EXELIXIS, INC.
Form 10-Q
May 01, 2019
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q
ý QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 29, 2019
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)
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 ý 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 ý 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	ý	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 ý
As of April 22, 2019, there were 301,767,356 shares of the registrant's common stock outstanding.

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QUARTERLY REPORT ON FORM 10-Q
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PART I - FINANCIAL INFORMATION
Item 1. Financial Statements
EXELIXIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)
(unaudited)

	March 31, 2019	December 31, 2018*
ASSETS		
Current assets:		
Cash and cash equivalents	$373,937	$314,775
Short-term investments	425,713	378,559
Trade receivables, net	107,670	162,771
Other receivables	7,445	16,056
Inventory, net	10,143	9,838
Unbilled collaboration revenue	7,244	—
Prepaid expenses and other current assets	14,146	15,017
Total current assets	946,298	897,016
Long-term investments	218,619	157,187
Long-term restricted cash and investments	1,100	1,100
Property and equipment, net	50,553	50,897
Operating lease right-of-use assets	13,921	5,867
Deferred tax assets, net	243,717	244,111
Goodwill	63,684	63,684
Other long-term assets	3,902	2,424
Total assets	$1,541,794	$1,422,286
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$9,748	$10,901
Accrued clinical trial liabilities	23,055	18,231
Accrued compensation and benefits	22,550	32,142
Rebates and fees due to customers	19,708	14,954
Accrued collaboration liabilities	7,556	7,419
Current portion of deferred revenue	2,376	—
Other current liabilities	40,139	21,825
Total current liabilities	125,132	105,472
Long-term portion of lease liabilities	19,958	12,178
Long-term portion of deferred revenue	8,323	15,897
Other long-term liabilities	3,361	1,286
Total liabilities	156,774	134,833
Commitments		
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized and no shares issued	—	—
Common stock, $0.001 par value; 400,000,000 shares authorized; issued and outstanding: 301,519,885 and 299,876,080 at March 31, 2019 and December 31, 2018, respectively	302	300
Additional paid-in capital	2,188,578	2,168,217
Accumulated other comprehensive income (loss)	728	(701)
Accumulated deficit	(804,588)	(880,363)
Total stockholders' equity	1,385,020	1,287,453

Total liabilities and stockholders' equity	$1,541,794	$1,422,286

* The Condensed Consolidated Balance Sheet as of December 31, 2018 has been derived from the audited financial statements as of that date.

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

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

	Three Months Ended March 31,	
	2019	2018
Revenues:		
Net product revenues	$179,581	$134,272
Collaboration revenue	35,906	79,447
Total revenues	215,487	213,719
Operating expenses:		
Cost of goods sold	7,501	5,639
Research and development	63,289	37,757
Selling, general and administrative	60,138	54,016
Total operating expenses	130,928	97,412
Income from operations	84,559	116,307
Other income (expense), net:		
Interest income	6,087	1,895
Other, net	25	169
Total other income (expense), net:	6,112	2,064
Income before income taxes	90,671	118,371
Provision for income taxes	(14,896)	(2,514)
Net income	$75,775	$115,857
Net income per share, basic	$0.25	$0.39
Net income per share, diluted	$0.24	$0.37
Shares used in computing net income per share, basic	300,542	296,421
Shares used in computing net income per share, diluted	314,644	313,691

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

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

	Three Months Ended March 31,	
	2019	2018
Net income	$75,775	$115,857
Other comprehensive income (loss):		
Net unrealized gains or losses on available-for-sale securities, net of tax impact of $394 and $0, respectively [(1)]	1,429	(540)
Total other comprehensive income (loss)	1,429	(540)
Comprehensive income	$77,204	$115,317

(1) Reclassification adjustments to net income resulting from realized gains or losses on the sale of securities and the related tax impact were nominal or zero during those periods.

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

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EXELIXIS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2017	296,209,426	$ 296	$2,114,184	$ (347)	$(1,829,172)	$ 284,961
Adoption of Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606)	—	—	—	—	258,505	258,505
Net income	—	—	—	—	115,857	115,857
Other comprehensive loss	—	—	—	(540)	—	(540)
Issuance of common stock under equity incentive and stock purchase plans	484,904	1	1,677	—	—	1,678
Stock-based compensation	—	—	9,305	—	—	9,305
Balance at March 31, 2018	296,694,330	$ 297	$2,125,166	$ (887)	$(1,454,810)	$ 669,766

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2018	299,876,080	$ 300	$2,168,217	$ (701)	$ (880,363)	$ 1,287,453
Net income	—	—	—	—	75,775	75,775
Other comprehensive income	—	—	—	1,429	—	1,429
Issuance of common stock under equity incentive and stock purchase plans	1,643,805	2	7,832	—	—	7,834
Stock-based compensation	—	—	12,529	—	—	12,529
Balance at March 31, 2019	301,519,885	$ 302	$2,188,578	$ 728	$ (804,588)	$ 1,385,020

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

	Three Months Ended March 31,	
	2019	2018
Net income	$ 75,775	$ 115,857
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	1,962	371
Stock-based compensation	12,529	9,305
401(k) matching contributions made in common stock	2,469	1,880
Amortization and other right-of-use assets	(7,730)	—
Gain on other equity investments	—	(209)
Accretion of investments, net and other	(1,415)	(158)
Changes in operating assets and liabilities:		
Trade receivables, net	55,101	(10,819)
Other receivables	8,741	64
Inventory, net	(305)	(906)
Unbilled collaboration revenue	(7,753)	(38,014)
Prepaid expenses and other current assets	871	1,900
Other long-term assets	(4,854)	(346)
Accounts payable	(1,294)	(183)
Accrued compensation and benefits	(9,592)	(317)
Accrued clinical trial liabilities	4,824	(4,498)
Rebates and fees due customers	4,754	4,424
Accrued collaboration liability	137	(1,000)
Current and long-term deferred revenue	(1,313)	(2,652)
Long-term portion of lease liabilities	7,517	(35)
	21,169	(2,856)

Other current and long-term liabilities						
Net cash provided by operating activities	161,593			71,808		
Cash flows from investing activities:						
Purchases of property and equipment	(2,307	)		(2,947	)	
Purchases of investments	(239,869	)		(116,537	)	
Proceeds from maturities of investments	129,820			87,504		
Proceeds from sale of investments	4,699			6,238		
Proceeds from other equity investments	—			209		
Net cash used in investing activities	(107,657	)		(25,533	)	
Cash flows from financing activities:						
Proceeds from exercise of stock options	6,817			1,875		
Taxes paid related to net share settlement of equity awards	(1,580	)		(2,129	)	
Principal payments on financing lease obligation	(11	)		—		
Net cash provided by (used in) financing activities	5,226			(254	)	
Net increase in cash, cash equivalents and restricted cash	59,162			46,021		
Cash, cash equivalents and restricted cash at beginning of period	315,875			188,314		
Cash, cash equivalents and restricted cash at end of period	$	375,037		$	234,335	

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

	Three Months Ended March 31,	
	2019	2018
Supplemental cash flow disclosure		
Right-of-use assets obtained in exchange for lease obligations [1]	$8,170	$17,180
Unpaid liabilities incurred to acquire Property and equipment	$141	$6,608

(1) Amounts for the three months ended March 31, 2019 include receipt of a tenant inventive payment. Amounts for the three months ended March 31, 2018 include the transition adjustment for the adoption of Accounting Standards Codification (ASC) Topic 842, Leases.

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

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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. Since we were founded in 1994, four products resulting from our discovery efforts have progressed through clinical development and received regulatory approval; three have a growing commercial presence in markets worldwide, and we expect that the fourth will soon enter the marketplace in Japan. Two are derived from cabozantinib, an inhibitor of multiple tyrosine kinases including MET, AXL, VEGF receptors and RET. These are: CABOMETYX® (cabozantinib) tablets approved for advanced renal cell carcinoma and previously treated hepatocellular carcinoma and COMETRIQ® (cabozantinib) capsules approved for progressive, metastatic medullary thyroid cancer. The other two products resulting from our discovery efforts are: COTELLIC® (cobimetinib), an inhibitor of MEK, approved as part of a combination regimen to treat a specific form 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, recently approved for the treatment of hypertension in Japan and licensed to Daiichi Sankyo Company, Limited (Daiichi Sankyo).

Basis of Consolidation

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.

Basis of Presentation

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.

We have adopted a 52- or 53-week fiscal year policy that generally ends on the Friday closest to December 31st. Fiscal year 2019 will end on January 3, 2020 and fiscal year 2018 ended on December 28, 2018. For convenience, references in this report as of and for the fiscal periods ended March 29, 2019 and March 30, 2018, and as of and for the fiscal years ending January 3, 2020 and ended December 28, 2018, are indicated as being as of and for the periods ended March 31, 2019 and March 31, 2018, and the years ending December 31, 2019 and ended December 31, 2018, respectively. Similarly, references in this report to the first day of the fiscal year ended January 3, 2020 are indicated as being as of January 1, 2019.

Operating results for the three months ended March 31, 2019 are not necessarily indicative of the results that may be expected for the year ending December 31, 2019 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, 2018, included in our Annual Report on Form 10-K filed with the SEC on February 22, 2019.

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.

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Use of Estimates

The preparation of the accompanying Condensed Consolidated Financial Statements conforms to accounting principles generally accepted in the U.S., which requires management to make judgments, estimates and assumptions that affect the reported amounts of assets, liabilities, equity, revenues and expenses, and related disclosures. On an ongoing basis, 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, sales allowances, and milestone payments included in collaboration arrangements; the amounts of revenues and expenses under our profit and loss sharing agreement; the recoverability of inventory; the amounts of operating lease right-of-use assets and lease liabilities; 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. Actual results could differ materially from those estimates.

Reclassifications

Certain prior period amounts in the accompanying Condensed Consolidated Financial Statements have been reclassified to conform to current period presentation.

Total revenues and Selling, general and administrative expenses for the three months ended March 31, 2018 have been adjusted to reflect the reclassification of the $1.4 million profit related to the profit-sharing arrangement with Genentech for the commercialization of COTELLIC. In our Condensed Consolidated Financial Statements included in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, the net profit had been classified as Selling, general and administrative expenses as we expected an overall loss under the agreement for the year ended December 31, 2018. Subsequent to March 31, 2018, we determined that the U.S. commercialization of COTELLIC would result in a profit for the year ended December 31, 2018 and therefore, we had reclassified the profit for the three months ended March 31, 2018 from Selling, general and administrative expenses to Collaboration revenues in our financial statements issued after March 31, 2018. Accordingly, we have also reclassified the profit for the three months ended March 31, 2018 in the accompanying Condensed Consolidated Financial Statements to be consistent with our presentation for the year ended December 31, 2018. For more information on our collaboration agreement with Genentech, 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, 2018.

Recently Adopted Accounting Pronouncements

On January 1, 2019, we adopted ASU 2018-02, Income Statement—Reporting Comprehensive Income (Topic 220) (ASU 2018-02). There was no financial impact from the adoption of ASU 2018-02 and we did not make an election to reclassify the income tax effects of the Tax Cuts and Jobs Act of 2017 from Accumulated other comprehensive income (loss) to Accumulated deficit. In connection with the adoption of ASU 2018-02, we have adopted the individual unit of account approach for releasing income tax effects from Accumulated other comprehensive income (loss).

On January 1, 2019, we also adopted ASU 2017-08, Receivables—Nonrefundable Fees and Other Costs (Subtopic 310-20) (ASU 2017-08). ASU 2017-08 shortens the amortization period for certain callable debt securities held at a premium. Specifically, ASU 2017-08 requires the premium to be amortized to the earliest call date. ASU 2017-08 does not require an accounting change for securities held at a discount; the discount continues to be amortized to maturity. The financial impact from the adoption of ASU 2017-08 was nominal.

Recent Accounting Pronouncements Not Yet Adopted

In November 2018, the Financial Accounting Standards Board (the FASB) issued 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 revenue under 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 also adds a reference in Topic 808 to the unit of account guidance in ASC 606 and requires that it be applied only to assess whether transactions in a collaborative arrangement are in the

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scope of Topic 606. ASU 2018-18 will preclude entities from presenting amounts related to transactions with a counterparty in a collaborative arrangement that is not a customer as revenue from contracts with customers. ASU 2018-18 is effective for us for all interim and annual reporting periods beginning after December 15, 2019. Early adoption is permitted. We are in the process of assessing the impact of ASU 2018-18 on our Condensed Consolidated Financial Statements.

In August 2018, the FASB issued ASU No. 2018-15, Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract (ASU 2018-15). ASU 2018-15 aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). Accordingly, ASU 2018-15 requires a customer in a hosting arrangement that is a service contract to follow the guidance in Subtopic 350-40 to determine which implementation costs to capitalize as an asset related to the service contract and which costs to expense. ASU 2018-15 also requires us to expense the capitalized implementation costs of a hosting arrangement that is a service contract over the term of the hosting arrangement, which includes reasonably certain renewals. ASU 2018-15 is effective for us for all interim and annual reporting periods beginning after December 15, 2019. Early adoption is permitted. We are in the process of assessing the impact of ASU 2018-15 on our Condensed Consolidated Financial Statements.

In January 2017, the FASB issued ASU No. 2017-04, Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment (ASU 2017-04). ASU 2017-04 eliminated Step 2 from the goodwill impairment test. Instead, under the amendments in ASU 2017-04, an entity should perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit’s fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. Additionally, an entity should consider income tax effects from any tax deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss, if applicable. ASU 2017-04 is effective for all interim and annual reporting periods beginning after December 15, 2019. Early adoption is permitted. We do not expect the adoption of ASU 2017-04 to have a material impact on our Condensed Consolidated Financial Statements.

In June 2016, the FASB issued 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, an entity will recognize as an allowance its estimate of expected credit losses. 2016-13 is effective for all interim and annual reporting periods beginning after December 15, 2019. Early adoption is permitted. We do not expect the adoption of ASU 2016-13 to have a material impact on our Condensed Consolidated Financial Statements.

NOTE 2. REVENUES

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

	Three Months Ended March 31,	
	2019	2018
Product revenues:		
Gross product revenues	$223,750	$159,436
Discounts and allowances	(44,169)	(25,164)
Net product revenues	179,581	134,272
Collaboration revenues:		
License revenues [1]	24,509	69,030
Research and development service revenues [2]	11,928	10,099
Other collaboration revenues [3]	(531)	318
Total collaboration revenues	35,906	79,447
Total revenues	$215,487	$213,719

(1) License revenues included the immediate recognition of the portion of milestones 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 revenue reversal would not occur, as well as royalty revenues from Ipsen Pharma SAS (Ipsen) and Genentech.

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(2) Research and development service revenues included the recognition of deferred revenue for the portion of upfront and milestone payments that have been allocated to research and development service performance obligations, as well as development cost reimbursements earned on our collaboration agreements.

(3) Other collaboration revenues included the profit on the U.S. commercialization of COTELLIC from Genentech and revenues on product supply services provided to Ipsen and Takeda Pharmaceutical Company Ltd. (Takeda), which were partially offset by the 3% royalty we are required to pay GlaxoSmithKline (GSK) on the net sales by Ipsen of any product incorporating cabozantinib.

Net product revenues, License revenues and Research and development services revenues were recorded in accordance with Topic 606 for all periods presented. Net product revenues and License revenues related to goods and intellectual property licenses transferred at a point in time and Research and development services revenues related to services performed over time. Other collaboration revenues, which included the profit on the U.S. commercialization of COTELLIC and net losses on product supply services, were recorded in accordance with ASC Topic 808, Collaborative Arrangements for all periods presented.

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

	Three Months Ended March 31,	
	2019	2018
CABOMETYX	$175,890	$128,934
COMETRIQ	3,691	5,338
Net product revenues	$179,581	$134,272

Total revenues disaggregated by significant customer were as follows (dollars in thousands):

	Three Months Ended March 31,					
	2019			2018		
	Dollars	Percent of total		Dollars	Percent of total	
Caremark L.L.C.	$32,698	15	%	$26,388	12	%
Affiliates of McKesson Corporation	25,311	12	%	21,331	10	%
Accredo Health, Incorporated	22,495	10	%	18,286	9	%
Affiliates of AmerisourceBergen Corporation	21,902	10	%	15,736	7	%
Ipsen	21,868	10	%	53,809	25	%
Others, individually less than 10% of Total revenues for all periods presented	91,213	43	%	78,169	37	%
Total revenues	$215,487	100	%	$213,719	100	%

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

	Three Months Ended March 31,	
	2019	2018
U.S.	$182,126	$136,993
Europe	21,868	53,809
Rest of the world	11,493	22,917
Total revenues	$215,487	$213,719

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

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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	Returns	Total
Balance at December 31, 2018	$ 2,322	$ 3,038	$11,916	$ —	$17,276
Provision related to sales made in:					
Current period	27,153	3,875	12,905	—	43,933
Prior periods	—	9	227	—	236
Payments and customer credits issued	(27,367)	(4,189)	(8,073)	—	(39,629)
Balance at March 31, 2019	$ 2,108	$ 2,733	$16,975	$ —	$21,816

Chargebacks and discounts for prompt payment are recorded as a reduction of trade receivables and the remaining reserve balances are classified as Other current liabilities in the accompanying Condensed Consolidated Balance Sheets.

Contract Assets and Liabilities

We receive payments from our licensees based on billing schedules established in each contract. Amounts are recorded as accounts receivable when our right to consideration is unconditional. Upfront and milestone payments may require deferral of revenue recognition to a future period until we perform our obligations under these arrangements and are recorded as deferred revenue upon receipt or when due. We may also recognize revenue in advance of the contractual billing schedule and such amounts are recorded as unbilled collaboration revenue when recognized. Changes in our contract assets and liabilities under Topic 606 were as follows (in thousands):

	Contract Assets: Unbilled Collaboration Revenue		Contract Liabilities: Deferred Revenue	
	Current Portion	Long-term Portion	Current Portion	Long-term Portion
Balance at December 31, 2018	$ —	$ —	$ —	$ 15,897
Increases as a result of a change in transaction price and recognition of revenues as services are performed	10,222	1,450	—	—
Transfer to receivables from contract assets recognized at the beginning of the period	(543)	—	—	—
Increases as a result of the deferral of milestones achieved in period, excluding amounts recognized as revenue	—	—	—	—
Revenue recognized that was included in the contract liability balance at the beginning of the period	—	—	(1,313)	—
Other adjustments [1]	(2,435)	(1,450)	3,689	(7,574)
Balance at March 31, 2019	$ 7,244	$ —	$ 2,376	$ 8,323

(1) Includes reclassification of deferred revenue from long-term to current and adjustments made due to netting of contract assets and liabilities by collaboration agreement.

During the three months ended March 31, 2019 and 2018, we recognized $25.3 million and $71.3 million, respectively, in revenues under Topic 606 for performance obligations satisfied in previous periods. Such revenues primarily related to milestone and royalty payments allocated to our license performance obligations of our collaborations with Ipsen, Takeda and Bristol-Myers Squibb Company (BMS).

NOTE 3. COLLABORATION AGREEMENTS

We have established multiple collaborations with leading pharmaceutical companies for the commercialization and further development of cabozantinib, as well as with smaller, discovery-focused biotechnology companies to expand our product pipeline. Additionally, in line with our business strategy prior to the commercialization of our first product,

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COMETRIQ, we entered into other collaborations with leading pharmaceutical companies including Genentech, Daiichi Sankyo and BMS for other compounds and programs in our portfolio. 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, 2018 for a description of each of our collaboration agreements.

Under these collaborations, we are generally entitled to receive milestone and royalty payments, and for certain collaborations, payments for product supply services, development cost reimbursements, and/or profit-sharing payments. See “Note 2. Revenues” for information on collaboration revenues recognized during the three months ended March 31, 2019 and 2018.

Cabozantinib Commercial Collaborations

Ipsen Collaboration

In February 2016, we entered into a collaboration and license agreement with Ipsen for the commercialization and further development of cabozantinib. Pursuant to the terms of the collaboration agreement, Ipsen received exclusive commercialization rights for current and potential future cabozantinib indications outside of the U.S., Canada and Japan. The collaboration agreement was subsequently amended in December 2016 to include commercialization rights in Canada. We have also agreed to collaborate with Ipsen on the development of cabozantinib for current and potential future indications. Collaboration revenues under the collaboration agreement with Ipsen were as follows (in thousands):

	Three Months Ended March 31,	
	2019	2018
Ipsen collaboration revenues	$21,868	$53,809

As of March 31, 2019, $46.8 million of the transaction price allocated to our research and development services performance obligation had not been satisfied. As of March 31, 2019, the net contract liability for the collaboration agreement with Ipsen was $10.7 million, of which 2.4 million was included in the Current portion of deferred revenue and $8.3 million was included in the Long-term portion of deferred revenue in the accompanying Condensed Consolidated Balance Sheets.

Takeda Collaboration

In January 2017, we entered into a collaboration and license agreement with Takeda. See “Note 11. Subsequent Events - Amendment to Collaboration Agreement with Takeda” for information regarding an amendment to our collaboration agreement with Takeda. Pursuant to this collaboration agreement, 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. Collaboration revenues under the collaboration agreement with Takeda were as follows (in thousands):

	Three Months Ended March 31,	
	2019	2018
Takeda collaboration revenues	$11,493	$2,917

As of March 31, 2019, $25.2 million of the transaction price allocated to our research and development services performance obligation had not been satisfied. As of March 31, 2019, the net contract asset for the collaboration agreement with Takeda was $7.2 million, which was included in Unbilled collaboration revenue in the accompanying Condensed Consolidated Balance Sheets.

GlaxoSmithKline (GSK)

In October 2002, we established a product development and commercialization collaboration agreement with GSK. Under the terms of the collaboration agreement, GSK had the right to choose cabozantinib for further development and commercialization, but notified us in October 2008 that it had waived its right to select the compound for such activities. Although the collaboration agreement was terminated in December 2014, GSK continues to be entitled to a 3% royalty we are required to pay on all net sales of any product incorporating cabozantinib by us and our collaboration partners. Royalties accruing to 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 revenues for sales by Ipsen. Such royalties accruing to GSK were as follows (in thousands):

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	Three Months Ended March 31,	
	2019	2018
Royalties accruing to GSK	$7,282	$5,125

Genentech Collaboration

In December 2006, we out-licensed the development and commercialization of cobimetinib to Genentech pursuant to a worldwide collaboration agreement. Under the terms of the collaboration agreement, we developed cobimetinib through the determination of the maximum tolerated dose in a phase 1 clinical trial, and Genentech had the option to co-develop cobimetinib, an option that Genentech exercised, and in March 2009, we granted to Genentech an exclusive worldwide revenue-bearing license to cobimetinib, at which point Genentech became responsible for completing the phase 1 clinical trial and the subsequent clinical development.

In November 2015, the U.S. Food and Drug Administration approved cobimetinib, under the brand name COTELLIC, in combination with Genentech's Zelboraf (vemurafenib) as a treatment for 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. Profits on U.S. commercialization and Royalty revenues on ex-U.S. sales were as follows (in thousands):

	Three Months Ended March 31,	
	2019	2018
Profits on U.S. commercialization	$1,055	$1,373
Royalty revenues on ex-U.S. sales	$1,490	$1,349

NOTE 4. CASH AND INVESTMENTS

Cash, Cash Equivalents and Restricted Cash

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

	March 31, 2019	December 31, 2018	March 31, 2018	December 31, 2017
Cash and cash equivalents	$373,937	$ 314,775	$232,331	$183,164
Restricted cash included in short-term restricted cash and investments	—	—	504	504
Restricted cash included in long-term restricted cash and investments	1,100	1,100	1,500	4,646
Cash, cash equivalents, and restricted cash as reported within the accompanying Condensed Consolidated Statements of Cash Flows	$375,037	$ 315,875	$234,335	$188,314

Restricted cash includes certificates of deposit used to collateralize letters of credit and, in prior periods, a purchasing card program.

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Cash and Investments

Cash and investments by security type were as follows (in thousands):

	March 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Investments available-for-sale:				
Money market funds	$75,171	$ —	$ —	$75,171
Commercial paper	414,317	—	—	414,317
Corporate bonds	417,303	1,257	(175)	418,385
U.S. Treasury and government sponsored enterprises	84,448	41	(2)	84,487
Total investments available-for-sale	991,239	1,298	(177)	992,360
Cash and restricted cash	1,019	—	—	1,019
Certificates of deposit	25,990	—	—	25,990
Total cash and investments	$1,018,248	$ 1,298	$ (177)	$1,019,369

	December 31, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Investments available-for-sale:				
Money market funds	$47,744	$ —	$ —	$47,744
Commercial paper	381,134	—	(1)	381,133
Corporate bonds	344,741	180	(857)	344,064
U.S. Treasury and government sponsored enterprises	55,224	2	(25)	55,201
Total investments available-for-sale	828,843	182	(883)	828,142
Cash and restricted cash	6,883	—	—	6,883
Certificates of deposit	16,596	—	—	16,596
Total cash and investments	$852,322	$ 182	$ (883)	$851,621

Gains and losses on the sales of investments available-for-sale were nominal during the three months ended March 31, 2019 and 2018.

The fair value and gross unrealized losses on investments available-for-sale in an unrealized loss position were as follows (in thousands):

	March 31, 2019					
	In an Unrealized Loss Position Less than 12 Months		In an Unrealized Loss Position 12 Months or Greater		Total	
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
Corporate bonds	$49,233	$ (39)	$45,010	$ (136)	$94,243	$ (175)
U.S. Treasury and government sponsored enterprises	—	—	7,990	(2)	7,990	(2)
Total	$49,233	$ (39)	$53,000	$ (138)	$102,233	$ (177)

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	December 31, 2018					
	In an Unrealized Loss Position Less than 12 Months		In an Unrealized Loss Position 12 Months or Greater		Total	
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
Corporate bonds	$236,162	$ (606)	$39,627	$ (251)	$275,789	$ (857)
U.S. Treasury and government sponsored enterprises	28,105	(16)	9,182	(9)	37,287	(25)
Commercial paper	7,091	(1)	—	—	7,091	(1)
Total	$271,358	$ (623)	$48,809	$ (260)	$320,167	$ (883)

There were 69 and 199 investments in an unrealized loss position as of March 31, 2019 and December 31, 2018, respectively. During the three months ended March 31, 2019 and 2018 we did not record any other-than-temporary impairment charges on our available-for-sale 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. Based on the scheduled maturities of our investments and our determination 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, we concluded that the unrealized losses in our investment securities were not other-than-temporary.

The fair value of investments available-for-sale by contractual maturity were as follows (in thousands):

	March 31, 2019	December 31, 2018
Maturing in one year or less	$784,432	$ 674,455
Maturing after one year through five years	207,928	153,687
Total investments available-for-sale	$992,360	$ 828,142

Related Party Transactions

BlackRock, Inc. (BlackRock), a global provider of investment, advisory and risk management solutions, reported that as of December 31, 2018, the most recent date for which they reported ownership data, their beneficial ownership was more than 10% of our outstanding common stock. BlackRock manages a portion of our cash and investments portfolio. As of March 31, 2019 and December 31, 2018, respectively, the fair value of cash and investments managed by BlackRock was $356.0 million and $298.5 million, which included $0.8 million and $3.0 million invested in the BlackRock Liquidity Money Market Fund. We incurred $0.1 million in fees for BlackRock advisory services performed during the three months ended March 31, 2019.

NOTE 5. INVENTORY

Inventory consisted of the following (in thousands):

	March 31, 2019	December 31, 2018
Raw materials	$ 2,245	$ 1,922
Work in process	6,514	6,170
Finished goods	4,862	3,836
Total	$ 13,621	$ 11,928
Balance Sheet classification:		
Current portion included in Inventory	$ 10,143	$ 9,838
Long-term portion included in Other long-term assets	3,478	2,090
Total	$ 13,621	$ 11,928

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Write-downs related to excess and expiring inventory are charged to Cost of goods sold or the cost of supplied product included in Collaboration revenues. Such write-downs were $0.2 million for the three months ended March 31, 2019. There were no such write-downs for the three months ended and March 31, 2018.

Inventory not expected to be used in production or sold in the next 12 months is classified as Other long-term assets in the accompanying Condensed Consolidated Balance Sheets. As of both March 31, 2019 and December 31, 2018, the long-term portion of inventory consisted of portions of our raw materials and finished goods, and as March 31, 2019, also a portion of our work in process.

NOTE 6. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following (in thousands):

	March 31, 2019	December 31, 2018
Leasehold improvements	$33,811	$ 33,941
Computer equipment and software	15,110	15,022
Furniture and fixtures	12,908	12,709
Laboratory equipment	6,764	5,668
Construction in progress	1,231	866
	69,824	68,206
Less: accumulated depreciation and amortization	(19,271)	(17,309)
Property and equipment, net	$50,553	$ 50,897

Depreciation expense was $2.0 million and $0.4 million for the three months ended March 31, 2019 and 2018, 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 March 31,	
	2019	2018
Research and development	$4,306	$3,033
Selling, general and administrative	8,223	6,272
Total stock-based compensation	$12,529	$9,305

We have several equity incentive plans under which we have granted stock options and restricted stock units (RSUs) to employees and directors. At March 31, 2019, 14,586,459 shares were available for grant under our equity incentive plans.

We used a Monte Carlo simulation pricing model to value stock options that include market vesting conditions and a Black-Scholes Merton option pricing model to value other stock options and ESPP purchases. The weighted average grant-date fair value per share of stock options and ESPP purchases were as follows:

	Three Months Ended March 31,	
	2019	2018
Stock options	$9.21	$11.52
ESPP	$4.67	$7.39

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The grant-date fair value of stock option grants and ESPP purchases was estimated using the following assumptions:

	Three Months Ended March 31,	
	2019	2018
Stock options:		
Risk-free interest rate	2.22 %	2.40 %
Dividend yield	— %	— %
Volatility	49 %	54 %
Expected life	4.0 years	4.0 years
ESPP:		
Risk-free interest rate	2.48 %	1.53 %
Dividend yield	— %	— %
Volatility	57 %	53 %
Expected life	6 months	6 months

We considered our implied volatility and our historical volatility in developing our estimates of expected volatility. The assumptions for the expected life of stock options were based on historical exercise patterns and post-vesting termination behavior. The risk-free interest rate is based on U.S. Treasury rates with the same or similar term as the underlying award. Our dividend rate is based on historical experience and our investors' current expectations.

The fair value of RSUs was based on the closing price of the underlying common stock on the date of grant.

Activity for stock options during the three months ended March 31, 2019 was as follows (dollars in thousands, except per share amounts):

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Options outstanding at December 31, 2018	22,674,062	$ 8.71		
Granted	246,820	$ 22.94		
Exercised	(1,413,766)	$ 4.91		
Forfeited	(44,200)	$ 14.32		
Expired	(22,925)	$ 22.12		
Options outstanding at March 31, 2019	21,439,991	$ 9.10	3.6 years	$ 317,143
Exercisable at March 31, 2019	15,714,721	$ 6.01	2.9 years	$ 280,307

As of March 31, 2019, there was $44.1 million of unrecognized compensation expense related to our unvested stock options. The compensation expense for the unvested stock options will be recognized over a weighted-average period of 2.5 years.

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Activity for RSUs during the three months ended March 31, 2019 was as follows (dollars in thousands, except per share amounts):

	Shares	Weighted Average Grant Date Fair Value Per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
RSUs outstanding at December 31, 2018	4,857,334	$ 18.42		
Awarded	123,410	$ 22.94		
Vested and released	(194,296)	$ 7.83		
Forfeited	(100,630)	$ 18.13		
RSUs outstanding at March 31, 2019	4,685,818	$ 18.98	2.0 years	$111,522

During 2018, in connection with our long-term incentive compensation program, we awarded 693,131 RSUs that will vest upon the achievement of certain product revenue, late-stage clinical development and pipeline expansion performance targets (PSUs). The PSUs were designed to drive the performance of our management team toward the achievement of key corporate objectives and will be forfeited if the performance targets are not met by December 31, 2021. Expense recognition for PSUs commences when it is determined that attainment of the performance goal is probable. As of March 31, 2019, we have not recognized any compensation expense related to these PSUs and the total unrecognized compensation expense was $12.7 million.

As of March 31, 2019, there was $77.0 million of unrecognized compensation expense related to our unvested RSUs, including the PSUs described above. The compensation expense for the unvested RSUs will be recognized over a weighted-average period of 2.9 years.

NOTE 8. INCOME TAXES

Our effective income tax rate was 16.4% during the three months ended March 31, 2019 as compared to 2.1% for the three months ended March 31, 2018. The Provision for income taxes relating to our pre-tax income for the three months ended March 31, 2018 was largely offset by a valuation allowance against our net operating loss carryforwards and other deferred tax assets. At December 31, 2018, we released substantially all of our valuation allowance against our deferred tax assets, after we determined that it was more likely than not that these deferred tax assets would be realized.

The effective tax rate for the three months ended March 31, 2019 differed from the U.S. federal statutory rate of 21% primarily was due to excess tax benefits related to the exercise of certain stock options during the quarter.

NOTE 9. NET INCOME PER SHARE

The computation of basic and diluted net income per share was as follows (in thousands, except per share amounts):

	Three Months Ended March 31,	
	2019	2018
Numerator:		
Net income	$75,775	$115,857
Denominator:		
Weighted-average shares of common stock outstanding used in computing basic net income per share	300,542	296,421
Dilutive securities	14,102	17,270
Weighted-average shares of common stock outstanding and dilutive securities used in computing diluted net income per share	314,644	313,691
Net income per share, basic	$0.25	$0.39
Net income per share, diluted	$0.24	$0.37

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Dilutive securities include outstanding stock options, unvested RSUs and ESPP contributions. Potential shares of common stock not included in the computation of diluted net income per share because to do so would be anti-dilutive was as follows (in thousands):

	Three Months Ended March 31,	
	2019	2018
Potentially dilutive securities	5,089	1,907

NOTE 10. FAIR VALUE MEASUREMENTS

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

	March 31, 2019		
	Level 1	Level 2	Total
Money market funds	$75,171	$—	$75,171
Commercial paper	—	414,317	414,317
Corporate bonds	—	418,385	418,385
U.S. Treasury and government sponsored enterprises	—	84,487	84,487
Total investments available-for-sale	75,171	917,189	992,360
Certificates of deposit	—	25,990	25,990
Total financial assets carried at fair value	$75,171	$943,179	$1,018,350
	December 31, 2018		
	Level 1	Level 2	Total
Money market funds	$47,744	$—	$47,744
Commercial paper	—	381,133	381,133
Corporate bonds	—	344,064	344,064
U.S. Treasury and government sponsored enterprises	—	55,201	55,201
Total investments available-for-sale	47,744	780,398	828,142
Certificates of deposit	—	16,596	16,596
Total financial assets carried at fair value	$47,744	$796,994	$844,738

We did not have any financial liabilities measured and recorded at fair value on a recurring basis as of March 31, 2019 or December 31, 2018. We did not have any financial assets or liabilities classified as Level 3 in the fair value hierarchy as of March 31, 2019 or December 31, 2018. There were no transfers of financial assets or liabilities between Levels 1, 2 and 3 during the three months ended March 31, 2019 or 2018.

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.

See “Note 11. Commitments” to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2018 for a description of the determination of the amount of our operating lease liabilities. Our remaining financial assets and liabilities include cash and restricted cash, Trade receivables, net, Other receivables, Accounts payable, Accrued compensation and benefits, Accrued clinical trial liabilities, Accrued collaboration liabilities, Rebates and fees due to customers and other current and long-term liabilities. Those financial assets and liabilities are carried at cost which approximates their fair values.

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NOTE 11. SUBSEQUENT EVENTS

Lease Amendment

On April 1, 2019, we entered into an amendment to the existing Lease Agreement (the Lease) relating to our corporate headquarters located at 1851, 1801, and 1751 Harbor Bay Parkway, Alameda, California (the Premises). The Lease Amendment provides, among other things, for the (i) expansion of the Premises by 37,544 square feet of office facilities located at 1601 Harbor Bay Parkway, Alameda, California (the 1601 Expansion Space) and (ii) surrender of 2,703 square feet of office facilities located at 1751 Harbor Bay Parkway, Alameda, California (the 1751 Space). We surrendered the 1751 Space on April 15, 2019 and the term for the 1601 Expansion Space will begin ninety days after the landlord's delivery of the entire 1601 Expansion Space (the 1601 Expansion Space Commencement Date). The term for the 1601 Expansion Space is expected to commence on December 1, 2019, and will run coterminous with the term of the Lease for the existing space, which ends on January 31, 2028. We have been provided an allowance of $1.7 million for tenant improvements to the 1601 Expansion Space.

Following April 15, 2019, the monthly base rent for the Premises, other than the 1601 Expansion Space, is $224,505 through January 31, 2020, increasing throughout the remainder of the term to $283,933 at the end of the term. Following the 1601 Expansion Space Commencement Date, the monthly base rent for the 1601 Expansion Space will be $71,334 through November 30, 2020, increasing throughout the remainder of the term to $90,481 at the end of the term. The aggregate contractual base rent for the entire 169,606 square feet of the Premises from April 15, 2019, through the remainder of the Lease term will be approximately $34.6 million. In addition, we are required to pay the landlord for certain operating expenses and taxes they incur related to the Premises.

Amendment to Collaboration Agreement with Takeda

On April 29, 2019, we executed an amendment to our January 2017 collaboration agreement with Takeda (the Amendment), which will become effective on May 7, 2019. The Amendment, among other things, reduces the amount of reimbursements we will receive from Takeda for costs associated with our required global pharmacovigilance activities and limits those reimbursements to $1.0 million per year. It also increases the total potential development, regulatory and first-sale milestone payments to be paid to us by Takeda for second-line renal cell carcinoma (RCC), first-line RCC and second-line hepatocellular carcinoma by an aggregate of $12.0 million to $102.0 million, including an increase from $10.0 million to $16.0 million for the milestone we expect to receive for the April 2019 submission of a regulatory application for cabozantinib as a treatment for patients with advanced RCC to the Japanese Ministry of Health, Labour and Welfare. We continue to be eligible to receive additional development, regulatory and first-sale milestone payments for other potential future indications. The Amendment also increases the amount of Takeda's potential sales-based milestones by an aggregate of $3.0 million to $86.0 million. We continue to be eligible to receive royalties on net sales of cabozantinib in Japan.

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, 2018 filed with the Securities and Exchange Commission (SEC) on February 22, 2019.

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 and received regulatory approval; three have a growing commercial presence in markets worldwide, and we expect that the fourth will soon enter the marketplace in Japan. Two are derived from cabozantinib, our flagship molecule, an inhibitor of multiple tyrosine kinases including MET, AXL, VEGF receptors and RET. These 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). The other two products resulting from our discovery efforts are: COTELLIC® (cobimetinib), an inhibitor of MEK, approved as part of a combination regimen to treat a specific form 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, recently approved for the treatment of hypertension in Japan and licensed to Daiichi Sankyo Company, Limited (Daiichi Sankyo).

CABOMETYX was first approved by the U.S. Food and Drug Administration (FDA) for previously treated patients with advanced RCC in April 2016, and then 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 as a treatment for patients with HCC who have been previously treated with sorafenib. This most recent approval was based on results from CELESTIAL, our phase 3 pivotal trial evaluating cabozantinib in patients with previously treated HCC, which demonstrated a statistically significant and clinically meaningful improvement in overall survival (OS) versus placebo. We remain highly focused on optimizing the execution of the commercial launch in HCC in the U.S. through our commercial and medical affairs organizations and established distribution network.

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 Ltd. (Takeda). Ipsen has been granted rights to cabozantinib outside of the U.S. and Japan, and Takeda has been granted rights to cabozantinib in Japan. Both partners 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, recently receiving regulatory approval from the European Commission (EC) for CABOMETYX as a treatment for HCC in adults who have previously been treated with sorafenib. Takeda has also made significant progress on bridging studies in both RCC and HCC and achieved an important regulatory milestone in April 2019 with its application to the Japanese Ministry of Health, Labour and Welfare (MHLW) for approval to manufacture and sell CABOMETYX as a treatment for unresectable and metastatic RCC in Japan.

In addition to our regulatory and commercialization efforts in the U.S. and the support provided to our partners for rest of world regulatory and commercialization activities, we are also focused on the cabozantinib clinical development program, pursuing other indications that have the potential to expand 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 75 ongoing or planned clinical trials across multiple indications. We, along with our clinical and commercial 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 late-stage development program. One pivotal trial that has resulted from this effort is COSMIC-311, our ongoing phase 3 pivotal trial evaluating cabozantinib in patients with radioactive iodine (RAI)-refractory differentiated thyroid cancer (DTC) who have progressed after up to two VEGF receptor-targeted therapies.

We are particularly interested in examining cabozantinib's potential in combination with immune checkpoint inhibitors (ICIs) to determine if such 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 in multiple clinical trials. The most advanced of these combination studies include

CheckMate 9ER, a phase 3 pivotal trial evaluating cabozantinib in combination with nivolumab in previously untreated advanced or metastatic RCC, for which enrollment was completed in April 2019, and CheckMate 040, a 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. Both trials are in collaboration with Bristol-Myers Squibb Company (BMS). Additionally, as part of our clinical collaboration with BMS, we are initiating 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, and plan to further evaluate the combination of cabozantinib and nivolumab, with or without ipilimumab, in various other tumor types, including urothelial carcinoma (UC). Diversifying our exploration of combinations with ICIs, we also initiated COSMIC-312, a phase 3 pivotal trial evaluating cabozantinib in combination with the Roche Group's (Roche's) ICI, atezolizumab, versus sorafenib in previously untreated advanced HCC, and COSMIC-021, a phase 1b study evaluating the safety and tolerability of cabozantinib in combination with atezolizumab in patients with locally advanced or metastatic solid tumors. The study 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 demonstrate that the combination was well-tolerated and showed encouraging anti-tumor activity in patients with advanced RCC. The expansion phase of COSMIC-021 comprises eighteen tumor expansion cohorts evaluating the combination of cabozantinib and atezolizumab, including multiple therapeutic settings of RCC, UC, and non-small cell lung cancer (NSCLC) and single therapeutic settings of HCC, castration-resistant prostate cancer, triple-negative breast cancer, epithelial ovarian cancer, endometrial cancer, gastric or gastroesophageal junction adenocarcinoma, colorectal adenocarcinoma, DTC and head and neck cancer of squamous cell histology, and is currently enrolling. Depending on the results from COSMIC-021, we may also evaluate this combination in various other tumor types, including NSCLC. COSMIC-021 also includes two additional exploratory cohorts that will evaluate cabozantinib as a single-agent therapy in NSCLC and UC indications.

As we continue to work to maximize the clinical and commercial potential of cabozantinib, we also remain committed to building our product pipeline by discovering and developing new cancer therapies for patients. In this regard, we have reinitiated internal drug discovery efforts with the goal of identifying new product candidates to advance into clinical trials. Notably, these efforts are led by some of the same experienced scientists responsible for the discovery of cabozantinib and cobimetinib, which have been approved for commercialization by regulatory authorities, as well as other promising compounds resulting from our discovery efforts in various stages of clinical, regulatory and commercial development pursuant to our collaborations with Daiichi Sankyo and BMS. Using our expertise in medicinal chemistry, tumor biology and pharmacology, we are advancing drug candidates toward and through preclinical development. Furthest along in these internal drug discovery efforts is XL092, a next-generation oral tyrosine kinase inhibitor (TKI) that is currently in a phase 1 clinical trial in patients with advanced solid malignancies. These internal drug discovery activities are augmented by efforts to identify and in-license promising, early-stage oncology assets and then further develop them utilizing our established clinical development infrastructure. In furtherance of this strategy, we entered into an exclusive global collaboration and license agreement with StemSynergy, Inc. (StemSynergy) for the discovery and development of novel oncology compounds aimed to inhibit tumor growth by targeting Casein Kinase 1 , a component of the Wnt signaling pathway implicated in key oncogenic processes. We also entered into a collaboration and license agreement with Invenra, Inc. (Invenra), which is focused on developing next-generation biologics, for the discovery and development of multispecific antibodies for the treatment of cancer. To further enhance our early-stage pipeline, in the near future we expect to enter into additional, external collaborative relationships around assets and technologies that complement our in-house drug discovery and development efforts.

First Quarter 2019 Business Updates and Financial Highlights

During the first quarter of 2019, we continued to execute on our business objectives, generating significant revenue from operations and enabling us to maximize the clinical and commercial potential of our products and expand our product pipeline. Significant business updates and financial highlights for the quarter and subsequent to quarter-end include:

Business Updates

- In January 2019, we announced that our partner Daiichi Sankyo received approval from the Japanese MHLW for MINNEBRO as a treatment for patients with hypertension in Japan. MINNEBRO is a compound identified during our

research collaboration with Daiichi Sankyo, which the companies entered into in March 2006, and has been subsequently developed by Daiichi Sankyo.

- In January 2019, the FDA approved CABOMETYX as a treatment for patients with HCC who have been previously treated with sorafenib. The FDA's approval of CABOMETYX was based on results from CELESTIAL, our phase 3 pivotal trial evaluating cabozantinib in patients with previously treated HCC, which demonstrated a statistically significant and clinically meaningful improvement in OS versus placebo.
- In January 2019, the FDA accepted our Investigational New Drug application for XL092, a next-generation oral TKI and the first compound to advance from our new discovery organization.
- In February 2019, we initiated a phase 1 dose escalation trial, evaluating the pharmacokinetics, safety and tolerability of XL092 in patients with advanced solid tumors, with the primary objective of determining a dose for daily oral administration suitable for further evaluation.
- In April 2019, CheckMate 9ER, the phase 3 pivotal trial evaluating the combination of cabozantinib and nivolumab versus sunitinib in patients with previously untreated advanced or metastatic RCC completed enrollment, including in Japan where the last few patients are in the process of being randomized.
- In April 2019, Takeda applied to the Japanese MHLW for approval to manufacture and sell CABOMETYX as a treatment for unresectable and metastatic RCC in Japan.
- In May 2019, we announced the initiation of 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, which will be conducted in collaboration with BMS.

Financial Highlights

- Net income for the first quarter of 2019 was $75.8 million, or $0.25 per share, basic and $0.24 per share, diluted, compared to $115.9 million, or $0.39 per share, basic and $0.37 per share diluted, for the first quarter of 2018.
- Net product revenues for the first quarter of 2019 increased to $179.6 million, compared to $134.3 million for the first quarter of 2018.
- Total revenues for the first quarter of 2019 increased to $215.5 million, compared to $213.7 million for the first quarter of 2018.
- Research and development expenses for the first quarter of 2019 increased to $63.3 million, compared to $37.8 million for the first quarter of 2018.
- Selling, general and administrative expenses for the first quarter of 2019 increased to $60.1 million, compared to $54.0 million for the first quarter of 2018.
- Provision for income taxes for the first quarter of 2019 increased to $14.9 million, compared to $2.5 million for the first quarter of 2018.
- Cash and investments increased to $1,019.4 million at March 31, 2019, compared to $851.6 million at December 31, 2018.

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

Challenges and Risks

We will continue to face challenges and risks that may impact our ability to execute on our 2019 business objectives. In particular, for the foreseeable future, we expect our ability to maintain or meaningfully increase unrestricted cash flow to fund our business operations and growth will depend upon the continued commercial success of CABOMETYX as a treatment for advanced RCC and previously treated HCC, and potentially for other indications for which cabozantinib is in late-stage clinical trials, if warranted by the data generated from such trials. The commercial success of CABOMETYX in its approved indications is subject to a variety of factors, most importantly, the drug's perceived benefit/risk profile as compared to the benefit/risk profiles of other competitive treatments available or in development for these conditions. CABOMETYX will only continue to be successful commercially 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 2019 business objectives will also depend on the success of the development and commercialization strategies we have formulated to navigate increased competition, including that from, but not

limited to, ICIs, as well as the use of combination therapy to treat cancer. Our research and development objectives may be impeded by the challenges associated with scaling our organization to meet the demands of expanded drug development and discovery activities. In connection with efforts to expand our product pipeline, we may be unsuccessful in discovering new drug candidates or we may not be able to successfully identify 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 pharmaceutical industry with development and commercial operations. For a complete discussion of challenges and risks we face, see “Risk Factors” in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Fiscal Year Convention

We have adopted a 52- or 53-week fiscal year policy that generally ends on the Friday closest to December 31st. Fiscal year 2019 will end on January 3, 2020 and fiscal year 2018 ended on December 28, 2018. For convenience, references in this report as of and for the fiscal periods ended March 29, 2019 and March 30, 2018, and as of and for the fiscal years ending January 3, 2020 and ended December 28, 2018, are indicated as being as of and for the periods ended March 31, 2019 and March 31, 2018, and the years ending December 31, 2019 and ended December 31, 2018, respectively.

Results of Operations

Revenues

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

	Three Months Ended March 31,		Percentage Change
	2019	2018	
Net product revenues	$179,581	$134,272	34 %
Collaboration revenues	35,906	79,447	(55)%
Total revenues	$215,487	$213,719	1 %

Net Product Revenues

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

	Three Months Ended March 31,		Percentage Change
	2019	2018	
Gross product revenues	$223,750	$159,436	40 %
Discounts and allowances	(44,169)	(25,164)	76 %
Net product revenues	$179,581	$134,272	34 %
Product revenues by product:			
CABOMETYX	$175,890	$128,934	36 %
COMETRIQ	3,691	5,338	(31)%
Net product revenues	$179,581	$134,272	34 %

The increase in product revenues for CABOMETYX for the three months ended March 31, 2019, as compared to the comparable period in 2018, was primarily due to a 26% increase in the number of units of CABOMETYX sold and, to a lesser extent, an increase in the average selling price of the product. The increase in CABOMETYX sales volumes reflects the continued growth of CABOMETYX in advanced RCC following FDA approvals in April 2016 of CABOMETYX for the treatment of patients with advanced RCC who have received prior anti-angiogenic therapy and in December 2017 for previously untreated patients with advanced RCC, as well as the U.S. launch of CABOMETYX for the treatment of patients with HCC who have been previously treated with sorafenib, following FDA approval in January 2019. The decrease in product revenues for COMETRIQ for the three months ended March 31, 2019, as compared to the comparable period in 2018, was primarily due to a 35% decline in the number of units of COMETRIQ sold. COMETRIQ sales volume has continued to decrease since the launch of CABOMETYX in April 2016.

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, 2018. The increase in discounts and allowances for the

three months ended March 31, 2019, as compared to the comparable period in 2018, was primarily the result of the overall increase in product sales volume described above, increases in the volume and dollar amount of chargebacks associated with public health service hospitals, and an increase to the discount provided to Medicare Part D beneficiaries as required by our

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participation in the Medicare Part D Coverage Gap Discount Program. We expect our discounts and allowances as a percentage of gross product revenues to increase during 2019 as compared to 2018 as our business evolves and the number of patients participating in government programs increases, the discounts and rebates paid to government payers increase and as a result of the engagement in commercial contracting that may result in additional discounts or rebates.

Collaboration Revenues

Collaboration revenues were as follows (dollars in thousands):

	Three Months Ended March 31,		Percentage Change
	2019	2018	
Collaboration revenues:			
License revenues [1]	$24,509	$69,030	(64)%
Research and development service revenues [2]	11,928	10,099	18 %
Other collaboration revenues [3]	(531)	318	n/m
Total collaboration revenues	$35,906	$79,447	(55)%

(1) License revenues included the immediate recognition of the portion of milestones 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 revenue reversal would not occur, as well as royalty revenues from Ipsen and Genentech.

(2) Research and development service revenues included the recognition of deferred revenue for the portion of upfront and milestone payments that have been allocated to research and development service performance obligations, as well as development cost reimbursements earned on our collaboration agreements.

(3) Other collaboration revenues included the profit on the U.S. commercialization of COTELLIC from Genentech and revenues on product supply services provided to Ipsen and Takeda, which were partially offset by the 3% royalty we are required to pay GlaxoSmithKline (GSK) on the net sales by Ipsen of any product incorporating cabozantinib.

The decrease in collaboration revenues was primarily the result of a decrease in milestones revenues, which was partially offset by an increase in royalty revenues under our collaboration agreement with Ipsen and development cost reimbursements by Ipsen and Takeda.

Milestone revenues were $10.0 million for the three months ended March 31, 2019, as compared to $66.5 million for the comparable period in 2018. Milestone revenues for the three months ended March 31, 2019 primarily related to $9.4 million in revenues recognized in connection with an expected $10.0 million milestone from Takeda for the submission in April 2019 of a regulatory application for cabozantinib as a treatment for patients with advanced RCC to the Japanese MHLW. See “Note 11. Subsequent Events - Amendment to Collaboration Agreement with Takeda” in the “Notes to Condensed Consolidated Financial Statements” contained in Part I, Item 1 of this Quarterly Report on Form 10-Q for information regarding an amendment to our January 2017 collaboration agreement with Takeda.

Milestone revenues for the three months ended March 31, 2018 primarily related to $45.8 million in revenues recognized in connection with a $50.0 million milestone from Ipsen we expected to, and did, earn in the second quarter of 2018 for the approval of CABOMETYX for the first-line treatment of adults with intermediate- or poor-risk RCC by the EC and a $20.0 million milestone upon Daiichi Sankyo’s submission to the Japanese MHLW of a regulatory application for esaxerenone as a treatment for patients with essential hypertension. Due to uncertainties surrounding the timing and achievement of regulatory and development milestones, it is difficult to predict future milestone revenues and such milestones can vary significantly from period to period.

Royalties on net sales of cabozantinib by Ipsen outside of the U.S. and Japan were $14.0 million for the three months ended March 31, 2019, as compared to $4.4 million for the comparable period in 2018. 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 is currently approved and commercially available in 40 and 27 countries outside of the U.S., respectively. We were entitled to receive a tiered royalty of 2% to 12% on the

initial $150.0 million of net sales; this amount was reached in the second quarter of 2018. As of June 30, 2018 and going forward, we are entitled to receive a tiered royalty of 22% to 26% on annual net sales (with separate tiers for Canada); these 22% to 26% royalty tiers reset each calendar year. In Canada, we are entitled to receive a tiered royalty of 22% on the first CAD$30.0 million of annual net sales and a tiered royalty thereafter of 22% to 26% on annual net sales; these 22% to 26% royalty tiers for Canada will also reset each calendar year. For 2019, we expect the royalty revenues to increase as compared to 2018 as a result of achieving the 22% minimum royalty tier.

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Development cost reimbursements in connection with our collaboration arrangements with Ipsen and Takeda were $10.3 million for the three months ended March 31, 2019, as compared to $5.7 million for the comparable period in 2018. The increase was primarily the result of reimbursements from Ipsen and Takeda for their share of the increase in spending on the CheckMate 9ER study.

Profits on the U.S. commercialization of COTELLIC and royalties on ex-U.S. net sales of COTELLIC under our collaboration agreement with Genentech were $2.5 million for the three months ended March 31, 2019, as compared to $2.7 million for the comparable period in 2018. Sales of COTELLIC in the U.S. have declined following Genentech's decision to scale back the personal promotion of COTELLIC commencing in January 2018.

For three months ended March 31, 2019 and 2018, collaboration revenues were reduced by $1.9 million and $1.1 million, respectively, for the 3% royalty we are required to pay GSK on the net sales by Ipsen of any product incorporating cabozantinib. As royalty generating sales of cabozantinib by Ipsen have increased as described above, our royalty payments to GSK have also increased.

Cost of Goods Sold

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

	Three Months Ended March 31,		Percentage Change
	2019	2018	
Cost of goods sold	$7,501	$5,639	33 %
Gross margin	96 %	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 increase in Cost of goods sold for the three months ended March 31, 2019, as compared to the comparable period in 2018, was primarily the result of the increase in product sales volume described above. We do not expect our gross margin to change significantly during the remainder of 2019.

Research and Development Expenses

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

	Three Months Ended March 31,		Percentage Change
	2019	2018	
Research and development expenses	$63,289	$37,757	68 %

Research and development expenses consist primarily of clinical trial costs, personnel expenses, stock-based compensation, consulting and outside services, the allocation of general corporate costs and license costs.

The increase in Research and development expenses for the three months ended March 31, 2019, as compared to the comparable period in 2018, was primarily related to increases in clinical trial costs, personnel expenses, the allocation of general corporate costs and stock-based compensation. Clinical trial costs, which includes services performed by third-party contract research organizations and other vendors who support our clinical trials, and comparator drug purchases, increased $17.0 million for the three months ended March 31, 2019, as compared to the comparable period in 2018. The increase in clinical trial costs was primarily due to costs associated with the expanding clinical trial program for cabozantinib that now includes four phase 3 pivotal studies (CheckMate 9ER, COSMIC-311, COSMIC-312 and COSMIC-313), as well as the multi-cohort phase 1b study, COSMIC-021. Personnel expenses, the allocation of general corporate costs and stock-based compensation increased $3.8 million, $1.8 million and $1.3 million, respectively, for the three months ended March 31, 2019, as compared to the comparable period in 2018, primarily due to increases in headcount to support our expanded discovery and development efforts.

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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: Development, Drug discovery and 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 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 March 31,	
	2019	2018
Research and development expenses:		
Development:		
Clinical trial costs	$28,187	$11,196
Personnel expenses	13,587	10,658
Consulting and outside services	2,712	1,945
Other development costs	4,134	3,388
Total development	48,620	27,187
Drug discovery [(1)]	7,040	5,990
Other [(2)]	7,629	4,580
Total research and development expenses	$63,289	$37,757

(1) Primarily includes personnel expenses, consulting and outside services, laboratory supplies and license costs for our collaboration and license agreements with Invenra and StemSynergy.

(2) Includes stock-based compensation and the allocation of general corporate costs to research and development.

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. Such factors include enrollment in clinical trials for our drug candidates, preliminary data from and final results of 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 our near-term research and development expenses to primarily relate to the clinical development of cabozantinib. We expect to continue to incur significant development costs for cabozantinib in future periods as we evaluate its potential in a broad development program comprising over 75 ongoing or planned clinical trials across multiple indications. Notable studies of this program include: CheckMate 9ER and CheckMate 040, each in collaboration with BMS; company-sponsored COSMIC-021 and COSMIC-312, for which Roche is providing atezolizumab free of charge; company-sponsored COSMIC-313, for which BMS is providing nivolumab and ipilimumab free of charge; and company-sponsored COSMIC-311. In addition, post-marketing commitments in connection with the approval of COMETRIQ in progressive, metastatic MTC dictate that we conduct an additional study in that indication.

We are also committed to building our product pipeline by discovering and developing new cancer therapies for patients. In this regard, we are conducting internal drug discovery activities with the goal of identifying new product candidates to advance into clinical trials. These internal drug discovery activities are augmented by efforts to identify and in-license promising, early-stage oncology assets and then further develop them utilizing our established clinical development infrastructure. As a result, for 2019 we expect our Research and development expenses to increase as we continue to expand the cabozantinib development program and our product pipeline.

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

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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 complete costs associated with the development of cabozantinib or any of our other research and development projects.

In any event, 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 March 31,		Percentage Change
	2019	2018	
Selling, general and administrative expenses	$60,138	$54,016	11 %

Selling, general and administrative expenses consist primarily of personnel expenses, consulting and outside services, stock-based compensation, marketing costs and corporate giving.

The increase in Selling, general and administrative expenses for the three months ended March 31, 2019, as compared to the comparable period in 2018, was primarily related to increases in consulting and outside services, personnel expenses, stock-based compensation, marketing costs and depreciation expense; those increases were partially offset a decrease in corporate giving. Consulting and outside services and marketing costs increased $3.3 million and $1.5 million, respectively, for the three months ended March 31, 2019 as compared to the comparable period in 2018, primarily due to increases in marketing activities in support of the CABOMETYX launch in HCC and continued support of the product in an increasingly competitive RCC market. Personnel expenses and stock-based compensation each increased $2.0 million for the three months ended March 31, 2019, as compared to the comparable period in 2018, primarily due to increases in general and administrative headcount to support our commercial and research and development organizations. Depreciation expense increased $1.4 million for the three months ended March 31, 2019, as compared to the comparable period in 2018, primarily as a result of our office and research facilities in Alameda, California being placed into service in June 2018. Our expense for the Branded Prescription Drug Fee, which is also included in Selling, general and administrative expenses, increased $1.4 million for the three months ended March 31, 2019, as compared to the comparable period in 2018. Corporate giving, consisting predominantly of donations to independent patient support foundations, decreased $2.8 million for the three months ended March 31, 2019, as compared to the comparable period in 2018.

For 2019, we expect modest increases in Selling, general and administrative expenses to support our overall organizational growth.

Other Income (Expense), Net

Other income (expense), net, was as follows (dollars in thousands):

	Three Months Ended March 31,		Percentage Change
	2019	2018	

Interest income	$6,087	$1,895	221	%
Other, net	25	169	(85	)%
Total other income (expense), net	$6,112	$2,064	196	%

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The increase in Interest income for the three months ended March 31, 2019, as compared to the comparable period in 2018, was the result of both an increase in our investment balances and an increase in the yield earned on those investments.

Provision for Income Taxes

The Provision for income taxes was as follows (in thousands):

	Three Months Ended March 31,		Percentage Change
	2019	2018	
Provision for income taxes	$14,896	$2,514	493 %

Our effective income tax rate was 16.4% during the three months ended March 31, 2019 as compared to 2.1% for the comparable period in 2018. The Provision for income taxes relating to our pre-tax income for the three months ended March 31, 2018 was largely offset by a valuation allowance against our net operating loss carryforwards and other deferred tax assets. At December 31, 2018, we released substantially all of the remaining valuation allowance against our deferred tax assets, after we determined that it was more likely than not that these deferred tax assets would be realized.

Liquidity and Capital Resources

As of March 31, 2019, we had $1.0 billion in cash and investments. 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. The sufficiency of our cash resources depends on numerous assumptions, including assumptions related to product sales and operating expenses, as well as the other factors set forth in “Risk Factors” under the headings “Risks Related to our Capital Requirements, Accounting and Financial Results,” in Part I, Item 1A of this Annual Report on Form 10-K. Our assumptions may prove to be wrong or other factors may adversely affect our sources of cash and, as a result, we may not have the cash resources to fund our operations as currently planned, which would have a material adverse effect on our business.

We expect to continue to spend significant amounts to fund the continued development and commercialization of cabozantinib. In addition, we intend to rebuild our product pipeline through our reinitiated 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 if 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.

Sources and Uses of Cash

The following table summarizes our cash flow activities (in thousands):

	Three Months Ended March 31,	
	2019	2018
Net cash provided by operating activities	$161,593	$71,808
Net cash used in investing activities	$(107,657)	$(25,533)
Net cash provided by (used in) financing activities	$5,226	$(254)

Operating Activities

Our operating activities provided cash of $161.6 million for three months ended March 31, 2019, compared to $71.8 million of for the comparable period in 2018.

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 share-based compensation charges, 401(k) matching contributions made in common stock and depreciation and amortization; 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.

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The most significant factors that contributed to the increase in cash provided by operating activities for the three months ended March 31, 2019, as compared to the comparable period in 2018, was a $45.3 million increase in Net product revenues and $60.0 million in milestone payments received from Ipsen. This was partially offset by a $33.5 million increase in operating expenses for the three months ended March 31, 2019, as compared to the comparable period in 2018.

Investing Activities

Our investing activities used cash of $107.7 million for the three months ended March 31, 2019, as compared to $25.5 million during the comparable period in 2018.

Cash used in investing activities for the three months ended March 31, 2019 was primarily due to investment purchases of $239.9 million and Property and equipment purchases of $2.3 million, less cash provided by the maturity and sale of investments of $129.8 million and $4.7 million, respectively.

Cash provided by investing activities for the three months ended March 31, 2018 was primarily due to investment purchases of $116.5 million and Property and equipment purchases of $2.9 million. less cash provided by the maturity and sale of investments of $87.5 million and $6.2 million, respectively.

Financing Activities

Cash provided by financing activities was $5.2 million for the three months ended March 31, 2019, as compared to $0.3 million cash used during the comparable period in 2018.

Cash provided by financing activities for the three months ended March 31, 2019 was primarily a result of $6.8 million in proceeds from the issuance of common stock under our equity incentive plans, partially offset by $1.6 million of taxes paid related to net share settlements.

Cash used in financing activities for the three months ended March 31, 2018 was the result of $2.1 million taxes paid related to net share settlements, partially offset by $1.9 million in proceeds from the issuance of common stock under our equity incentive plans.

Contractual Obligations

As of March 31, 2019, there have been no material changes outside of the ordinary course of business in our contractual obligations from those as of December 31, 2018.

On April 1, 2019, we entered into an amendment to the existing Lease Agreement (the Lease) relating to our corporate headquarters located at 1851, 1801, and 1751 Harbor Bay Parkway, Alameda, California. See “Note 11. Subsequent Events” in our “Notes to Condensed Consolidated Financial Statements” contained in Part I, Item 1 of this Quarterly Report on Form 10-Q for more about the amendment to the Lease.

Off-Balance Sheet Arrangements

As of March 31, 2019, we did not have any material off-balance-sheet arrangements, as defined by applicable SEC regulations.

Critical Accounting 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, sales allowances, and milestone payments included in collaboration arrangements; the amounts of revenues and expenses under our profit and loss sharing agreement; the recoverability of inventory; the amounts of operating lease right-of-use assets and lease liabilities; the amounts of deferred tax assets and liabilities including the

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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 option valuation and income taxes reflect the more significant estimates and assumptions used in the preparation of our Consolidated Financial Statements.

There have been no significant changes in our critical accounting policies and estimates during the three months ended March 31, 2019, 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, 2018 filed with the SEC on February 22, 2019.

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 at March 31, 2019 have not changed significantly from those described in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2018.

Our exposure to market risk for changes in interest rates relates to our investment portfolio. As of March 31, 2019, an increase in the interest rates of one percentage point would have had a net adverse change in the fair value of interest rate sensitive assets of $4.7 million as compared to $3.4 million as of December 31, 2018.

Our exposure to market risk for changes in currency exchange rates relates to Royalty revenues and sales-based milestones we receive from our collaboration agreements are a percentage of the net sales made by those partners from sales made in countries outside the U.S. and are denominated in currencies in which the product is sold, which is predominantly the Euro. For the quarter ended March 31, 2019 and the year ended December 31, 2018, an average 10% strengthening of the U.S. dollar relative to the currencies in which these products are sold would have resulted in revenues being reduced by approximately $1.5 million and $3.8 million, respectively.

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.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We are not a party to any material legal proceedings. We may from time to time become a party or subject to various 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 factors discussed elsewhere in this report and our other reports filed with the SEC, 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.

Our mission is to maximize the clinical and commercial potential of cabozantinib, and to position us for future growth through our discovery efforts and expansion of our development pipeline. We anticipate that for the foreseeable future, our ability to maintain or meaningfully increase unrestricted cash flow to fund our business operations and growth will depend upon the continued commercial success of CABOMETYX as a treatment for advanced RCC and previously treated HCC, and potentially for other indications for which cabozantinib is in late-stage clinical trials, if warranted by the data generated from such trials. The commercial success of CABOMETYX in its approved indications is subject to a variety of factors, most importantly, the drug's perceived benefit/risk profile as compared to the benefit/risk profiles of other treatments available or in development for these conditions. If revenue from CABOMETYX decreases or remains flat, or if we fail to achieve anticipated product royalties and collaboration milestones, we may need to reduce our operating expenses, access other sources of cash or otherwise modify our business plans, which could have a material adverse impact on our business, financial condition and results of operations. Furthermore, as a consequence of our collaboration agreements with Ipsen and Takeda, we rely heavily upon their regulatory, commercial, medical affairs, market access and other expertise and resources for commercialization of CABOMETYX in their respective territories outside of the U.S. We cannot control the amount and timing of resources that our collaborators 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 collaborators 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, foreign sales of CABOMETYX by our collaborators could be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions or barriers and changes in tariffs, including as a result of the pending withdrawal of the United Kingdom (UK) from the European Union (EU) (commonly referred to as "Brexit") and the uncertainty surrounding the date and the terms of the withdrawal, escalating global trade and political tensions, or otherwise. If our collaborators are unable to, or do not invest the resources necessary to successfully commercialize CABOMETYX in the EU 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.

CABOMETYX has been approved for the treatment of advanced RCC and previously treated HCC in the U.S., the EU and other territories. With these approvals, our ability to grow our company remains contingent upon, among other things, further success in the clinical development, regulatory approval and market acceptance of cabozantinib, the active pharmaceutical ingredient in CABOMETYX, in potential additional indications. 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. Even if we and

our partners receive the required regulatory approvals to market cabozantinib for any additional indications or in additional territories, we and our partners may not be able to effectively commercialize CABOMETYX in these additional indications or territories.

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Our ability to grow revenues from sales of CABOMETYX will depend upon the degree of market acceptance among physicians, patients, health care payers, and the medical community.

Our ability to increase 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 health care payers such as Medicare and Medicaid, commercial health care plans and the medical community. If CABOMETYX does not continue to be prescribed broadly for the treatment of its approved RCC and HCC indications, we may not be able to grow product revenues. The degree of market acceptance of CABOMETYX will depend upon a number of factors, including:

- the effectiveness, or perceived effectiveness, of CABOMETYX in comparison to competing products;
- the safety of CABOMETYX, including the existence of serious side effects of CABOMETYX and their severity in comparison to those of competing products;
- CABOMETYX's relative convenience and ease of administration;
- potential unexpected results connected with analysis of data from future or ongoing clinical trials of cabozantinib;
- the timing of CABOMETYX label expansions for additional indications, if any, relative to competitive treatments;
- the price of CABOMETYX relative to competitive therapies;
- price increases taken by us and the impact on the net sales price of CABOMETYX as a result of any new laws, regulations or other government initiatives affecting pharmaceutical pricing;
- the strength of CABOMETYX sales efforts, marketing, market access and product distribution support;
- our ability to obtain and maintain coverage and reimbursement for CABOMETYX from commercial and government payers; and
- our ability to enforce our intellectual property rights with respect to CABOMETYX.

Further, in the event that any of these or other factors cause market acceptance of CABOMETYX to decrease, this could negatively impact our revenues, 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 pharmaceutical, biopharmaceutical and biotechnology industries are competitive, highly diversified and are characterized by rapid technological change, particularly in the area of novel oncology therapies. Many of the organizations competing with us have greater capital resources, larger research and development staff and facilities, more experience in obtaining regulatory approvals and more extensive product manufacturing and commercial capabilities than we do, which may allow them to have a competitive advantage. Further, our competitors may be more effective at using their technologies to develop commercial products. As a result, our competitors may be able to more easily develop products that would render our products, and those of our collaborators, obsolete and noncompetitive. There may also be drug candidates that we are not aware of at an earlier stage of development that may compete with our marketed products and product candidates. 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 research activities similar to ours. Delays in the development of cabozantinib for the treatment of additional tumor types, for example, could allow our competitors to bring products to market before us.

Furthermore, the specific indications for which CABOMETYX is approved 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 technological advances and the shifting landscape of therapeutic strategy following the advent of ICIs. While we have adapted our cabozantinib development strategy to address the fact that the approach to treating cancer with ICIs in combination with other therapeutic agents has become highly prevalent in indications for which our products are approved, we cannot ensure that our clinical trials will show efficacy in comparison to competing products or product combinations. Furthermore, the complexities of such a development strategy has and may continue to require collaboration with some of our competitors.

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We also may face competition from manufacturers of generic versions of our marketed products, and both Congress and the FDA are seeking to promote generic competition, including through proposals that may limit or reduce the term for patent exclusivity or regulatory exclusivity for branded products. Such generic competition often results in very significant decreases in the overall sales or prices at which branded products can be sold.

If we are unable to maintain or scale adequate sales, marketing, market access and product distribution capabilities for our products or enter into or maintain agreements with third parties to do so, 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 managing 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 pre-commercial-stage oncology-focused biotechnology companies seeking to build out their commercial organizations, as well as other large pharmaceutical 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. If we cannot maintain effective sales, marketing, market access and product distribution capabilities, we may be unable to maximize the commercial potential of CABOMETYX and COMETRIQ in their approved indications. Also, to the extent that the commercial opportunities for CABOMETYX grow over time, we may not properly judge the requisite size and experience of our current commercialization teams or the level of distribution necessary to market and sell CABOMETYX successfully in multiple indications. If we are unable to maintain or scale our organization appropriately, we may not be able to maximize product revenues, which could have a material adverse impact on our business, financial condition and results of operations.

Our ability to successfully commercialize our products will depend, in part, on the extent to which we are able to adequately distribute the products to eligible patients. We currently rely on third-party providers for storage and distribution of our commercial supplies of both CABOMETYX and COMETRIQ in the U.S. Furthermore, we rely on our collaboration partners for ongoing and further 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) with the effect of introducing earlier patient access to CABOMETYX and COMETRIQ.

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 to the marketplace on a timely and competitive basis. These third parties may not provide services in the time required to meet our commercial timelines and objectives or to meet regulatory requirements. We may not be able to maintain or renew our arrangements with third parties, or enter into new arrangements, on acceptable terms, or at all. Third parties could terminate or decline to renew our arrangements based on their own business priorities. If we are unable to contract for these third-party services related to the distribution of CABOMETYX and COMETRIQ 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. 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. 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. Third-party payers continue to scrutinize and manage access to pharmaceutical products and services and press manufacturers for

discounts and rebates. Payers may also limit reimbursement for newly approved products and indications.

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We are subject to certain 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 certain healthcare laws and regulations and enforcement 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 conduct or inaccurate reporting, the laws that may affect our ability to operate include, without limitation:

- the federal Anti-Kickback Statute (AKS), which governs our business activities, including our marketing practices, medical educational programs, pricing policies, and relationships with healthcare providers or other entities. The AKS has been broadly interpreted to apply to manufacturer arrangements with prescribers, purchasers and formulary managers, among others. Among other things, this statute prohibits persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. Remuneration is not defined in the AKS and has been broadly interpreted to include anything of value, including for example, gifts, discounts, coupons, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests, value-added services to customers, and providing anything at less than its fair market value;
- 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, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;
- 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 and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts 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;
- the Foreign Corrupt Practices Act, a U.S. law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals) and its foreign equivalents;
- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
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federal, state and municipal pharmaceutical price and price reporting laws, both existing (e.g., California's SB-17 and Oregon's HB 4005) and under consideration (e.g. the U.S. Senate's Stopping the Pharmaceutical

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Industry from Keeping Drugs Expensive (SPIKE) Act (S. 474)), which require or propose to require us to provide notice of price increases and/or file complex ancillary reports concerning prices and pricing and discount practices. The legal and regulatory landscape, and associated compliance obligations imposed on pharmaceutical companies, may increase general and administrative costs, cause revenue fluctuations due to speculative buying practices by purchasers, or diminish our revenues as a result of the imposition of caps on pricing and price increases.

These federal and state healthcare fraud and abuse laws, FDA rules and regulations, as well as false claims laws, including the civil False Claims Act, govern certain marketing practices, including off-label promotion. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we, or our officers or employees, may be subject to 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, reputational harm, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement, 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. These individuals, commonly known as relators or “whistleblowers,” may potentially then share in amounts paid by the entity to the government in fines or settlement. The filing of qui tam actions has caused a number of pharmaceutical, medical device and other healthcare companies to have to defend civil False Claims Act actions. When an entity is determined to have violated the civil False Claims Act, 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, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

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

The U.S. and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to continue to commercialize CABOMETYX and COMETRIQ profitably. Among policy makers and payers in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

Specifically, we may face uncertainties as a result of executive, legislative and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the PPACA. On December 14, 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. The decision has been appealed to the U.S. Court of Appeals for the Fifth Circuit, and the Trump administration communicated its support of the decision of the Texas District Court judge in a legal filing on March 25, 2019. While the Texas District Court Judge, as well as the Trump Administration and the Centers for Medicare and Medicaid Services (CMS), have stated that the ruling will have no immediate effect pending the appeal, it is unclear how this decision, subsequent appeals and other efforts to repeal and replace the PPACA will impact the PPACA. There is no assurance that the PPACA, as currently enacted or as amended 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. The Trump Administration has also indicated an intention to regulate prescription drug pricing, and recent Congressional hearings have brought increased public attention to the costs of prescription drugs. These actions and the uncertainty about the future of the PPACA and healthcare laws may put downward pressure on pharmaceutical pricing and increase our regulatory burdens and operating costs.

There are pending federal Congressional proposals that would significantly expand government-provided health insurance coverage. Proposals range from establishing a single-payer, national health insurance system (e.g., Medicare for All Act of 2019 (H.R. 1384), to more limited buy-in options that would be available to individuals above a certain

age (e.g., Medicare at 50 Act (S. 470). There is also legislation that would authorize states to permit individuals to "buy-in" to their state Medicaid program (e.g., State Public Option Act (S. 489, H.R. 1277)). If enacted, these proposals will likely have a significant impact on the healthcare industry. At this stage, we cannot predict how future legislation will affect our business.

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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, including yearly program fees in the case of most New Drug Application (NDA)-approved prescription drugs. The legislation 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. The FDA has also released a Drug Competition Action Plan, which proposes actions to broaden access to generic drugs and lower consumers' health care 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 that would limit or reduce the term for patent exclusivity or regulatory exclusivity in the biopharmaceutical industry. While we cannot currently predict the specific outcome or impact on our business of such regulatory actions or legislation, they do have the potential to facilitate the development and future approval of generic versions of our products or otherwise limit or reduce the term for our market exclusivity, which could result in very significant decreases in the overall sales or prices of our marketed products and materially harm our business and financial condition.

As a result of the overall trend towards managed healthcare in the U.S., third-party payers are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs. Insurers also continue to pursue means of contracting for pharmaceutical "value" or "outcomes." These entities could refuse or limit coverage for CABOMETYX and COMETRIQ, such as by using tiered reimbursement or pressing for new forms of value-based contracting, which would adversely affect demand for CABOMETYX and COMETRIQ. They may also refuse to provide coverage for uses of CABOMETYX and COMETRIQ for medical indications other than those for which the FDA has granted market approval. As a result, significant uncertainty exists as to whether and how much third-party payers will cover newly approved drugs, which in turn will put pressure on the pricing of drugs. Due to the volatility in the current economic and market dynamics, we are unable to predict the impact of any unforeseen or unknown legislative, regulatory, third-party payer or policy actions, which may include cost containment and healthcare reform measures. These policy actions could have a material adverse impact on our business, financial condition and results of operations.

Pricing for pharmaceutical products has come under increasing scrutiny by 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.

Many companies in our industry have received a governmental request for documents and information relating to drug pricing and patient support programs. Requests could originate in various forms, including through a Congressional inquiry (e.g., from the U.S. Senate Finance Committee) or a subpoena from the U.S. Department of Justice. We could receive a similar request, which would require us to incur significant expense and result in distraction for our management team. 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. It is possible that these inquiries could result in: negative publicity or other negative actions that could harm our reputation; changes in our product pricing and distribution strategies; reduced demand for our approved products; and/or reduced reimbursement of approved products, including by federal health care programs such as Medicare and Medicaid and state health care programs.

Specifically, there have been several recent U.S. Congressional inquiries, hearings and proposed and enacted federal legislation designed to, among other things, bring more transparency to drug pricing (including requirements for pharmaceutical manufacturers to report price increases and provide a public justification for these increases if they exceed certain benchmarks), review the relationship between pricing and manufacturer patient programs, reduce the price of drugs under Medicare, reform government program reimbursement methodologies for drugs, expedite the development and approval of generic drugs and biosimilars, and facilitate value-based arrangements between manufacturers and payers. Also, the Trump Administration's budget proposal for fiscal year 2020 contains drug price control measures that could be enacted during the 2020 appropriations process or in other future legislation, including measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some

states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs and biosimilars for low-income patients. While most of the proposed measures will require authorization through additional legislation to become effective, both Congress and the Trump Administration have indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. For example, in November 2018, CMS proposed a rule that allows Medicare Part D and Medicare Advantage plans to limit coverage under certain defined circumstances for certain drugs, including cancer medicines, pursuant to exceptions to the existing “protected classes” policy. Additionally, in January 2019, the U.S. Department of Health and Human Services (HHS) Office of Inspector General issued a proposed rule, which would amend the AKS discount safe harbor to exclude manufacturer rebates to pharmacy benefit managers (PBMs), Part D plans and Medicaid-managed care organizations, as

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well as create new safe harbors to protect point-of-sale price reductions offered by manufacturers and to protect fixed fees that manufacturers pay to PBMs for certain services. We cannot know what form any final regulations promulgated by CMS or the HHS Office of Inspector General might look like or how they could affect our business.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, to encourage importation from other countries and bulk purchasing, including the National Medicaid Pooling Initiative. With respect to drug pricing transparency, for example, in October 2017, Jerry Brown, the Governor of California at the time, signed B-17, which requires, among other provisions, pharmaceutical manufacturers to provide notice of price increases above a defined threshold to certain purchasers and related reports to the government. SB-17 is currently subject to challenge, but in the meantime, manufacturers must comply with its requirements. It is possible that these laws would encourage federal and state healthcare programs to reduce the amount of reimbursements they provide for prescription drugs, and any reduction in reimbursement from these government healthcare programs may result in a similar reduction in payments from private payers. We also believe that pricing transparency requirements, such as the requirement for us, in certain circumstances, to provide lengthy notices of price increases to purchasers, may influence customer ordering patterns for CABOMETYX and COMETRIQ, and that this, in turn, may increase the volatility of our revenues as a reflection of changes in inventory volumes. 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 current products and/or those for which we may receive regulatory approval in the future.

Further, in some foreign countries, particularly in the EU, the pricing and reimbursement of prescription pharmaceuticals is subject to governmental control under the respective national health system. In these EU countries, pricing and reimbursement negotiations with governmental authorities or payers can take six to twelve 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 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 our collaboration partner, Ipsen, might establish for CABOMETYX, which would result in lower license revenues to us.

Enhanced governmental and private scrutiny over, or investigations or litigation involving, pharmaceutical manufacturer donations to patient assistance programs offered by charitable foundations may require us to modify our programs and 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 in affording pharmaceuticals have become the subject of scrutiny. In recent years, some pharmaceutical manufacturers were named in class action lawsuits challenging the legality of their patient assistance programs and support of independent charitable patient support foundations under a variety of federal and state laws. Our patient assistance program and support of independent charitable foundations could become the target of similar litigation. At least one insurer also has directed its network pharmacies to no longer accept manufacturer co-payment coupons for certain specialty drugs the insurer identified. In addition, certain state and federal enforcement authorities and members of Congress have initiated inquiries about co-pay assistance programs. Some state legislatures have also been considering proposals that would restrict or ban co-pay coupons.

In addition, there has been regulatory review, Congressional interest and enhanced government scrutiny of donations by pharmaceutical companies to patient assistance programs operated by charitable foundations. The HHS Office of Inspector General has established specific guidelines permitting pharmaceutical manufacturers to make donations to charitable organizations who provide co-pay assistance to Medicare patients, provided that such organizations are bona fide charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a

first-come basis according to consistent financial criteria, and do not link aid to use of a donor’s product. If we are deemed not to have complied with laws or regulations in the operation of these programs, we could be subject to damages, fines, penalties or other criminal, civil or administrative sanctions or enforcement actions. Further, numerous organizations, including pharmaceutical manufacturers, have received subpoenas from the U.S. Department of Justice and other enforcement authorities seeking information related to their patient assistance programs and support, and certain of these organizations

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have entered into, or have otherwise agreed to, significant civil settlements with applicable enforcement authorities. Additionally, in March 2019, the Senate Finance Committee launched an inquiry into alleged ties between pharmaceutical manufacturers and patient assistance charitable foundations. It is possible that future legislation may propose establishing requirements that affect pharmaceutical manufacturers and such charitable organizations. We cannot ensure that our compliance controls, policies and procedures will be sufficient to protect against acts of our employees, business partners or vendors that may violate the laws or regulations of the jurisdictions in which we operate. Regardless of whether we have complied with the law, a government investigation could negatively impact our business practices, harm our reputation, divert the attention of management and increase our expenses.

We are subject to government regulations relating to privacy and data protection that have required us to modify certain of our policies and procedures with respect to the collection and processing of personal data, and future regulations may cause us to incur additional expenses or otherwise limit our ability to collect and process personal data. Failure to maintain compliance with these regulations could jeopardize certain business transactions and create additional liabilities for us.

The legislative and regulatory landscape for privacy and data protection in the U.S. continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect our business, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws governing the collection, use and disclosure of personal information. For example, in September 2018, Jerry Brown, the Governor of California at the time, signed into law an amended version of the California Consumer Privacy Act of 2018 (CCPA), which takes effect on January 1, 2020 and will give California residents expanded privacy rights and protections and will provide for civil penalties for violations and a private right of action for data breaches. There are similar legislative proposals being advanced in other states, as well as in Congress. In addition, most healthcare providers who are expected to prescribe our products, and from whom we obtain patient health information, 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 a HIPPA-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), which became enforceable on May 25, 2018, 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 United States. Switzerland is updating the Swiss Data Protection Act, and updates to data protection laws in other countries may occur in due course. In connection with these new laws, in particular the CCPA and GDPR, we have modified certain of our policies and procedures with respect to the collection and processing of personal data to the extent necessary given our operations and commensurate with similar companies in our industry. We will continue to review all future privacy and other regulations implemented pursuant to the CCPA, GDPR and other applicable laws to assess whether additional procedural safeguards are warranted, which may cause us to incur additional expenses or otherwise limit our ability to collect and process personal data. Failure to provide adequate privacy and data security protections and maintain compliance with these laws and regulations could jeopardize certain domestic and cross-border business transactions and create additional liabilities for us, including the imposition of sanctions or other penalties, as well as increase our cost of doing business.

If competitors use litigation and regulatory means to obtain approval for generic versions of our marketed products, our business will suffer.

Under the FDCA, the FDA can approve an Abbreviated New Drug Application (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 an 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-The Hatch-Waxman Act" in our Annual Report on Form 10-K for the year ended December 31, 2018 filed with the SEC on February 22, 2019. In either case, if an ANDA or 505(b)(2) applicant submits an application referencing one of our drugs prior to the expiry of one or more listed patents for the drug, we may end up engaging in litigation with the potential generic competitor

to protect our patent rights, which would require us to incur significant expense and result in distraction for our management team, and could also have an adverse impact on our stock price. Moreover, if any such ANDAs or 505(b)(2) NDAs were to be approved, and if our listed patents covering cabozantinib were held to be invalid (or if any such competing generic versions of cabozantinib were found not to infringe our patents), we would have generic competitors in the market, and the resulting generic competition would negatively affect our business, financial condition and results of operations. In particular, generic cabozantinib products would be significantly less costly than ours to bring to market. Thus, regardless of the regulatory approval pathway, the

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introduction of a generic version of any of our marketed products could result in significant decreases in the overall sales or prices of these marketed products and materially harm our business and financial condition.

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 potential 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 in a particular indication. Moreover, the results of preliminary studies do not necessarily predict clinical or commercial success, and later stage clinical trials may fail to confirm the results observed in earlier 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 testing, that could delay or prevent commercialization of cabozantinib in new indications, or of our other product candidates, including:

- lack of efficacy or a tolerable safety profile;
- negative or inconclusive clinical trial results that require us to conduct further testing or to abandon projects that we had expected to be promising;
- 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, many of which may already be engaged in other clinical trial programs;
- lower-than-anticipated patient registration or enrollment in our clinical testing, resulting in the delay or cancellation of clinical testing;
- failure by our collaborators 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 of cabozantinib or another product candidate, 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 we were to have significant delays in or termination of the clinical testing of cabozantinib or our other product candidates as a result of any of the events described above or otherwise, our expenses could increase and our ability to generate revenues could be impaired, either of which could adversely impact our financial results. Furthermore, we rely on our clinical and commercial collaboration partners to fund a significant portion of the clinical development of cabozantinib and our product candidates. Should one or all of our collaboration partners decline to support future planned clinical trials, we will be entirely responsible for the financial obligations associated with 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 rapidly or effectively continue 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, including those identified based on our discussions with the FDA or such other regulatory authorities. 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;

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- the duration of patient follow-up that is appropriate in view of the results or required by regulatory authorities;
- the number of clinical sites included in the trials; and
- the length of time required to enroll suitable patient subjects.

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. and by comparable authorities in other countries. The process 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 can vary substantially based upon the type, complexity and novelty of the product candidates involved. For example, before an NDA or supplemental New Drug Application (sNDA) can be submitted to the FDA, or a marketing authorization application to the European Medicines Agency 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. For example, the FDA could determine that the design of a clinical trial is inadequate to produce reliable results. The regulatory process also requires preclinical testing, and data obtained from preclinical and clinical activities are susceptible to varying interpretations. The FDA has substantial discretion in the approval process and may refuse to approve any NDA or sNDA and 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, delays or rejections may be encountered based upon changes in regulatory policy for product approval during the period of product development and regulatory agency review, which may 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 indications beyond advanced RCC, previously treated HCC and MTC, or approves one of our other product candidates, such approval may be limited, imposing significant restrictions on the indicated uses, conditions for use, labeling, distribution, advertising, promotion, marketing and/or production of the product and could impose ongoing requirements for post-approval studies, including additional research and development and clinical trials. For example, in connection with the FDA’s approval of COMETRIQ for the treatment of progressive, metastatic MTC in November 2012, we are subject to a post-marketing requirement to conduct a clinical study comparing a lower dose of cabozantinib to the approved dose of 140 mg daily cabozantinib in progressive, metastatic MTC. 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 eliminate the commercialization of cabozantinib. Further, these agencies may also impose various administrative, civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval.

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 are pursuing internal drug discovery efforts with the goal of identifying new product candidates to advance into clinical trials. Internal discovery efforts to identify new product candidates require substantial technical, financial and human resources. These internal discovery efforts may initially show promise in identifying potential product candidates, yet ultimately fail to yield product candidates for clinical development for a number of reasons. For example, potential 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.

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Apart from our internal 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 well-established and diverse revenue streams may have a competitive advantage over us due to their size, financial resources and more extensive clinical development and commercialization capabilities. 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 relevant product candidates on acceptable terms that would allow us to realize an appropriate return on our investment. If we are unable to develop suitable product candidates through internal discovery efforts or if we are unable to successfully obtain rights to suitable product candidates, our business and prospects for growth could suffer. 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 operating results.

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 evolving social media communication guidelines and comply with applicable laws and regulations, 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 cause us to be found in violation 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 materially 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

We may be unable to maintain or increase profitability.

Although we reported net income of $75.8 million and $690.1 million for the three months ended March 31, 2019 and the year ended December 31, 2018, respectively, we may not be able to maintain or increase profitability on a quarterly or annual basis, and we are unable to predict the extent of long-range 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 with Ipsen and Takeda; the amount of royalties from sales of CABOMETYX and COMETRIQ outside of the U.S. under our collaboration agreements with Ipsen and Takeda; other collaboration revenues; and the level of our expenses, including development and commercialization activities for cabozantinib and any pipeline expansion efforts. We expect to continue to spend significant additional amounts to fund the continued development of cabozantinib for additional indications and the commercialization of our approved products. In addition, we will continue to expand our product pipeline through our drug discovery efforts and the execution of strategic transactions that align with our oncology drug development expertise, which efforts could involve substantial costs. To offset these costs, we will need to generate substantial revenues. If these costs exceed our expectations, or we fail to achieve anticipated revenue

targets, the market value of our common stock may decline.

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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.

As of March 31, 2019, we had $1.0 billion in cash and investments as compared to $851.6 million as of December 31, 2018. Our business operations grew substantially during 2018 and experienced further expansion during the three months ended March 31, 2019. In order to maintain business growth, 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 level of our investments in the expansion of our pipeline through drug discovery and corporate development activities;
- our ability to control costs;
- 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 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 any disruptions resulting from government shutdowns, the uncertainty surrounding the date and the terms of the pending Brexit, 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 money 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. Accordingly, 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.

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Certain accounting policies are critical to the presentation of our financial condition and results of operations. The preparation of our financial statements requires us to make significant estimates, assumptions and judgments that affect the amounts of assets, liabilities, revenues and expenses and related disclosures. We believe our critical accounting policies relating to revenue recognition, clinical trial accruals, inventory and stock-based compensation reflect the more significant estimates and judgments used in the preparation of our Condensed 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, particularly those relating to the way we account for revenues and costs. New pronouncements from the Financial Accounting Standards Board (FASB) 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.

The recently passed comprehensive tax reform bill could have a material adverse impact on our business, financial condition and results of operations.

The Tax Cuts and Jobs Act could be amended or subject to technical correction, which could change the financial impacts that were recorded at December 31, 2018 and March 31, 2019, or are expected to be recorded in future periods. Additionally, further guidance may be forthcoming from the FASB and SEC, as well as regulations, interpretations and rulings from federal and state tax agencies, which could result in additional impacts, possibly with retroactive effect.

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 earnings and applicable tax rates in the various places that we operate, the accounting for stock options and share 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 such as the passage of the Tax Cuts and Jobs Act, 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, 2018, we had federal and state net operating loss carryforwards of approximately $1,067 million. The federal and state net operating loss carryforwards will begin to expire, if not utilized, beginning in 2031 for federal income tax purposes and 2028 for California state income tax purposes. 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 net operating losses and credit carryforwards before utilization. Based on our review and analysis, we concluded, as of December 31, 2018, 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.

The transition away from the London Interbank Offered Rate (LIBOR) could affect the value of certain short-term investments, as well as our ability to seek additional debt financing.

Actions by governmental entities may impact certain financial instruments in which we have invested or may invest in the future. For example, some of these financial instruments may rely in some fashion upon LIBOR, which is an average interest rate, determined by the ICE Benchmark Administration, that banks charge one another for the use of short-term money. The UK's Financial Conduct Authority, which regulates LIBOR, has announced plans to phase out

the use of LIBOR by the end of 2021. While only a small percentage of our short-term investments include financial instruments subject to

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LIBOR, and while we do not currently have any outstanding debt that is subject to LIBOR, there remains uncertainty regarding the future utilization of LIBOR and the nature of any replacement rate, and any potential effects of the transition away from LIBOR on certain instruments in to which we may enter in the future are not known. The transition process may involve, among other things, increased volatility or illiquidity in markets for instruments that currently rely on LIBOR. The transition may also result in reductions in the value of certain instruments or the effectiveness of related transactions such as hedges, increased borrowing costs, uncertainty under applicable documentation, or difficult and costly consent processes. Any such effects of the transition away from LIBOR, as well as other unforeseen effects, result in expenses, difficulties, complications or delays in connection with future financing efforts, which could have a material adverse impact on our business, financial condition and results of operations.

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

Brexit has created significant uncertainty concerning the terms of the UK withdrawal from the EU and the future relationship between the UK and the EU. On April 11, 2019, the European Council agreed at its Special Meeting to extend the UK's departure date to October 31, 2019. It is possible the UK could withdraw from the EU prior to October 31, 2019 pursuant to agreed terms for a transition period; however, both the EU and the UK are preparing for a "no deal" scenario in which the UK will leave the EU as a "third country" without the benefit of any transition arrangements.

The "no deal" scenario has been recognized by the policy makers in the UK and the EU as likely to cause significant market and economic disruption. The effects of Brexit will depend on whether the UK retains access to EU markets either during a transitional period or more permanently. Brexit could disrupt the single internal market principle, which ensures the free movement of goods, services and people between the UK and the EU, undermine bilateral cooperation in key policy areas and significantly disturb trade relationships between the UK and the EU. In addition, Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the UK determines which EU laws to replace, amend or adopt.

Given the lack of comparable precedent, it is unclear what financial, trade, regulatory and legal implications the withdrawal of the UK from the EU would have and how such withdrawal would 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 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 collaborator Ipsen to market our products in Europe. Furthermore, the announcement of Brexit caused significant volatility in global stock markets and currency exchange rate fluctuations, and the pending withdrawal of the UK from the EU may also 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 operations.

Risks Related to Our Relationships with Third Parties

We are dependent upon our collaborations with major companies, which subject us to a number of risks.

We have established collaborations with leading pharmaceutical and biotechnology companies, including, Ipsen, Takeda, Genentech, Daiichi Sankyo and BMS for the development and ultimate commercialization of certain compounds generated from our research and development efforts. Our dependence on our relationships with collaborators for the development and commercialization of compounds subjects us to, a number of risks, including:

- our inability to control the amount and timing of resources that our collaborators or potential future collaborators will devote to the development or commercialization of drug candidates or to their marketing and distribution;
- the possibility that collaborators may delay clinical trials, fail to supply us on a timely basis with the product required for a combination trial, deliver product that fails to meet appropriate quality and regulatory standards and results in a market recall or withdrawal, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a

drug candidate, repeat or conduct new clinical trials or require a new formulation of a drug candidate for clinical testing;

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- disputes that may arise between us and our collaborators that result in the delay or termination of the research, 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 that diverts management's attention and resources;
- our inability to control the U.S. commercial resourcing decisions made and resulting costs incurred by Genentech for COTELLIC, which costs we are obligated to share, in part, under our collaboration agreement with Genentech;
- the possibility that our collaborators may experience financial difficulties;
- our collaborators' lack of success in their efforts to obtain regulatory approvals in a timely manner, or at all;
- our collaborators' 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;
- our collaborators' failure to comply with the terms of our collaboration agreements and related ancillary agreements;
- our collaborators' failure to comply with applicable healthcare laws, as well as established guidelines, laws and regulations related to Good Manufacturing Practice, Good Clinical Practice, Good Distribution Practice and Good Pharmacovigilance Practice;
- business combinations or significant changes in a collaborator's business strategy may adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- the possibility that our collaborators could independently move forward with competing drug candidates, developed either independently or in collaboration with others, including our competitors;
- our inability to enter into additional collaboration arrangements with third parties in an area or field of exclusivity;
- the possibility that future collaborators may require us to relinquish some important rights, such as marketing and distribution rights; and
- the possibility that collaborations may be terminated or allowed to expire, which would delay, and may increase the cost of, development of our drug candidates.

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 could be delayed, all of which could have a material adverse impact on our business, financial condition and results of operations.

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, including our post-marketing commitments in connection with the approval of COMETRIQ in progressive, metastatic MTC, 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, 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 drug discovery efforts, which would impede our ability to identify, develop and commercialize our potential product candidates.

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We lack internal manufacturing capabilities necessary for us to 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 clinical or commercial production and distribution of our products. Instead, we have multiple contractual agreements in place with third-party contract manufacturing organizations that, on our behalf, manufacture clinical and commercial supplies of CABOMETYX and COMETRIQ. As our operations expand due to our clinical development and commercial progress, we are appropriately expanding our supply chain by entering into new agreements with additional third-party contract manufacturers and suppliers. This will continue for the foreseeable future for all of our product candidates, as well as our current and future commercial products.

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 ensure 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 development and commercial needs and applicable regulatory requirements. 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 supply and manufacturing arrangements, we may not have adequate remedies for any breach. Furthermore, their failure to supply us could impair or preclude our ability to meet our commercial supply requirements, or our supply needs for clinical trials, including those being conducted in collaboration with our partners, which could delay our product development efforts and have a material adverse impact on our business, financial condition and results of operations. Through our third-party contract manufacturers and data service providers, we have implemented product serialization designed to comply with the Drug Supply Chain Security Act (DSCSA), pursuant to which, subject to limited exemptions, all prescription pharmaceutical products manufactured and distributed in the U.S. were required to be serialized as of November 27, 2018. 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 collaborators' ability to successfully develop and commercialize CABOMETYX and COMETRIQ and generate revenues to which we are entitled under the collaborations.

Our collaborations with outside scientific advisors and collaborators may be subject to restriction and change.

We work with scientific and clinical advisors and collaborators at academic and other institutions that assist us in our research and development efforts, including in drug discovery and preclinical development strategy. These advisors and collaborators are not our employees and may have other commitments or pursue other opportunities that limit their availability to us. Although these advisors and collaborators 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 advisors and collaborators or otherwise limit our access to these experts, or that the advisors themselves may now be more reluctant to work with industry partners. In any of these circumstances, we may lose work performed by these advisors and collaborators or be unable to engage them in the first place, and 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. In addition, although our advisors and collaborators sign agreements not to disclose our confidential information, it is possible that valuable proprietary knowledge may become publicly known through them.

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Risks Related to Our Information Technology, Data Privacy 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 business partners. We have also outsourced significant elements of our information technology infrastructure and, as a result, 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 cyber-security efforts commensurate with the growth and complexity of our business, our systems and those of third-party service providers may be vulnerable to a cyber-attack. In addition, we are heavily dependent on the functioning of our information technology infrastructure to carry out our business processes, such as external and internal communications or access to clinical data and other key business information. Accordingly, both inadvertent disruptions to this infrastructure and cyber-attacks could cause us to incur significant remediation or litigation costs, result in product development delays, disrupt key business operations and divert attention of management and key information technology resources.

We believe that companies have been increasingly subject to a wide variety of security incidents, cyber-attacks 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 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 motive (including corporate espionage). Cyber threats may be generic, or they may be custom-crafted against our information systems. Cyber-attacks continue to become more prevalent and much harder to detect and defend against. Our network and storage applications and those of our contract manufacturing organizations, contract research organizations or vendors may be subject to unauthorized access by hackers or breached due to operator error, malfeasance or other system disruptions. 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 and 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, and 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 cyber-security systems 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

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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. In addition, should any third parties receive FDA approval of an ANDA for a generic version of cabozantinib or an 505(b)(2) NDA with respect to cabozantinib, and if our patents covering cabozantinib were held to be invalid (or if such competing generic versions of cabozantinib were found to not infringe our patents), then they could introduce generic versions of cabozantinib or other such 505(b)(2) products before our patents expire, and the resulting generic competition would negatively affect 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, collaborators and consultants, we cannot assure you 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, including the diversion of management and technical personnel, in defending ourselves against any such claims or enforcing our own patents. In the event that a successful

claim of 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.

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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 management's attention. 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 severely harm our business.

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, operational and financial resources, and our current and planned personnel, facilities, systems, procedures and controls may not be adequate to support our growth. To effectively manage our growth, we must continue to improve existing, and implement new, operational and financial systems, procedures and controls and must 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, or are unsuccessful in recruiting qualified management personnel, there could be a material adverse impact on our business, financial condition and results of operations, and our prospects may be adversely affected.

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 and scientific personnel will be critical to support activities related to advancing the development program for cabozantinib and our other compounds, successfully executing upon our commercialization plan for cabozantinib and our internal proprietary research and development efforts. Competition is intense for experienced clinical, commercial and scientific personnel, and we may be unable to retain or recruit such personnel with the expertise or experience necessary to allow us to successfully develop and commercialize our products. Further, all of our employees are employed "at will" and, therefore, may leave our employment at any time.

Additionally, in the second quarter of 2018, we moved our corporate headquarters from South San Francisco, California to Alameda, California. This relocation may make it more difficult to retain certain employees, and any resulting loss of talent and need to recruit and train new employees could be disruptive to our business.

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. We have limited earthquake insurance, which 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, 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. In addition, a disaster could cause significant delays in our programs and make it difficult for us to recover due to the unique nature of our research activities. Accordingly, an earthquake or other disaster could materially and adversely harm our ability to conduct business.

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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 and 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. Our operations produce hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. We may face liability for any injury or contamination that results from our use or the use by third parties of these materials, and such liability may exceed our insurance coverage and our total assets. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development and production efforts.

In addition, our collaborators may use hazardous materials in connection with our collaborative efforts. In the event of a lawsuit or investigation, we could be held responsible for any injury caused to persons or property by exposure to, or release of, any hazardous materials used by these parties. Further, we may be required to indemnify our collaborators against all damages and other liabilities arising out of our development activities or products produced in connection with these collaborations.

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 collaborators 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, health care 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 pharmaceutical, biopharmaceutical and biotechnology 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

We expect that our quarterly results of operations will fluctuate, and this fluctuation could cause our stock price to decline, causing investor losses.

Our quarterly operating results have fluctuated in the past and are likely to fluctuate in the future. A number of factors, many of which we cannot control, could subject our operating results to volatility, including:

- the commercial success of both CABOMETYX and COMETRIQ and the revenues we generate from those approved products;
- customer ordering patterns for CABOMETYX and COMETRIQ, which may vary significantly from period to period as a result of multiple factors, including pricing information required to be disclosed by us pursuant to drug pricing transparency laws;
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the overall level of demand for CABOMETYX and COMETRIQ, including the impact of any competitive products and the duration of therapy for patients receiving CABOMETYX or COMETRIQ;

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- the achievement of stated regulatory and commercial milestones and royalties paid under our collaboration agreements;
- the commercial success of and revenues generated by products marketed under our collaboration and license agreements, including COTELLIC and MINNEBRO;
- changes in the amount of deductions from gross sales, including changes to the discount percentage of rebates and chargebacks mandated by the government programs in which we participate, including increases in the government discount percentage resulting from price increases we have taken or may take in the future, or due to different levels of utilization by entities entitled to government rebates and chargebacks and changes in patient demographics;
- costs associated with maintaining our sales, marketing, market access, medical affairs and product distribution capabilities for CABOMETYX and COMETRIQ;
- the progress and scope of other development and commercialization activities for cabozantinib and our other compounds;
- future clinical trial results;
- our future investments in the expansion of our pipeline through drug discovery and business development activities;
- the inability to obtain adequate product supply for any approved drug product or inability to do so at acceptable prices;
- recognition of upfront licensing or other fees or revenues;
- payments of non-refundable upfront or licensing fees, or payment for cost-sharing expenses, to third parties;
- the introduction of new technologies or products by our competitors;
- the timing and willingness of collaborators to further develop or, if approved, commercialize our product candidates out-licensed to them;
- the termination or non-renewal of existing collaborations or third-party vendor relationships;
- regulatory actions with respect to our product candidates and any approved products or our competitors' products;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- the timing and amount of expenses incurred for clinical development and manufacturing of cabozantinib;
- adjustments to expenses accrued in prior periods based on management's estimates after the actual level of activity relating to such expenses becomes more certain;
- the impairment of acquired goodwill and other assets;
- significant fluctuations in interest rates or foreign currency exchange rates;
- general and industry-specific economic conditions that may affect our or our collaborators' research and development expenditures; and
- other factors described in this "Risk Factors" section.

In addition, in the fourth quarter of 2018, we determined, based on our facts and circumstances, that it was more likely than not that a substantial portion of our deferred tax assets would be realized and, as a result, substantially all of our valuation allowance against deferred tax assets was released. Therefore, beginning in 2019, we record income tax expense at an estimated tax rate that will likely approximate statutory tax rates, adjusted for discrete tax items, which has resulted in a significant reduction in our net income and net income per share.

Due to the possibility of such fluctuations in our revenues and expenses, we believe that quarter-to-quarter comparisons of our operating results are not a good indication of our future performance. As a result, in some future quarters, our operating results may not meet the expectations of securities analysts and investors, which could result in a decline in the price of 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:

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- adverse or inconclusive results or announcements related to our or our collaborators' clinical trials or delays in those clinical trials;
- the announcement of FDA approval or non-approval, or delays in the FDA review process with respect to cabozantinib, our collaborators' product candidates being developed in combination with cabozantinib, or our competitors' product candidates;
- the commercial success of both CABOMETYX and COMETRIQ and the revenues we generate from those approved products;
- the timing of achievement of our clinical, regulatory, partnering and other milestones, such as the commencement of clinical development, the completion of a clinical trial, the filing for regulatory approval or the establishment of collaborative arrangements for cabozantinib or any of our other programs or compounds;
- 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 seeking a path to U.S. approval of generic versions of our marketed products;
- quarterly variations in our or our competitors' results of operations;
- developments in our relationships with our collaborators, including the termination or modification of our agreements;
- the announcement of an in-licensed product candidate or strategic acquisition;
- conflicts or litigation with our collaborators;
- litigation, including intellectual property infringement and product liability lawsuits, involving us;
- changes in earnings estimates or recommendations by securities analysts and any failure to achieve the operating results projected by securities analysts;
- 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 extent to which coverage and reimbursement is available for both CABOMETYX and COMETRIQ from government and health administration authorities, private health insurers, managed care programs and other third-party payers;
- disposition of any of our technologies or compounds; and
- general market, economic and political conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

These factors, as well as general economic, political and market conditions, may materially adversely affect 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. For example, negative publicity regarding drug pricing and price increases by pharmaceutical companies has negatively impacted, and may continue to negatively impact, the markets for biotechnology and pharmaceutical stocks. Likewise, as a result of the uncertainty of the date and the terms of the pending Brexit and/or significant changes in U.S. social, political, regulatory and economic conditions or in laws and policies governing foreign trade and health care spending and delivery, including possible repeal and/or replacement of or adverse judicial rulings against all or portions of PPACA or increases or changes in tariffs and other trade restrictions stemming from Trump administration and foreign government policies, or future U.S. federal government shutdowns, the financial markets could experience significant volatility that could also 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.

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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 management's attention and resources, 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 classified Board of Directors;
- a prohibition on actions by our stockholders by written consent;
- the inability of our stockholders to call special meetings of stockholders;
- 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;
- limitations on the removal 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

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

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Exhibit Number	Exhibit Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit/ Appendix Reference	Filing Date	
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	
3.6	Amended and Restated Bylaws of Exelixis, Inc.	8-K	000-30235	3.1	2/21/2019	
4.1	Specimen Common Stock Certificate	S-1, as amended	333-96335	4.1	4/7/2000	
10.1*	Amendment No. 1 dated March 8, 2019 to the Clinical Trial Collaboration Agreement dated February 24, 2017, by and between Exelixis, Inc. and Bristol-Meyers Squibb Company					X
10.2	Non-Employee Director Equity Compensation Policy					X
10.3	Cash Compensation Information for Non-Employee Directors					X
10.4	Policy for Recoupment of Variable Compensation					X
10.5	Form of Stock Option Agreement under the Exelixis, Inc. 2017 Equity Incentive Plan					X
10.6	Form of Restricted Stock Unit Agreement under the Exelixis, Inc. 2017 Equity Incentive Plan					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					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					X

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* 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.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

EXELIXIS, INC.

May 1, 2019 By: /s/ CHRISTOPHER J. SENNER
Date Christopher J. Senner
Executive Vice President and Chief Financial Officer
(Duly Authorized Officer and Principal Financial and Accounting Officer)