 2019, was primarily the result of an increase in Public Health Service hospital utilization and the dollar amount of the related chargebacks.

We expect our discounts and allowances as a percentage of gross revenues to increase during the remainder of 2020.

License Revenues

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 related period that the milestone would be achieved

and a significant reversal of revenues would not occur, as well as royalty revenues and the profit on the U.S. commercialization of COTELLIC from Genentech.

Milestone revenues, which are allocated between license revenues and collaboration services revenues, were $13.5 million and $57.1 million for the three and nine months ended September 30, 2020, respectively, as compared to $50.6 million and $81.1 million for the comparable periods in 2019. Milestone revenues by period included the following:

- Milestone revenues for the three and nine months ended September 30, 2020 included $9.2 million in revenues recognized in connection with a $10.0 million milestone we expect to achieve upon Takeda's and Ono's submission of a supplemental application to the Japanese MHLW for Manufacturing and Marketing Approval of CABOMETYX in combination with Opdivo for the treatment of patients with unresectable, advanced or metastatic RCC.
- Milestone revenues for the nine months ended September 30, 2020 included $25.3 million in revenues recognized in connection with $31.0 million in milestones we achieved upon Takeda's first commercial sale of CABOMETYX for the treatment of patients with curatively unresectable or metastatic RCC in Japan and $18.9 million in revenues recognized in connection with a $20.0 million development milestone from Ipsen we determined was probable of achievement. The milestone was achieved on October 1, 2020.
- Milestone revenues for the three and nine months ended September 30, 2019 included recognition of a $50.0 million commercial milestone from Ipsen that we earned in the third quarter of 2019 upon Ipsen's achievement of $250.0 million in net sales of cabozantinib in its territories over four consecutive quarters.
- Milestone revenues for the nine months ended September 30, 2019 also included recognition of a $20.0 million milestone from Daiichi Sankyo Company, Limited (Daiichi Sankyo) for the launch of MINNEBRO tablets for the treatment of patients with hypertension in Japan and $9.7 million in revenues recognized in connection with a $16.0 million milestone from Takeda for the submission in April 2019 of a regulatory application for cabozantinib for the treatment of patients with advanced RCC to the Japanese MHLW.

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.

Royalties increased primarily as a result of increases in royalties earned on Ipsen's net sales of cabozantinib outside of the U.S. and Japan. Ipsen royalties were $19.9 million and $54.1 million for the three and nine months ended September 30, 2020, respectively, compared to $16.4 million and $45.3 million for the comparable periods in 2019. Ipsen's net sales of cabozantinib have continued to grow since their first commercial sale of the product in the fourth quarter of 2016, primarily due to increased demand of CABOMETYX, which, as of September 30, 2020, is approved in 55 countries outside of the U.S. Royalties also increased due to the commercial launch of CABOMETYX for the treatment of patients with curatively unresectable or metastatic RCC in Japan by Takeda during the second quarter of 2020.

Our share of profits on the U.S. commercialization of COTELLIC under our collaboration agreement with Genentech was $1.6 million and $4.4 million for the three and nine months ended September 30, 2020, respectively, as compared to $1.1 million and $3.5 million for the comparable periods in 2019. We also earned royalties on ex-U.S. net sales of COTELLIC by Genentech of $1.4 million and $3.8 million for the three and nine months ended September 30, 2020, compared to $1.6 million and $4.4 million for the comparable periods in 2019.

We expect our license revenues to modestly decrease in 2020, as compared to fiscal 2019, as a result of a decrease in milestones expected to be achieved during the year.

Collaboration Services Revenues

Collaboration services revenues include the recognition of deferred revenue 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, product supply revenues, net of product supply costs, and the royalties we paid to GlaxoSmithKline (GSK) on sales by Ipsen of products containing cabozantinib.

Development cost reimbursements were $26.3 million and $60.3 million for the three and nine months ended September 30, 2020, respectively, as compared to $12.0 million and $32.5 million for the comparable periods in 2019. The increases in development cost reimbursements were primarily a result of the reimbursements from Ipsen and Takeda associated with their decision to opt in and co-fund CONTACT-02 and additional cohorts of COSMIC-021 studies in 2020 and their respective share of the increase in spending on the COSMIC-312, COSMIC-021 and CONTACT-02 studies.

Collaboration services revenues were reduced by $2.9 million and $7.6 million for the 3% royalty we are required to pay GSK on the net sales by Ipsen and Takeda of any product incorporating cabozantinib for the three and nine months ended September 30, 2020, respectively, compared to $2.2 million and $6.2 million for the comparable periods in 2019. As royalty generating sales of cabozantinib by Ipsen have increased as described above, our royalty payments to GSK have also increased.

We expect collaboration services revenues to increase in 2020, as compared to fiscal 2019, as a result of higher development cost reimbursements earned under our collaboration agreements.

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
	2020	2019		2020	2019	
Cost of goods sold	$ 8,725	$ 7,537	16 %	$ 27,235	$ 22,577	21 %
Gross margin	95 %	96 %		95 %	96 %	

Cost of goods sold is related to our product revenues and consists primarily of a 3% royalty payable to GSK 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 and excess inventory, and other third-party logistics costs. The increases in cost of goods sold for the three and nine months ended September 30, 2020, as compared to the comparable periods in 2019, were primarily the result of increases in write-downs of excess and expiring inventory and certain period costs. We do not expect our gross margin to change significantly during the remainder of 2020.

Research and Development Expenses

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

	Three Months Ended September 30,		Percent Change	Nine Months Ended September 30,		Percent Change
	2020	2019		2020	2019	
Research and development expenses	$ 176,762	$ 97,295	82 %	$ 393,572	$ 242,516	62 %

Research and development expenses consist primarily of clinical trial costs, personnel expenses, license and other collaboration costs, stock-based compensation, and consulting and outside services.

The increases in research and development expenses for the three and nine months ended September 30, 2020, as compared to the comparable periods in 2019, were primarily related to increases in clinical trial costs, licensing and other collaboration costs, stock-based compensation and personnel expenses, partially offset by the impact of increased development cost reimbursements. Clinical trial costs, which include services performed by third-party contract research organizations and other vendors who support our clinical trials, and comparator drug purchases, increased $34.2 million and $93.6 million for the three and nine months ended September 30, 2020, respectively, as compared to the comparable periods in 2019. The increases in clinical trial costs were primarily due to costs associated with the expanding clinical trial program for cabozantinib, which includes CONTACT-02, COSMIC-313, COSMIC-312, and COSMIC-021. Licensing and other collaboration costs increased $24.9 million and $19.6 million for the three and nine months ended September 30, 2020, respectively, as compared to the comparable periods in 2019, primarily due to increases in upfront license fee payments from recent business development activities with two additional collaboration and license agreements focused on the discovery and development of ADCs. Stock-based compensation increased $14.6 million and $16.4 million for the three and nine months ended September 30, 2020, respectively, as compared to the comparable periods in 2019, primarily due to the determination that a performance target for the PSUs granted in 2019 became probable of achievement. Personnel expenses increased $7.8 million and $22.6 million for the three and nine months ended September 30, 2020, respectively, as compared to the comparable periods in 2019, primarily due to increases in headcount to support our expanding discovery and development efforts.

Research and development expenses for the three and nine months ended September 30, 2020 were reduced by $6.3 million and $11.3 million, respectively, as a result of development cost reimbursements in connection with our collaboration arrangement with Roche; there were no such reimbursements during the comparable periods in 2019.

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 such that we are able 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,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and development expenses:				
Development:				
Clinical trial costs	$ 72,232	$ 38,055	$ 188,182	$ 94,612
Personnel expenses	21,388	14,964	62,286	44,077
Consulting and outside services	4,852	4,084	11,907	10,884
Other development costs	5,836	3,754	15,771	11,824
Total development	104,308	60,857	278,146	161,397
Drug discovery:				
License and other collaboration costs	45,761	20,910	58,013	38,390
Other drug discovery [1]	7,703	6,896	20,844	17,870
Total drug discovery	53,464	27,806	78,857	56,260
Other [2]	18,990	8,632	36,569	24,859
Total research and development expenses	$ 176,762	$ 97,295	$ 393,572	$ 242,516

(1) Primarily includes personnel expenses, consulting and outside services and laboratory supplies.
(2) Includes stock-based compensation, the allocation of general corporate costs to research and development, and development cost reimbursements in connection with our December 2019 collaboration arrangement with Roche.

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 for our drug candidates, the 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 our development efforts primarily on cabozantinib to maximize the therapeutic and commercial potential of this compound and, as a result, we expect that a significant 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 company-sponsored studies resulting from this program include: COSMIC-021 and COSMIC-312, for which Roche is providing atezolizumab free of charge; COSMIC-313, for which BMS is providing nivolumab and ipilimumab free of charge; CONTACT-02 for which Roche is sharing in the development costs including the provision of atezolizumab free of charge; and COSMIC-311.

We also remain committed to building our product pipeline by discovering and developing new therapies for cancer patients. In this regard, we conduct internal drug discovery activities with the goal of identifying new product candidates to advance into clinical trials. In addition, we have augmented our internal drug discovery activities with multiple partnerships, including several that enable us to discover and advance various biologics, such as bispecific antibodies and ADCs, and we continue to engage in business development initiatives aimed at identifying and in-licensing promising, early-stage oncology assets, which we can further develop utilizing our established clinical development infrastructure.

We expect our research and development expenses to increase in 2020, as compared to fiscal 2019, driven by our ongoing clinical evaluation of cabozantinib and business development activities.

The length of time required for clinical development of a particular product candidate and our development costs for that product candidate may be impacted by the scope and timing of enrollment in clinical trials for the product

candidate, our decisions to develop a product candidate for additional indications and whether we pursue development of the product candidate or a particular indication with a collaborator or independently. For example, cabozantinib is being developed in multiple indications, and we do not yet know for how many of those indications we will ultimately pursue regulatory approval. In this regard, our decisions to pursue regulatory approval of cabozantinib for additional indications depend on several variables outside of our control, including the strength of the data generated in our prior, ongoing and potential future clinical trials. Furthermore, the scope and number of clinical trials required to obtain regulatory approval for each pursued indication is subject to the input of the applicable regulatory authorities, and we have not yet sought such input for all potential indications that we may elect to pursue. Even after having given such input, applicable regulatory authorities may subsequently require additional clinical studies prior to granting regulatory approval based on new data generated by us or other companies, or for other reasons outside of our control. As a condition to any regulatory approval, we may also be subject to post-marketing development commitments, including additional clinical trial requirements. As a result of the uncertainties discussed above, we are unable to determine the duration of, or total costs associated with the development of cabozantinib or any of our other research and development projects.

Our potential therapeutic products are subject to a lengthy and uncertain regulatory process that may not result in our receipt of the necessary regulatory approvals. Failure to receive the necessary regulatory approvals would prevent us from commercializing the product candidates affected, including cabozantinib in any additional indications. In addition, clinical trials of our potential product candidates may fail to demonstrate safety and efficacy, which could prevent or significantly delay regulatory approval. A discussion of the risks and uncertainties with respect to our research and development activities, including completing the development of our product candidates, 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
	2020	2019		2020	2019	
Selling, general and administrative expenses	$ 88,185	$ 51,265	72 %	$ 210,916	$ 170,218	24 %

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, 2020, as compared to the comparable periods in 2019, were primarily related to the increases in stock-based compensation and personnel expenses; the increase for the three months ended September 30, 2020 was also related to an increase in marketing costs.

Stock-based compensation increased $27.9 million and $28.7 million for the three and nine months ended September 30, 2020, respectively, as compared to the comparable periods in 2019, primarily due to the determination that a performance target for the PSUs granted in 2019 became probable of achievement. Personnel expenses increased $3.2 million and $10.3 million for the three and nine months ended September 30, 2020, respectively, as compared to the comparable periods in 2019, primarily due to increases in administrative headcount to support our commercial and research development organizations. Marketing costs increased $3.9 million for the three months ended September 30, 2020, as compared to the comparable period in 2019, in preparation for the launch of CABOMETYX in combination with Opdivo for the treatment of patients with advanced RCC.

We expect our selling, general and administrative expenses to increase in 2020, as compared to fiscal 2019, driven by our continued commercial investment in CABOMETYX, the growth of the broader organization and higher stock-based compensation expense.

Non-operating Income

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

	Three Months Ended September 30,		Percent Change	Nine Months Ended September 30,		Percent Change
	2020	2019		2020	2019	
Interest income	$ 3,994	$ 7,191	(44 %)	$ 16,376	$ 20,253	(19 %)
Other income (expense), net	565	(140)	(504 %)	571	688	(17 %)
Non-operating income	$ 4,559	$ 7,051	(35 %)	$ 16,947	$ 20,941	(19 %)

The decreases in non-operating income for the three and nine months ended September 30, 2020, as compared to the comparable periods in 2019, were primarily the result of the decreases in interest income due to lower interest rates.

Provision for (Benefit from) Income Taxes

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

	Three Months Ended September 30,		Percent Change	Nine Months Ended September 30,		Percent Change
	2020	2019		2020	2019	
Provision for (benefit from) income taxes	$ (5,981)	$ 25,205	(124 %)	$ 19,317	$ 60,826	(68 %)
Effective income tax rate	15.7 %	20.5 %		18.8 %	19.4 %	

We recorded an income tax benefit for the three months ended September 30, 2020 as a result of a current period pre-tax loss, as compared to the comparable period in 2019 in which we reported pre-tax income. The decrease in provision for income taxes for the nine months ended September 30, 2020 as compared to the comparable period in 2019, was due the decrease in pre-tax income during the period. The effective tax rate for the three and nine months ended September 30, 2020 differed from the U.S. federal statutory rate of 21% primarily due to excess tax benefits related to the exercise of certain stock options and federal tax credits, offset by non-deductible executive compensation during the periods. The effective tax rate for the three and nine months ended September 30, 2019 differed from the U.S. federal statutory rate of 21% primarily due to excess tax benefits related to the exercise of certain stock options and federal tax credits during the periods.

Liquidity and Capital Resources

As of September 30, 2020, we had $1.5 billion in cash and investments, compared to $1.4 billion as of December 31, 2019. We anticipate that the aggregate of our current cash and cash equivalents, short-term investments available for operations, 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.

We expect to continue to spend significant amounts to fund the continued development and commercialization of cabozantinib. In addition, we intend to continue to expand our product pipeline through our internal drug discovery efforts and the execution of strategic transactions that align with our oncology drug 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 due to market conditions or strategic considerations. The COVID-19 pandemic has caused volatility in the U.S. and global financial markets and a downturn in the U.S. and global economy, which could adversely impact our rates of return for our invested cash resources, the availability and cost of credit, as well as our ability to raise additional funds in the capital markets. Among other things, our inability to access additional funds could in the future inhibit our ability to engage in larger-scale strategic transactions or investments.

Sources and Uses of Cash

Cash flow activities were as follows (in thousands):

	Nine Months Ended September 30,	
	2020	2019
Net cash provided by operating activities	$ 175,689	$ 368,935
Net cash used in investing activities	$ (101,706)	$ (457,046)
Net cash (used in) provided by financing activities	$ (6,438)	$ 15,553

Operating Activities

Cash flows provided by operating activities represent the cash receipts and disbursements related to all of our activities other than investing and financing 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 (Loss), the most significant of which may include the timing of milestones payments from our collaboration partners.

The most significant factors that contributed to the decrease in cash provided by operating activities for the nine months ended September 30, 2020, as compared to the comparable period in 2019, were an increase in cash paid for operating expenses, a $53.0 million decrease in milestone payments received, and other net changes in operating assets and liabilities described above.

Investing Activities

Cash used in investing activities for the nine months ended September 30, 2020 consisted of investment purchases of $867.0 million and purchases of property, equipment and other of $16.1 million, less cash provided by the maturities and sales of investments of $781.3 million.

Cash used in investing activities for the nine months ended September 30, 2019 consisted of investment purchases of $887.7 million and property and equipment purchases of $5.6 million, less cash provided by the maturities and sales of investments of $436.2 million.

Financing Activities

Cash used in financing activities for the nine months ended September 30, 2020 consisted of $26.1 million of withholding taxes paid related to net share settlements of equity awards, partially offset by $19.7 million in proceeds from the issuance of common stock under our equity incentive and stock purchase plans.

Cash provided by financing activities for the nine months ended September 30, 2019 consisted of $19.0 million in proceeds from the issuance of common stock under our equity incentive and stock purchase plans, partially offset by $3.4 million of withholding taxes paid related to net share settlements of equity awards.

Contractual Obligations

There were no material changes outside of the ordinary course of business in our contractual obligations as of September 30, 2020 from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2019.

Off-Balance Sheet Arrangements

As of September 30, 2020, we did not have any material off-balance-sheet arrangements, as defined by applicable SEC regulations.

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 amounts of deferred tax assets and liabilities including the related valuation allowance; the accrual for certain liabilities including accrued clinical trial liabilities; and valuations of equity awards used to determine stock-based compensation, including certain awards with vesting subject to market or performance conditions. We base our estimates on historical experience and on various other market-specific and other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our senior management has discussed the development, selection and disclosure of these estimates with the Audit Committee of our Board of Directors. Actual results could differ materially from those estimates.

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

There have been no significant changes in our critical accounting policies and estimates during the nine months ended September 30, 2020, as compared to the critical accounting policies and estimates disclosed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on February 25, 2020.

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” contained 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, 2020 have not changed significantly from those described in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2019.

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

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. Patent Nos. 8,877,776, 9,724,342, 10,034,873 and 10,039,757, which are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations, also referred to as the *Orange Book.* MSN's initial notice letter did not provide a Paragraph IV certification against U.S. Patent No. 7,579,473, the composition of matter patent, or U.S. Patent No. 8,497,284, a method of use patent. On October 29, 2019, we filed a complaint in the United States District Court for the District of Delaware for patent infringement against MSN asserting 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 U.S. Patent No. 8,877,776 is invalid and not infringed. On May 5, 2020, we received notice from MSN that it had amended its ANDA to assert additional Paragraph IV certifications. The ANDA now requests approval to market a generic version of CABOMETYX tablets prior to expiration of the two previously-unasserted CABOMETYX patents: U.S. Patent No. 7,579,473 and U.S. Patent No. 8,497,284. On May 11, 2020, we filed a complaint in the United States District Court for the District of Delaware for patent infringement against MSN asserting U.S. Patent No. 7,579,473 and U.S. Patent No. 8,497,284 arising from MSN's amended ANDA filing with the FDA. On May 22, 2020, MSN filed its response to the complaint, alleging that each of U.S. Patent No. 7,579,473 and U.S. Patent No. 8,497,284 is invalid and not infringed. Neither of our complaints alleges infringement of U.S. Patent Nos. 9,724,342, 10,034,873 and 10,039,757. In our complaints, we are seeking, among other relief, an order that the effective date of any FDA approval of the ANDA would be a date no earlier than the expiration of all of U.S. Patent No. 7,579,473, U.S. Patent No. 8,497,284 and U.S. Patent No. 8,877,776, the latest of which expires on October 8, 2030, and equitable relief enjoining MSN from infringing these patents. These two lawsuits against MSN have been consolidated, and a bench trial has been scheduled for May 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 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 could be harmed.

Risks Related to Our Business and Industry

Our ability to grow our company is critically dependent upon the commercial success of CABOMETYX in its approved indications and the further clinical development, regulatory approval and commercial success of cabozantinib 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 or 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 has been or 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 cabozantinib to increase the number of cancer patients who could benefit from this medicine. However, we cannot be certain that the clinical trials we and our collaboration partners are currently conducting, or may conduct in the future, 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 we and our collaboration partners receive the required regulatory approvals to market cabozantinib for additional indications, 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 labeled indications in major commercial markets where CABOMETYX is approved, or if we fail to achieve anticipated product royalties and collaboration milestones, whether as a result of the COVID-19 pandemic or otherwise, 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.

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.

Our business could be materially and adversely impacted by the ongoing COVID-19 pandemic, a disease caused by a novel coronavirus, SARS-CoV-2, which has spread globally. To date, the COVID-19 pandemic has had a modest impact on our business operations, in particular on our clinical trial, drug discovery and commercial activities. For example, to varying degrees and at different rates across our clinical trials being conducted in regions impacted by COVID-19, we experienced declines in screening and enrollment activity, delays in new site activations, and restrictions on access to treatment sites that is necessary to monitor clinical study progress and initiation. However, as the COVID-19 pandemic continues to surge in various parts of the world, the impact on our clinical development operations could 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 COSMIC-311, COSMIC-312, COSMIC-313, COSMIC-021, CONTACT-01, CONTACT-02 and CONTACT-03 clinical trials. Disruptions to medical and administrative operations at clinical trial sites 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 delay our clinical trial plans or require certain trials to be temporarily suspended. Moreover, quarantines and travel restrictions have impeded and may continue to impede patient movement or interrupt healthcare services, which we anticipate over time, could also interfere with and potentially negatively impact clinical trial results. In addition, new and 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 administering those clinical trials to increase considerably. Specifically, with respect to our clinical trials evaluating cabozantinib in combination with therapies that must be administered via professional intravenous infusion, such as COSMIC-312, COSMIC-313, COSMIC-021, CONTACT-01, CONTACT-02 and CONTACT-03, limited patient movement or interrupted healthcare services at medical institutions have delayed in some instances and may continue to delay or prevent on-site infusion of the therapies being evaluated in combination with cabozantinib. If a sizable portion of patients in our combination studies are unable or unwilling to receive all components of the combination therapy being tested in accordance with the applicable clinical trial protocol, it could cause those studies to be delayed, suspended or prevented from producing statistically significant results. Depending upon the duration and severity of the COVID-19 pandemic, we could also experience delays in the commencement of new clinical trials of cabozantinib, or our earlier-stage investigative product candidates. The COVID-19 pandemic could also impede internal clinical operations and delay our planning and preparation timelines for new clinical trials, as well as adversely affect our ability to obtain regulatory approval for clinical protocols and increase the operating expenses connected with these new clinical trials.

In addition, the COVID-19 pandemic caused us to suspend internal drug discovery work in our laboratories temporarily while we observed the shelter in place orders issued by the State of California and Alameda County. We also experienced some modest delays with respect to the portion of drug discovery work outsourced to third-party contractors in regions first impacted by COVID-19. While both internal drug discovery work in our laboratories and outsourced drug discovery activities have since partially resumed, we may be unable to maximize the potential of these programs due to reduced staffing and the imposition of increased safety protocols, and should the COVID-19 pandemic grow in severity, we may have to further scale back or suspend activities in the future. For example, as a result of spikes or surges in infection, positivity or hospitalization rates, we may choose or be required to suspend work in our laboratories, which will once again impede our internal drug discovery efforts. Prior to the COVID-19 pandemic, we largely outsourced preclinical development work, as well as certain drug discovery activities, to third-party contractors, and although to date that work has continued without substantial delay or interference, the COVID-19 pandemic could impede these third parties from providing timely deliverables to us in the future. As a result, 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.

While we believe that our commercial business has, to date, only experienced a modest impact related to the COVID-19 pandemic, it remains possible that over a longer period, changes to our standard sales and marketing practices, including the shift from in-person to primarily telephonic and virtual interactions with healthcare professionals, 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.

Although as of the date of this Quarterly Report, we continue to maintain substantial safety stock inventories for our drug substance and drug products and have not experienced production delays or seen significant impairment to our supply chain as a result of the COVID-19 pandemic, our third-party contract manufacturers and suppliers could experience operational delays due to facility closures and other hardships as a result of the COVID-19 pandemic, which could impact our supply chain by potentially causing delays to or disruptions in the supply of our commercial or clinical products or product candidates. These delays or disruptions could be further exacerbated if the COVID-19 pandemic begins to impact essential distribution systems, which could substantially increase delivery times and costs, or otherwise adversely affect our ability to provide our products to customers and clinical trial sites and generate product revenues.

As of the date of this Quarterly Report, we have taken temporary precautions to help mitigate the risk of transmission of the virus, including: reducing the number of our employees working on-site at our Alameda headquarters under enhanced safety and social distancing protocols; suspending all non-essential business travel for our employees; and limiting the circumstances under which our field employees may engage in in-person promotional activities with healthcare professionals. Over a longer period, all of these measures could negatively affect our business operations and prospects in both foreseeable and unforeseeable ways. For instance, requiring employees to work remotely while we adhered to shelter in place orders limited our internal drug discovery activities, and although we have begun to allow our employees to return to our Alameda headquarters under enhanced safety and social distancing protocols, if we are forced to, or determine that we should, resume shelter in place restrictions for an extended period of time, this could eventually cause delays and otherwise negatively impact the effectiveness of these programs and impede our ability to execute on our long-term business plans. Further, extended periods of remote work could impede the focused attention of management or reduce the productivity of teams that would otherwise be working closely together. The COVID-19 pandemic has also caused volatility in the U.S. and global financial markets and a downturn in the U.S. and global economy, which could adversely impact our rates of return for our invested cash resources, the availability and cost of credit, as well as our ability to raise additional funds in the capital markets. Among other things, our inability to access additional funds could in the future inhibit our ability to engage in larger scale strategic transactions or investments.

While we expect the COVID-19 pandemic to continue to have varying degrees of adverse impact on our business operations and, potentially in the future, our financial results, the extent of such adverse impact arising from the COVID-19 pandemic to our business and our financial results, as well as to the value of and market for our common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the U.S. and in other countries, and the effectiveness of actions taken globally to contain and treat the disease. These effects could materially and adversely affect our business, financial condition, results of operations and growth prospects, as further explained in the risks and uncertainties described elsewhere in this ‘‘Risk Factors’’ section. In addition, to the extent the ongoing COVID-19 pandemic adversely impacts our business and financial results, it may also have the effect of exacerbating many of these other risks and uncertainties inherent to our business.

We rely on Ipsen and Takeda for the commercial success of CABOMETYX in its approved indications outside of the U.S., and 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. Further, the operations of our collaboration partners, and ultimately their foreign sales of CABOMETYX, could be adversely affected by the degree and effectiveness of their respective corporate responses to the COVID-19 pandemic, as well as by the imposition of governmental price or other controls, political and economic instability, trade restrictions or barriers and changes in tariffs, escalating global trade and political tensions, or otherwise. 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 ability to grow revenues from sales of CABOMETYX will depend 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, government healthcare payers such as Medicare and Medicaid, commercial healthcare plans and the medical community. Market acceptance for CABOMETYX could depend on 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, the impact to healthcare systems and our ability to successfully communicate product information to healthcare professionals resulting from the COVID-19 pandemic, and changes in pricing and reimbursement for CABOMETYX. If CABOMETYX does not continue to be prescribed broadly for the treatment of its approved RCC and HCC 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 future product candidates.

The biotechnology, biopharmaceutical and pharmaceutical industries are competitive and are characterized by constant technological change and diverse offerings of products, particularly in the area of novel 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 biotechnology, biopharmaceutical and pharmaceutical 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. We believe our future success will depend upon our ability to maintain a competitive position with respect to the shifting landscape of therapeutic strategy following the advent of ICIs. While we have adapted our cabozantinib development strategy to address the use of therapies that combine ICIs with other targeted agents in indications for which CABOMETYX is approved, we cannot ensure that our ongoing or planned clinical trials will show efficacy in comparison to competing product combinations. Moreover, the complexities of such a development strategy have required and are likely to continue to require collaboration with some of our competitors.

If we are unable to maintain or increase our internal 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 such a 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 biotechnology companies seeking to build out and maintain their commercial organizations, as well as other large pharmaceutical and biotechnology 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, or should we have to maintain primarily telephonic and virtual interactions in lieu of in-person meetings with healthcare professionals for an extended period of time as a result of the COVID-19 pandemic, 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 enter into or maintain agreements with third parties to store, distribute and commercialize 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.

Our ability to commercialize our products successfully will depend, in part, on the adequacy of our distribution of those products to eligible patients. We currently rely on third-party providers for storage and distribution and on collaboration partners for ongoing commercialization and distribution of CABOMETYX and COMETRIQ in their respective territories outside of the U.S., as well as for access and distribution activities for the approved products under named patient use programs (or similar programs).

Our current and anticipated future dependence upon the activities, support, and legal and regulatory compliance of third parties may adversely affect our ability to supply CABOMETYX and COMETRIQ on a timely and competitive basis. The services provided by these third parties may not be effective or timely, which risks may be increased as a result of the COVID-19 pandemic. In such cases, we may be unable to maintain, improve or renew our arrangements with these third parties or enter into new, alternative arrangements with other service providers, on acceptable terms or at all. If we are unable to contract successfully for effective third-party services on acceptable terms, our commercialization efforts and those of our collaboration partners may be delayed or otherwise adversely affected, 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 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. If third-party payers do not provide coverage or reimbursement for CABOMETYX or COMETRIQ, our revenues and results of operations will 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.

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 Anti-Kickback Statute, which governs our business activities, including our marketing practices, medical educational programs, pricing policies, and relationships with healthcare providers or other entities;
- the federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations, which prohibit, among other things, the introduction or delivery for introduction into interstate commerce of any drug that is adulterated or misbranded;
- federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- 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, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information on covered entities and business associates that access such information on behalf of a covered entity;
- state law equivalents of each of the above federal laws;

- the Open Payments program of the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act (PPACA), which was created under the Physician Payments Sunshine Act and its implementing regulations and requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the government information related to certain payments and other transfers of value to physicians (as defined by such law) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- 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, as well as state and local laws requiring the registration of pharmaceutical sales representatives; and
- state and federal pharmaceutical price and price reporting laws and regulations that require us to provide notice of price increases or the introduction of new high-cost products, and/or file complex ancillary reports concerning prices and pricing and discount practices.

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. 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, any of which would adversely affect our ability to sell our products and operate our business and also adversely affect our financial results. Of particular concern are suits filed under the civil False Claims Act, known as "*qui tam*" actions, which can be brought by any individual on behalf of the government. Under the False Claims Act, these individuals, commonly known as relators or "whistleblowers," may potentially share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the civil False Claims Act, or settles a lawsuit brought pursuant to the False Claims Act to avoid further prosecution, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, if any such action is brought against us, our business may be impaired, even if we are ultimately successful in our defense.

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, improving quality 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.

We face related uncertainties as a result of efforts to repeal, substantially modify or invalidate some or all of the provisions of the PPACA. Notably, in December 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the penalty enforcing the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. Then, in December 2019, the U.S. Court of Appeals for the 5th Circuit upheld this District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the PPACA are invalid as well. While the U.S. Supreme Court has agreed to review an appeal of the 5th Circuit's decision in November 2020, it is unclear how this decision, future decisions, subsequent appeals and other efforts will impact the PPACA. Additionally, the 2020 federal spending package permanently repealed, effective January 1, 2020, the PPACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device taxes, and, effective January 1, 2021, also eliminates the health insurer tax. Although such efforts have not significantly impacted our business to date, there is no assurance that the repeal, modification or invalidation of some or all of the provisions of the PPACA in the future, will not have a material adverse impact on our business, financial

condition and results of operations, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

In addition, there are pending federal and state-level legislative proposals that would significantly expand 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. It is also possible that additional governmental actions will be taken to address the ongoing COVID-19 pandemic, and that such actions would have a significant impact on these public health insurance programs. While we cannot predict how future legislation (or enacted legislation that has yet to be implemented) will affect our business, such proposals could have the potential to impact access to and sales of our products.

As a result of these developments and trends, third-party payers are increasingly attempting to contain healthcare costs by limiting coverage and the level of reimbursement of new drugs. These entities could refuse, limit or condition coverage for our products, such as by using tiered reimbursement or pressing for new forms of contracting, including, for example, the movement by insurers towards “value-based” contracting, any of which could adversely affect product sales. Furthermore, the expansion of the 340B Drug Discount Program has increased the number of purchasers who claim eligibility for significant discounts on branded drugs, including our marketed products. Due to the current volatility in regulatory and market dynamics, 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, any such measures could have 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. These activities may result in actions that have the effect of reducing our revenue or harming our business or reputation.

There have been several recent 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 the prices that Medicare reimburses for physician-administered drugs to the prices of drugs in other countries); reform the structure and financing of Medicare Part D pharmaceutical benefits, including through increasing manufacturer contributions to offset Medicare beneficiary costs; bring more transparency to drug pricing rationale and methodologies; revise rebate payments for prescription drugs under Medicaid and the methodologies to calculate average manufacturer price and best price; and facilitate the importation of certain lower-cost drugs from other countries. While we cannot know the final form of any such legislative, regulatory and/or administrative measures, some of the pending legislative proposals or executive rulemaking, such as those incorporating International Pricing Index or Most-Favored-Nation models, if enacted, 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.

In connection with its evaluation of proposals concerning the pricing of, and access to, pharmaceutical products, many companies in our industry have received governmental requests for documents and information relating to drug pricing and patient support programs. We could receive a similar request, which would require us to incur significant expense and divert the attention of management. Additionally, to the extent there are findings, or even allegations, of improper conduct on the part of the company, these findings could further harm our business, reputation and/or prospects.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological 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. For example, California adopted SB-17, which requires, among other provisions, pharmaceutical manufacturers to provide advance notice of price increases above a defined threshold to certain purchasers and related reports to the government. Such obligations to provide notices of price increases to purchasers 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 general and administrative costs and/or diminish our revenues as a result of the imposition of caps on pricing and price increases. Therefore, the implementation of these cost-containment measures or other healthcare reforms may result in fluctuations in our results of operations and limit our ability to generate product revenue or commercialize our products.

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., particularly in the EU, the pricing and reimbursement of prescription pharmaceuticals is generally subject to governmental control. In EU 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 partner Ipsen may also be required to conduct a study 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, could decrease the price we and Ipsen might establish for CABOMETYX, which would result in lower license revenues to us.

A significant and prolonged economic downturn, whether globally or just within the U.S., could have a substantial impact on our revenues and financial condition.

Our revenues are substantially dependent on the net pricing that we ultimately realize in payment for our marketed products, and commercial third-party payers do not receive the same degree of discounts and allowances that we provide to government payers. In the event of a significant and prolonged economic downturn, the number of patients enrolled in commercial health insurance programs is likely to decrease, particularly in the U.S. where workforce reductions could cause widespread loss of the private health insurance coverage typically provided by employers, and a commensurate shift of eligible individuals to government insurance programs or to the circumstance of lacking health insurance coverage altogether. The effects of the COVID-19 pandemic, among other catalysts, have already caused a downturn in the U.S. and global economy and significant levels of unemployment, and the duration and severity of this economic downturn are not yet known. Depending on the duration and severity of the COVID-19 pandemic, as well as other factors, we could experience a substantial decrease in revenues as a result of the increase in gross-to-net discounting applied to the price of our products due to a substantial shift from private health insurance coverage to government insurance coverage, and also a significant increase in demand for our patient assistance and/or free drug program, all or any of which would adversely affect our product revenues.

Enhanced governmental and private scrutiny over, or investigations or litigation involving, pharmaceutical manufacturer donations to patient assistance programs offered by charitable foundations 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 U.S. Department of Health and Human Services Office of Inspector General established specific 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. 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 and other enforcement authorities seeking information related to their patient assistance programs and support. Should we 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 globally and in the U.S. For example, the California Consumer Privacy Act of 2018 (CCPA) went into operation on January 1, 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. Similar legislative proposals are being advanced in other states and Congress is also considering federal privacy legislation. In addition, most healthcare providers are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA, we could be subject to criminal penalties if we knowingly encourage, assist or otherwise facilitate a HIPAA-covered entity (or its business associate) to 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, 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 restricts 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 and GDPR, we could be subject to sanctions or other penalties, litigation or an increase in our cost of doing business.

Legislation and regulatory action designed to facilitate the development, approval and adoption of generic drugs in the U.S., and the entrance of generic competitors, could limit the commercial potential of our products, which could have a material adverse impact on our business, financial condition and results of operations.

Under the 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 whole or in part on the agency's findings of safety and/or effectiveness for a previously approved drug. Both the ANDA and 505(b)(2) processes are discussed in more detail under "Item 1. Business—Government Regulation—FDA Review and Approval" in our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on February 25, 2020. In either case, if an ANDA or 505(b)(2) 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 and divert the attention of management, and could have an adverse impact on our stock price. For example, we received Paragraph IV certification notice letters from MSN concerning the ANDA that it had filed with the FDA seeking approval to market a generic version of CABOMETYX tablets. It is possible that MSN or other companies, following FDA approval of an ANDA or 505(b)(2) NDA, 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 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 could significantly decrease our revenues and thereby materially harm our business, financial condition and results of operations.

The U.S. federal government has also taken numerous legislative and regulatory actions to expedite the development and approval of generic drugs and biosimilars. In August 2017, President Trump signed the FDA Reauthorization Act of 2017, which reauthorized the FDA user fee programs for prescription drugs, generic drugs, medical devices, and biosimilars, under which applicants for such products partially pay for the FDA's pre-market review of their product candidates and pay other specified fees. The legislation also includes, *inter alia,* measures to expedite the development and approval of generic products, where generic competition is lacking even in the absence of exclusivities or listed patents. In addition, 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, and the FDA has taken steps to implement this plan. Moreover, both Congress and the FDA are considering 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 Creating and Restoring Equal Access To Equivalent Samples (CREATES) Act of 2019, signed into law as part of the 2019 year-end federal spending package, purports to promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar versions of those drugs and biological products, including by allowing generic manufacturers access to branded drug samples. While the FDA has yet to issue guidance on the provisions of CREATES, 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.

Clinical testing of cabozantinib for new indications, or of new potential product candidates, is a lengthy, costly, complex and uncertain process and may fail to demonstrate safety and efficacy.

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 that product for a particular 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 (or of other product candidates) in new indications, and in some cases, as described in the risk factor titled, "*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 COVID-19 pandemic has already increased and may further increase the potential for such developments to occur. These 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 trial sites;
- lower-than-anticipated patient registration or enrollment in our clinical testing;
- 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;
- 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, 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.

If there are further delays in or termination of the clinical testing of cabozantinib or our other product candidates due to any of the events described above or otherwise, including as a result of the COVID-19 pandemic, 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 cabozantinib 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 cabozantinib 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 may not result in an approvable product. The duration and the cost of clinical trials vary significantly as a result of factors relating to the clinical trial, including, among others: 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 trials; 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. Our partners under our collaboration agreements may experience similar risks with respect to the compounds we have out-licensed to them. If any of the events described above were to occur with such programs or compounds, the likelihood of receipt of milestones and royalties under such collaboration agreements could decrease.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy and uncertain and may not result in regulatory approvals for cabozantinib or 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 cabozantinib 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 authorities in other countries. 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 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. For example, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of cabozantinib for any individual additional indications. 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 our other product candidates.

Even if the FDA or a comparable authority in another jurisdiction approves cabozantinib for one or more new indications, 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-approval 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 in one or more new indications. For example, based on the regulatory feedback from the FDA, and if supported by the clinical data from COSMIC-021, we intend to file with the FDA for accelerated approval of cabozantinib in an mCRPC indication as early as 2021. We expect that as a condition of any potential approval under the FDA's accelerated approval pathway, the FDA will require us to perform confirmatory post-marketing clinical trials to confirm the clinical benefit, if any, of cabozantinib in combination with Roche's atezolizumab in patients with locally advanced or metastatic solid tumors, such as mCRPC. Failure to complete any post-marketing requirements 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 in any additional indications. Further, these regulatory agencies could also impose various administrative, civil or criminal sanctions for failure to comply successfully with regulatory requirements, including withdrawal of product approval.

In addition, on March 27, 2020, Congress enacted the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) in response to the COVID-19 pandemic. Amongst other provisions, the CARES Act made a number of changes to the FDCA aimed at preventing drug shortages. While we are still evaluating these and other CARES Act changes, these changes could impact our business. For example, in light of the COVID-19 pandemic, the FDA has issued a number of guidance documents describing the agency's expectations for how drug manufacturers should comply with various FDA requirements during the pandemic, including with respect to conducting clinical trials, distributing drug samples, and reporting post-marketing adverse events. In addition, as a result of the COVID-19 pandemic, there has been increasing political and regulatory scrutiny of foreign-sourced drugs and foreign drug supply chains, resulting in proposed legislative and executive actions to incentivize or compel drug manufacturing operations to relocate to the United States. These political and regulatory developments and any further guidance documents issued by FDA that impact the requirements to which we are subject, as well as any equivalent federal or state legislative or regulatory initiatives, or similar measures outside of the United States, could have a material adverse impact on our business, financial condition and results of operations.

We may be unable to expand our 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 internal drug discovery activities with the goal of identifying new product candidates to advance into clinical trials. Notwithstanding this investment, we temporarily suspended internal drug discovery in our laboratories due to the COVID-19 pandemic, among other limitations to our programs described in the risk factor titled, "*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.*" While we have since partially resumed our drug

discovery operations, even assuming we successfully return these operations to full capacity in the future, 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 internal 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. However, the in-licensing and acquisition of product candidates is a highly competitive area, and many other companies are pursuing the same or similar product candidates 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 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, the competitive business environment may result in higher acquisition or licensing costs, and our investment in these potential products 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, or retain key personnel of an acquired business. Furthermore, we could assume unknown or contingent liabilities or 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 internal drug discovery or business development efforts do not result in suitable product candidates, our business and prospects for growth could suffer.

Increasing use of social media could give rise to liability and result in harm to our business.

We and our employees are increasingly utilizing social media tools and our website as a means of communication. For example, we use Facebook and Twitter to communicate with the medical community and the investing public, although we do not intend to disclose material, nonpublic information through these means. Despite our efforts to monitor social media communications, there is risk that the unauthorized use of social media by us or our employees to communicate about our products or business, or any inadvertent disclosure of material, nonpublic information through these means, may result in violations of applicable laws and regulations, which may give rise to liability and result in harm to our business. In addition, there is also risk of inappropriate disclosure of sensitive information, which could result in significant legal and financial exposure and reputational damages that could potentially have a material adverse impact on our business, financial condition and results of operations. Furthermore, negative posts or comments about us or our products on social media could seriously damage our reputation, brand image and goodwill.

Risks Related to Our Capital Requirements, Accounting and Financial Results

Our profitability could be negatively impacted by our extensive clinical development, business development and commercialization activities for cabozantinib and pipeline expansion efforts relative to the revenues we generate.

Although we reported net income of $83.4 million for the nine months ended September 30, 2020 and $321.0 million for the year ended December 31, 2019, respectively, we reported a net loss of $32.0 million for the three months ended September 30, 2020. We may not be able to resume, 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.; achievement of clinical, 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 for development and commercialization activities for cabozantinib and for any pipeline expansion efforts. We expect to continue to spend substantial amounts to fund the continued development of cabozantinib for additional indications and the commercialization of our approved products. In addition, we intend to continue to expand our product pipeline through our internal drug discovery efforts and the execution of additional partnerships through business development activities or 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.

Our financial outlook may not be realized.

From time to time, in press releases and otherwise, we may publish estimates, forecasts or other forward-looking statements regarding our future financial or operating results, including estimated revenues, expenses and earnings. Any forecast of our future performance reflects various assumptions. These assumptions are subject to significant risks and uncertainties, and as a matter of course, any number of them may prove to be incorrect. Further, the achievement of any forecast depends on numerous assumptions and other factors (including those described in this discussion), many of which are beyond our control. Moreover, the impact of the COVID-19 pandemic on our profitability, especially if it is further prolonged or grows in severity, is difficult to predict. As a result, we cannot be certain that our performance will be consistent with any management estimates or forecasts or that the variation from such estimates or forecasts will not be material and adverse. Current and potential stockholders are cautioned not to base their entire analysis of our business and prospects upon isolated estimates or forecasts, but instead are encouraged to utilize our entire publicly available mix of historical and forward-looking information, as well as other available information regarding us, our products, the competitive landscape for our products, our commercialization, development and regulatory efforts, as well as those of our collaboration partners, and the biotechnology and pharmaceutical industry generally when evaluating our prospective financial or operating results.

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.

Cash and investments were $1.5 billion as of September 30, 2020, compared to $1.4 billion as of December 31, 2019. Our business operations grew substantially during 2019 and the first nine months of 2020. In order to maintain business growth during the remainder of 2020, we plan to continue to execute on our U.S. commercialization plans for CABOMETYX, while reinvesting in our product pipeline through the continued development of cabozantinib and our other product candidates, internal discovery activities, and the execution of strategic transactions. Our ability to achieve these business objectives will depend on many factors including but not limited to:

- the commercial success of both CABOMETYX and COMETRIQ and the revenues we generate from those approved products;
- costs associated with maintaining our expanded sales, marketing, market access, medical affairs and product distribution capabilities for CABOMETYX and COMETRIQ;
- the achievement of stated regulatory and commercial milestones and royalties paid under our collaboration agreements with Ipsen and Takeda;
- the commercial success of and revenues generated by products marketed under our collaboration and license agreements;
- future clinical trial results;
- the impact of the COVID-19 pandemic on our ability to conduct critical business operations, including internal drug discovery activities, clinical trials and commercial operations;
- the level of our investments in the expansion of our pipeline through internal drug discovery and business development activities;
- the number and size of clinical trials we conduct and the cost of drug supply for such clinical trials evaluating our products with other therapeutic agents;
- trends and developments in the pricing of oncologic therapeutics in the U.S. and abroad, especially in the EU;
- scientific developments in the market for oncologic therapeutics and the timing of regulatory approvals for competing oncologic therapies; and
- the filing, maintenance, prosecution, defense and enforcement of patent claims and other intellectual property rights.

Our commitment of cash resources to CABOMETYX and the reinvestment in our product pipeline through the continued development of cabozantinib and increasing internal drug discovery activities, as well as through the execution of strategic 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 economic conditions and financial, business and other

factors beyond our control. Disruptions in the U.S. and global financial markets, including disruptions that have resulted and may continue to result from the COVID-19 pandemic and the related downturn in the U.S. and global economy, as well as future potential U.S. federal government shutdowns, rising interest rate environments, increased or changed tariffs and trade restrictions or otherwise, may adversely impact the availability and cost of credit, as well as our ability to raise additional funds in the capital markets. Economic and capital markets conditions have been, and continue to be, volatile. Continued instability in these market conditions may limit our ability to access the capital necessary to fund and grow our business. In particular, our inability to access additional funds, whether due to the COVID-19 pandemic or otherwise, could in the future inhibit our ability to engage in larger scale strategic transactions or investments. 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.

Our financial results are impacted by management's selection of accounting methods, certain assumptions and estimates and future changes in accounting standards.

Our accounting policies and methods are fundamental to how we record and report our financial condition and results of operations. Our management must exercise judgment in selecting and applying many of these accounting policies and methods so they comply with generally accepted accounting principles and reflect management's judgment of the most appropriate manner to report our financial condition and results of operations. In some cases, management must select the accounting policy or method to apply from two or more alternatives, any of which may be reasonable under the circumstances, yet may result in our reporting materially different results than would have been reported under a different alternative.

Certain accounting policies are critical to the presentation of our financial condition and results of operations. We believe our critical accounting policies relating to revenue recognition, clinical trial accruals, inventory, stock-based compensation and income taxes reflect the more significant estimates and judgments used in the preparation of our Consolidated Financial Statements. Although we base our estimates and judgments on historical experience, our interpretation of existing accounting literature and on various other assumptions that we believe to be reasonable under the circumstances, if our assumptions prove to be materially incorrect, actual results may differ materially from these estimates.

In addition, future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our financial position or results of operations. New pronouncements from the Financial Accounting Standards Board and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future and, as a result, we may be required to make changes in our accounting policies. Those changes could adversely affect our reported revenues and expenses, our other results of operations or our current financial position.

Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts.

We are subject to income tax in the U.S. as well as numerous U.S. states and territories, municipalities, and other local jurisdictions. As a result, our effective tax rate is derived from various factors including the mix of forecast and actual earnings and applicable tax rates in the various places that we operate, the accounting for stock options and stock-based awards, and research and development spending. In preparing our financial statements, we estimate the amount of tax that will become payable in each jurisdiction. Our effective tax rate, however, may be different than experienced in the past due to numerous factors, including changes in tax laws, changes in the mix of our earnings from state to state, the results of examinations and audits of our tax filings, or our inability to secure or sustain acceptable agreements with tax authorities. Any of these factors could cause our effective tax rate to fluctuate.

Our ability to use net operating losses and tax credits to offset future taxable income may be subject to limitations.

As of December 31, 2019, we had federal and, subject to the recent California franchise tax law change affecting California state net operating losses mentioned below, state net operating loss carryforwards of approximately $675 million. Portions of the federal and state net operating loss carryforwards will begin to expire, if not utilized, beginning in 2035 for federal income tax purposes and 2020 for state income tax purposes. Portions of these net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Internal Revenue Code (the Code) and similar state provisions, certain substantial changes in our ownership could result in an annual

limitation on the amount of net operating loss carryforwards that can be utilized in future years to offset future taxable income. The annual limitation may result in the expiration of a portion of our net operating losses and credit carryforwards before utilization. Based on our review and analysis, we concluded, as of December 31, 2019, that an ownership change, as defined under Section 382, had not occurred. However, if there is an ownership change under Section 382 of the Code in the future, we may not be able to utilize a material portion of our net operating losses. Furthermore, our ability to utilize our net operating losses is conditioned upon our maintaining profitability and generating U.S. federal taxable income. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited. For example, California recently imposed limits on the usability of California state net operating losses to offset taxable income in tax years beginning after 2019 and before 2023.

The United Kingdom's (UK's) withdrawal from the EU may have a negative effect on global economic conditions, financial markets and our business.

Following the ratification of the Withdrawal Agreement by the European Parliament and UK Parliament, the UK left the EU on January 31, 2020 (commonly referred to as "Brexit"). The Withdrawal Agreement provides for a transition period until December 31, 2020, during which the UK remains in the single market and customs union and the free movement of goods, services, people and capital will continue, in order to ensure frictionless trade and business continuity until a long-term relationship is agreed. At the end of transition, the UK's relationship with the EU will be determined by the new agreements it has entered into on trade and other areas of cooperation. The new agreements must be reached before the transition period ends. If not, the UK would have to rely on previous international conventions for security cooperation and would trade with the EU on World Trade Organization terms. The exception is Northern Ireland, whose trade in goods with the EU would be covered by the provisions in the Northern Ireland Protocol. As a result of the COVID-19 pandemic, planned negotiating rounds for the UK's future relationship with the EU have not been progressing at a pace that would facilitate a final agreement on trade and cooperation between the UK and the EU prior to December 31, 2020. Under the formal withdrawal arrangements between the UK and the EU, the parties had until June 30, 2020 to agree to extend the transition period if required, and no such extension was agreed prior to such date. Under these circumstances, it is uncertain whether the UK and EU would agree to extend the transition period beyond December 31, 2020. Given the lack of comparable precedent, it is unclear what financial, trade, regulatory and legal implications Brexit will have and how it might affect us. For example, we rely on third-party contract manufacturing organization facilities located in the UK, responsible for packaging, labeling, storing and subsequently distributing supplies of our product to the EU. Any tariffs, differing regulatory requirements and other restrictions on the free movement of goods between the UK and the EU that ultimately result from Brexit may have an adverse impact on this part of our supply chain. Trade restrictions, changes to the regulatory approval or drug cost reimbursement systems, and additional administrative costs may impede the ability of our collaboration partner Ipsen to market our products in Europe. Furthermore, the initial announcement of Brexit caused significant volatility in global stock markets and currency exchange rate fluctuations; therefore, the Brexit transition may continue to adversely affect European and global economic and market conditions, which may cause third-party payers, including governmental organizations, to closely monitor their costs and reduce their spending budgets, and which could contribute to instability in the global financial and foreign exchange markets. Any of these effects of Brexit could have a material adverse impact on our business, financial condition and results of operations.

Risks Related to Our Relationships with Third Parties

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

We have established clinical and commercial collaborations with leading biotechnology, biopharmaceutical and pharmaceutical companies, including, Ipsen, Takeda, Roche and Genentech, BMS and Daiichi Sankyo, for the development and commercialization of our products, and our dependence on these collaboration partners subjects us to, a number of risks, including:

- 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 negligent 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 (including as a result of the COVID-19 pandemic), 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, including, without limitation, difficulties arising from the impact of the COVID-19 pandemic which prevent them from fulfilling their obligations under our agreements;
- our collaboration partners' inability to obtain regulatory approvals in a timely manner, or at all; 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 upon companies with which we have entered into in-licensing collaborations and similar business development relationships.

To expand our early-stage product pipeline, we have augmented our internal drug discovery activities with multiple in-licensing collaborations with smaller, discovery-focused biotechnology companies, including Aurigene, Iconic, StemSynergy, Invenra, Catalent and NBE. Our dependence on our relationships with these in-licensing partners subjects us to numerous risks, including:

- our 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 collaboration partners that result in the delay or termination of research activities with respect to the licensed assets;
- the possibility that our in-licensing partners may experience financial difficulties, including, without limitation, difficulties arising from the impact of the COVID-19 pandemic, which prevent them from fulfilling their obligations under our agreements;
- our 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; and
- our 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 potential 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 (including NCI-CTEP, a department of the National Institutes of Health, with whom we have our CRADA), 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, whether as a result of the COVID-19 pandemic or otherwise, 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 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 or other product candidates beyond currently approved indications. 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 further our internal drug discovery efforts, which would impede our ability to identify, develop and commercialize our potential product candidates.

We lack internal manufacturing capabilities necessary for us to produce materials required for certain preclinical activities and produce our products for clinical development or for commercial sale and rely on third parties to do so, which subjects us to various risks.

We do not own or operate manufacturing facilities, distribution facilities or resources 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 that, on our behalf, manufacture preclinical, clinical and commercial supplies of our products. As our operations continue to grow in these areas, we continue to appropriately expand our supply chain through secondary third-party contract manufacturers 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 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, including as a result of the COVID-19 pandemic. Although as of the date of this Quarterly Report, we continue to maintain substantial safety stock inventories for our drug substance and drug products and have not experienced production delays or seen significant impairment to our supply chain as a result of the COVID-19 pandemic, our third-party contract manufacturers and suppliers could experience operational delays due to facility closures and other hardships as a result of the COVID-19 pandemic, which could impact our supply chain by potentially causing delays to or disruptions in the supply of our commercial or clinical products or product candidates. If our third-party contract manufacturers 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 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

As part of our collaboration agreements with Ipsen and Takeda, we are responsible for the supply of CABOMETYX and COMETRIQ for global development and commercial purposes. Failure to meet our supply obligations under these collaboration agreements could impair our partners' ability to successfully develop and commercialize CABOMETYX and COMETRIQ and generate revenues to which we are entitled under the collaborations.

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 internal 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 external factors, 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 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 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. Such vulnerabilities may be further exacerbated by the fact that our workforce is operating remotely as we comply with shelter in place orders and the recent rise in COVID-19 phishing attacks targeting remote workers. 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.

Numerous companies have been subject to a wide variety of security incidents, cyber attacks (including through use of ransomware) and other attempts to gain unauthorized access or otherwise compromise information technology systems. In fact, although the aggregate impact of cyber attacks on our operations and financial condition has not been material to date, we and our third-party vendors have frequently been the target of threats of this nature and expect them to continue. These threats can come from a variety of sources, ranging in sophistication from an individual hacker to a state-sponsored attack, and such threats can also vary in motive (including corporate espionage). Cyber attacks continue to become more prevalent and much harder to detect and defend against, and it is often difficult to anticipate or immediately detect such incidents and the damage caused by such incidents. These data breaches and any 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. Any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients or employees, could harm 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 vendors 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 concerning the ANDA that it had filed with the FDA seeking approval to market a generic version of CABOMETYX tablets. Should MSN 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. 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 Europe, have compulsory licensing laws 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 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 rely on trade secret protection for some of our confidential and proprietary information. We have taken security measures to protect our proprietary information and trade secrets, but these measures may not provide adequate protection. While we seek to protect our proprietary information by entering into confidentiality agreements with employees, partners and consultants, 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, 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 that a successful claim of patent infringement is brought against us, 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.

We may be subject to damages resulting from claims that we, our employees or independent contractors have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees and independent contractors were previously employed at universities or other biotechnology, biopharmaceutical or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that we or these employees or independent contractors have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or used or sought to use patent inventions belonging to their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and divert the attention of management. If we fail in defending such claims, in addition to paying damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel and/or their work product could hamper or prevent our ability to develop or commercialize certain product candidates, which could have a material adverse impact on our business, financial condition and results of operations.

Risks Related to Employees and Location

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. 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 expect that we may need 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, including as result of the COVID-19 pandemic or otherwise, 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 program for cabozantinib and our other product candidates, successfully executing upon our commercialization plan for cabozantinib and our internal 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. Similarly, the COVID-19 pandemic could negatively impact the health of key personnel or make it difficult to recruit qualified personnel for critical positions. Further, all of our employees are employed “at will” and, therefore, may leave our employment at any time.

Our operations might be interrupted by the occurrence of a natural disaster or other catastrophic event.

Our headquarters in Alameda, California is located in the San Francisco Bay Area, and therefore our facilities are vulnerable to damage from earthquakes. Our earthquake insurance may not cover all of the damage we may suffer in the event of an earthquake. We are also vulnerable to damage from other types of disasters, including fires and floods, which have become a significant danger in California during recent years, as well as power loss, communications failures, aircraft disasters (due to the proximity of our headquarters to a major international airport), terrorism and similar events, and any insurance we may maintain may be inadequate to cover our losses. If any disaster were to occur, our ability to operate our

business at our facilities could be seriously, or potentially completely, impaired, causing significant delays in our programs and making it difficult for us to recover due to the unique nature of our research activities. Accordingly, an earthquake or other disaster could have a material adverse impact on our business, financial condition and results of operations.

Facility security breaches may disrupt our operations, subject us to liability and harm our operating results.

Any break-in or trespass at our facilities that results in the misappropriation, theft, sabotage or any other type of security breach with respect to our proprietary and confidential information, including research or clinical data, or that results in damage to our research and development equipment and assets, or that results in physical or psychological harm to any of our employees, could subject us to liability or otherwise have a material adverse impact on our business, financial condition and results of operations.

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, and such liability may exceed our insurance coverage and our total assets. 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. These claims might be made directly by consumers, healthcare providers, pharmaceutical companies or others selling or testing our products. We have obtained limited product liability insurance coverage for our clinical trials and commercial activities for cabozantinib in the amount of $20.0 million per occurrence and $20.0 million in the aggregate. However, our insurance may not reimburse us or 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. On occasion, juries have awarded large judgments in class action lawsuits for claims based on drugs that had unanticipated side effects. In addition, the biotechnology, biopharmaceutical and pharmaceutical industries, in general, have been subject to significant medical malpractice litigation. A successful product liability claim or series of claims brought against us could harm our reputation and business and would decrease our cash reserves.

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 we believe the trading price of our common stock will remain highly volatile and may fluctuate substantially due to factors such as the following, many of which we cannot control:

- the announcement of FDA approval or non-approval, or delays in the FDA review process with respect to cabozantinib, our collaboration partners' product candidates being developed in combination with cabozantinib, 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 cabozantinib or any of our other programs or product candidates;
- our ability to make future investments in the expansion of our pipeline through internal drug discovery and business development activities;
- 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;
- actions taken by regulatory agencies, both in the U.S. and abroad, with respect to cabozantinib or our clinical trials for cabozantinib;
- 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 ANDA, 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;
- the impairment of acquired goodwill and other assets;
- 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 biotechnology, biopharmaceutical or pharmaceutical 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;
- significant fluctuations in interest rates or foreign currency exchange rates; and
- general market, economic and political conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors, such as the impact of the COVID-19 pandemic on financial markets.

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 economic conditions, including the effects of the COVID-19 pandemic, policies governing foreign trade and healthcare spending and delivery, or future potential U.S. federal government shutdowns, 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 instituted. 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	Amended and Restated Certificate of Incorporation of Exelixis, Inc.	10-K	000-30235	3.1	3/10/2010	
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Exelixis, Inc.	10-K	000-30235	3.2	3/10/2010	
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Exelixis, Inc.	8-K	000-30235	3.1	5/25/2012	
3.4	Certificate of Change of Registered Agent and/or Registered Office of Exelixis, Inc.	8-K	000-30235	3.1	10/15/2014	
3.5	Certificate of Ownership and Merger Merging X-Ceptor Therapeutics, Inc. with and into Exelixis, Inc.	8-K	000-30235	3.2	10/15/2014	

Exhibit Number	Exhibit Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit/ Appendix Reference	Filing Date	
3.6	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Exelixis, Inc.	8-K	000-30235	3.1	5/23/2019	
3.7	Amended and Restated Bylaws of Exelixis, Inc.	8-K	000-30235	3.1	2/20/2020	
4.1	Specimen Common Stock Certificate	S-1, as amended	333-96335	4.1	4/7/2000	
10.1*	Third Amendment dated September 3, 2020, to the Collaboration and License Agreement dated January 30, 2017, by and between Exelixis, Inc. and Takeda Pharmaceutical Company Limited.					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
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
104	Cover Page Interactive Data File	Formatted as Inline XBRL and contained in Exhibit 101.				

* Portions of this exhibit have been omitted as being immaterial and would be competitively harmful if publicly disclosed.

‡ 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 5, 2020
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)

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Exhibit 10.1

THIRD AMENDMENT TO COLLABORATION AND LICENSE AGREEMENT

This **Third Amendment to the Collaboration and License Agreement** (the "**Amendment**") is entered into as of September 3, 2020 (the "**Amendment Effective Date**") by and between Exelixis, Inc., a Delaware company having an address at 1851 Harbor Bay Parkway, Alameda, CA, 94502, USA ("**Exelixis**") and Takeda Pharmaceutical Company Limited, a Japanese corporation with principal offices located at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, JAPAN ("**Collaborator**"). Exelixis and Collaborator may be referred to herein individually as a "**Party**" or collectively as the "**Parties**".

Recitals

Whereas, Exelixis and Collaborator are Parties to the Collaboration and License Agreement dated January 30, 2017, as amended on March 22, 2018, and May 7, 2019 (the "**License Agreement**"), under which the Parties have been collaborating on the development and commercialization of cabozantinib in Japan; and

Whereas, the Parties desire to enter into this Amendment to modify certain cost sharing obligations payable under the License Agreement on the terms and conditions set forth below.

Now, Therefore, in consideration of the foregoing premises and the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Tier 2 Indication

1.1 Section 1.79 of the License Agreement is hereby deleted in its entirety and replaced with the following:

1.79 "Tier 2 Indication" means [*].

2. Development Costs

2.1 Section 4.5(a) of the License Agreement is hereby deleted in its entirety and replaced with the following:

4.5 (a) Collaborative Work Costs.

(i) Except as set forth in Section 4.5(a)(ii) below, Exelixis shall be responsible for eighty percent (80%) and Collaborator shall be responsible for twenty percent (20%) of all Development Costs for any Development activities (including Clinical Trials) set forth in the GDP other than Independent Work, Collaborator Local Development Work and/or Exelixis Local Development Work (the "**Collaborative Work**"). For the avoidance of any doubt, such Development Costs with respect to the Collaborative Work shall include work performed by temporary workers and contractors on applicable activities and all Allowable Increases. For the purpose of this Section 4.5(a), "**Allowable Increases**" are defined as increased Development Costs in connection with the Collaborative Work resulting from (A) changes in study design after the Effective Date that are approved by the JDC [*] (up to the amount of a mutually-agreed budget increase), (B) changes in regulatory requirements arising after the Effective Date (including changes required or recommended by Regulatory Authorities, but excluding changes required or recommended specifically by a Regulatory Authority of the Exelixis Territory solely for the benefit of the Exelixis Territory), or (C) extensions in the duration of Clinical Trials resulting from a lower than anticipated patient accrual rate, rate of clinical events, or higher rates of survival. The Parties' foregoing Development Cost obligations with respect to the Collaborative Work (including Allowable Increases, if any) are subject to a maximum payment obligation of [*] of the amount specified in the Development

Budget (the "**Budget Cap**"). For clarification, notwithstanding Section 3.2(f), in the event that the Collaborative Work is conducted in accordance with the GDP and within the Budget Cap, no amendment of the Development Budget shall be required. In the event that Development Costs are expected or anticipated to exceed the Budget Cap, the Party conducting the applicable Clinical Trial shall notify the other Party and the JDC shall meet to discuss amending the Development Budget.

(ii) Notwithstanding the foregoing subsection (i), for the Clinical Trials identified in subsections (A), (B) and (C) below in the Collaborator Territory (together, the "**CONTACT Trials**"), the Parties shall be responsible, except for Third Party Work (defined herein below), for all Development Costs associated with such CONTACT Trials as such costs are described below, and shall have such further rights and responsibilities associated with the CONTACT Trials as further described in the [*].

A. Phase 3 Clinical Trial: CONTACT-01, Protocol Title: A Phase III, Multicenter, Randomized, Open-Label, Controlled Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of Atezolizumab Given in Combination with Cabozantinib Versus Docetaxel Monotherapy in Patients with Metastatic Non-Small Cell Lung Cancer Previously Treated with an Anti-PD-L1/PD-1 Antibody and Platinum-Containing Chemotherapy (Protocol Number GO41892);

B. Phase 3 Clinical Trial: CONTACT-02, Protocol Title: A Phase III, Randomized, Open-Label, Controlled Study of Cabozantinib (XL184) in Combination with Atezolizumab vs Second Novel Hormonal Therapy (NHT) in Subjects with High-Risk, Metastatic Castration-Resistant Prostate Cancer (Protocol Number XL184-315);

C. Phase 3 Clinical Trial: CONTACT-03, Protocol Title: A Phase III, Multicenter, Randomized, Open-Label Study to Evaluate the Efficacy and Safety of Atezolizumab Given in Combination with Cabozantinib Versus Cabozantinib Alone in Patients with Inoperable, Locally Advanced, or Metastatic Renal Cell Carcinoma Who Experienced Radiographic Tumor Progression During or After Immune Checkpoint Inhibitor Treatment (Protocol Number WO41994).

3. Third Party Work

3.1 The following section shall be added as Section 4.15 of the License Agreement:

"**4.15 Third Party Work.** If a Third Party is interested in pursuing additional Development work on a Product in Collaborator Territory that neither Party is interested in pursuing, then such Development work in Collaborator Territory may proceed with the approval of the JDC, and following each such approval such additional Development work shall be incorporated into the GDP by the JDC (the "**Third Party Work**"). Notwithstanding the foregoing, following the approval of the Third Party Work by the JDC, the Third Party may conduct the Third Party Work at its own costs unless agreed in writing with both Parties, provided that: (A) it shall do so in accordance with the amended GDP; (B) such Third Party Work shall be conducted under the oversight of the JDC; (C) such Third Party Work shall be conducted in accordance with a separate agreement between the Third Party and the Parties; and (D) no Third Party shall conduct Third Party Work in a manner that would have a material adverse effect on any Product(s) in either Party's territory.

4. General Provisions

4.1 Effect of Amendment. Except as expressly modified herein, all terms and conditions set forth in the License Agreement, as in effect on the Amendment Effective Date, shall remain in full force and effect.

4.2 Entire Agreement. The License Agreement as modified by this Amendment is both a final expression of the Parties' agreement and a complete and exclusive statement with respect to its subject matter.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

They supersede all prior and contemporaneous agreements and communications, whether written or oral, of the Parties regarding this subject matter.

4.3 Severability. If, for any reason, any part of this Amendment is adjudicated invalid, unenforceable, or illegal by a court of competent jurisdiction, such adjudication shall not, to the extent feasible, affect or impair, in whole or in part, the validity, enforceability, or legality of any remaining portions of this Amendment. All remaining portions shall remain in full force and effect as if the original Amendment had been executed without the invalidated, unenforceable, or illegal part.

4.4 Counterparts; Electronic or Facsimile Signatures. This Amendment may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument. This Amendment may be executed and delivered electronically or by facsimile and upon such delivery such electronic or facsimile signature will be deemed to have the same effect as if the original signature had been delivered to the other Party.

[Signature Page Follows]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

In Witness Whereof, the Parties hereto have caused this Third Amendment to be executed and entered into by their duly authorized representatives as of the Amendment Effective Date.

Exelixis, Inc.

By: /s/ Michael M. Morrissey
Name: Michael M. Morrissey, Ph.D.
Title: President and Chief Executive Officer

Takeda Pharmaceutical Company Limited

By: /s/ Takafumi Horii
Name: Takafumi (Taka) Horii
Title: Vice President,
Head of Japan Oncology Business Unit

[Signature Page to the Third Amendment to the Collaboration and License Agreement]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Exhibit 31.1

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

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

1. I have reviewed this Form 10-Q of Exelixis, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ MICHAEL M. MORRISSEY

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

Date: November 5, 2020

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 5, 2020

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 October 2, 2020, 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 5th day of November 2020.

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

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