EXELIXIS, INC.
Form 10-Q
November 01, 2018
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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 September 28, 2018
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 October 22, 2018, there were 298,983,135 shares of the registrant's common stock outstanding.

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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 data)
(unaudited)

	September 30, 2018	December 31, 2017*
ASSETS		
Current assets:		
Cash and cash equivalents	$ 353,623	$ 183,164
Short-term investments	281,000	204,607
Short-term restricted cash and investments	504	504
Trade and other receivables, net	104,634	81,192
Inventory, net	10,433	6,657
Unbilled collaboration revenue	24,489	—
Prepaid expenses and other current assets	12,279	8,750
Total current assets	786,962	484,874
Long-term investments	114,093	64,255
Long-term restricted cash and investments	1,100	4,646
Property and equipment, net	51,046	25,743
Goodwill	63,684	63,684
Operating lease right-of-use assets	5,989	—
Other long-term assets	1,492	12,092
Total assets	$ 1,024,366	$ 655,294
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 8,679	$ 9,575
Accrued compensation and benefits	27,283	21,073
Accrued clinical trial liabilities	18,958	19,849
Rebates and fees due to customers	11,689	7,565
Accrued collaboration liabilities	8,397	8,974
Current portion of deferred revenue	—	31,984
Other current liabilities	15,900	16,150
Total current liabilities	90,906	115,170
Long-term portion of deferred revenue	2,268	238,520
Long-term portion of lease liabilities	12,619	14,530
Other long-term liabilities	2,607	2,113
Total liabilities	108,400	370,333
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: 298,881,884 and 296,209,426 at September 30, 2018 and December 31, 2017, respectively	299	296
Additional paid-in capital	2,156,632	2,114,184
Accumulated other comprehensive loss	(513)	(347)
Accumulated deficit	(1,240,452)	(1,829,172)
Total stockholders' equity	915,966	284,961
Total liabilities and stockholders' equity	$ 1,024,366	$ 655,294

* The Condensed Consolidated Balance Sheet as of December 31, 2017 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 OPERATIONS
(in thousands, except per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
Net product revenues	$162,946	$96,416	$443,054	$253,297
Collaboration revenues	62,451	56,094	182,170	79,108
Total revenues	225,397	152,510	625,224	332,405
Operating expenses:				
Cost of goods sold	7,360	4,658	18,996	10,875
Research and development	44,741	28,543	124,986	79,967
Selling, general and administrative	48,120	38,129	153,989	113,084
Total operating expenses	100,221	71,330	297,971	203,926
Income from operations	125,176	81,180	327,253	128,479
Other income (expense), net:				
Interest income	3,507	1,133	8,099	3,497
Interest expense	(1)	—	(1)	(8,679)
Other, net	272	2,275	369	(3,638)
Total other income (expense), net	3,778	3,408	8,467	(8,820)
Income before income taxes	128,954	84,588	335,720	119,659
Provision for income taxes	2,324	3,206	5,739	3,921
Net income	$126,630	$81,382	$329,981	$115,738
Net income per share, basic	$0.42	$0.28	$1.11	$0.39
Net income per share, diluted	$0.41	$0.26	$1.05	$0.37
Shares used in computing net income per share, basic	298,416	294,269	297,700	292,776
Shares used in computing net income per share, diluted	312,346	312,940	313,200	311,555

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net income	$126,630	$81,382	$329,981	$115,738
Other comprehensive income (loss) [1]	218	67	(166)	364
Comprehensive income	$126,848	$81,449	$329,815	$116,102

(1) Other comprehensive income (loss) consisted solely of unrealized gains or losses, net, on available-for-sale securities arising during the periods presented. Reclassification adjustments to net income resulting from realized gains or losses on the sale of securities were nominal and there was no income tax expense related to other comprehensive income 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 CASH FLOWS
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2018	2017
Net income	$329,981	$115,738
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	2,876	842
Stock-based compensation	28,330	15,029
401(k) matching contributions made in common stock	3,232	1,373
Loss on extinguishment of debt	—	6,239
Amortization of debt discounts and debt issuance costs	—	182
Interest paid in kind	—	(11,825)
Gain on other equity investments	(209)	(2,980)
Other	(1,423)	157
Changes in assets and liabilities:		
Trade and other receivables, net	(15,645)	(49,241)
Inventory, net	(3,776)	(2,468)
Unbilled collaboration revenue	(32,673)	—
Prepaid expenses and other current assets	(3,529)	(2,530)
Operating lease right-of-use assets	2,732	—
Other long-term assets	(542)	689
Accounts payable	(1,248)	(577)
Accrued compensation and benefits	6,210	(420)
Accrued clinical trial liabilities	(891)	2,050
Rebates and fees due customers	4,124	1,723
Accrued collaboration liability	(577)	7,091
Deferred revenue	(1,548)	20,710
Long-term portion of lease liabilities	(974)	—
Other current and long-term liabilities	(3,321)	10,476
Net cash provided by operating activities	311,129	112,258
Cash flows from investing activities:		
Purchases of Property and equipment and other, net	(30,403)	(3,449)
Proceeds from sale of property and equipment	308	14
Purchases of investments	(368,304)	(248,046)
Proceeds from maturities of investments	231,204	266,335
Proceeds from sale of investments	11,935	37,294
Proceeds from other equity investments	209	2,980
Net cash (used in) provided by investing activities	(155,051)	55,128
Cash flows from financing activities:		
Principal repayments of debt	—	(185,788)
Proceeds from exercise of stock options	10,390	16,532
Proceeds from employee stock purchase plan	3,650	3,053
Taxes paid related to net share settlement of equity awards	(3,205)	(3,012)
Net cash provided by (used in) financing activities	10,835	(169,215)
Net increase (decrease) in cash, cash equivalents and restricted cash	166,913	(1,829)
Cash, cash equivalents and restricted cash at beginning of period	188,314	155,836

Cash, cash equivalents and restricted cash at end of period	$355,227	$154,007

Continued on next page

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

	Nine Months Ended September 30,	
	2018	2017
Supplemental cash flow disclosure - non-cash investing and financing activity:		
Property and equipment deemed to have been acquired under build-to-suit lease	$ —	$ 14,530
Right-of-use assets obtained in exchange for lease obligations (1)	$ 17,180	—
Unpaid liabilities incurred to acquire Property and equipment	$ 1,281	$ 245

(1) Amounts for the nine months ended September 30, 2018 include the transition adjustment for the adoption of Accounting Standards Update ("ASU") No. 2016-02, Leases (Topic 842) ("Topic 842").

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 a biotechnology company committed to the discovery, development and commercialization of new medicines to improve care and outcomes for people with cancer. Since our founding in 1994, three products discovered at Exelixis have progressed through clinical development, received regulatory approval, and entered the marketplace. Two are derived from cabozantinib, an inhibitor of multiple tyrosine kinases including MET, AXL, VEGF receptors, and RET: CABOMETYX® (cabozantinib) tablets approved for advanced renal cell carcinoma ("RCC"); and COMETRIQ® (cabozantinib) capsules approved for progressive, metastatic medullary thyroid cancer. The third product, COTELLIC® (cobimetinib) tablets, is an inhibitor of MEK, marketed under a collaboration agreement with Genentech, Inc. (a member of the Roche Group) ("Genentech"), and is approved as part of a combination regimen to treat advanced melanoma.

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 the results of operations and cash flows 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 2018 will end on December 28, 2018 and fiscal year 2017 ended on December 29, 2017. For convenience, references in this report as of and for the fiscal periods ended September 28, 2018, June 29, 2018, March 30, 2018 and September 29, 2017, and as of and for the fiscal years ended December 28, 2018 and December 29, 2017, are indicated as being as of and for the periods ended September 30, 2018, June 30, 2018, March 31, 2018 and September 30, 2017, and the years ended December 31, 2018 and December 31, 2017, respectively. Similarly, references in this report to the first day of the fiscal year ended December 28, 2018 are indicated as being as of January 1, 2018.

Operating results for the nine months ended September 30, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018 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, 2017, included in our Annual Report on Form 10-K filed with the SEC on February 26, 2018.

Segment Information

We operate in one business segment that focuses on discovery, development and commercialization of new medicines to improve care and outcomes for people with cancer. 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 and sales allowances as well as milestones included in collaboration arrangements; the amounts of revenues and expenses under our profit and loss sharing agreement; recoverability of inventory; operating lease assets and liabilities; the accrual for certain liabilities including accrued clinical trial liability; and valuations of equity awards used to determine stock-based compensation. 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.

Recently Adopted Accounting Pronouncements

Restricted Cash

In January 2018, we adopted Accounting Standards Update ASU No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash (a consensus of the FASB Emerging Issues Task Force), (“ASU 2016-18”). ASU 2016-18 requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents are included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 was adopted using the retrospective transition method in the accompanying Condensed Consolidated Financial Statements. As a result of the adoption of ASU 2016-18, we no longer include purchases of restricted cash and proceeds from maturities of restricted cash in our cash flows from investing activities. Accordingly, the adoption of ASU 2016-18 resulted in a $0.5 million increase in Net cash provided by investing activities for the nine months ended September 30, 2017.

See “Note 4. Cash and Investments - Cash, Cash Equivalents and Restricted Cash” for a reconciliation of cash and cash equivalents presented in our previously published Condensed Consolidated Statement of Cash Flows for the nine months ended September 30, 2017 and Cash, cash equivalents and restricted cash reported in the accompanying Condensed Consolidated Statement of Cash Flows for the same period.

Revenue

On January 1, 2018, we adopted ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606) (“Topic 606”) using the modified retrospective method applied to those contracts that were not completed as of January 1, 2018. Results for the three and nine months ended September 30, 2018 are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with our historic accounting under previous revenue recognition guidance, Accounting Standards Codification (“ASC”) Topic 605: Revenue Recognition (“Topic 605”).

Leases

On July 1, 2018 we early adopted Topic 842. We adopted Topic 842 using the modified retrospective approach with a cumulative-effect adjustment as of January 1, 2018 in accordance with ASU No. 2018-11, Leases (Topic 842) - Targeted Improvements. Results for the three and nine months ended September 30, 2018 are presented under Topic 842. We have not restated the results for the three and six months ended June 30, 2018 and three months ended March 31, 2018 as the adjustments required to present those periods under Topic 842 were not material. Other prior period amounts are not adjusted and continue to be reported in accordance with our historic accounting under previous lease guidance, ASC Topic 840: Leases (“Topic 840”). We elected the package of practical expedients permitted under the

transition guidance within

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the new standard, which among other things, allowed us to carry forward the historical lease classification of those leases in place as of January 1, 2018.

Impact of Adoption of Topic 606 and Topic 842

We recorded a net reduction of $258.5 million to opening accumulated deficit as of January 1, 2018, due to the cumulative impact of adopting Topic 606, with the impact primarily relating to a change in the recognition of upfront and non-substantive milestone payments received related to our collaboration arrangements with Ipsen Pharma SAS ("Ipsen") and Takeda Pharmaceutical Company Ltd. ("Takeda"). The adoption of Topic 606 did not have an impact on our recognition of revenue from product sales.

We also recorded a net reduction of $0.2 million to opening accumulated deficit as of January 1, 2018, due to the cumulative impact of adopting Topic 842, with the impact relating to a change in the classification of certain of our buildings in our Lease Agreement (the "Lease") with Ascentris 105, LLC ("Ascentris") from a build to suit lease to an operating lease. For a description of the Lease, see "Note 11. Leases."

The impact of the adoption of Topic 606 and Topic 842 on the accompanying Condensed Consolidated Balance Sheet as of January 1, 2018 was as follows (in thousands):

	December 31, 2017	Adjustments Due to the Adoption of Topic 606	Adjustments Due to the Adoption of Topic 842	January 1, 2018
Contract assets: unbilled collaboration revenue, gross:				
Current portion	$—	$9,588	$ —	$9,588
Long-term portion	$—	$12,247	$ —	$12,247
Trade and other receivables, net	$81,192	$—	$ 7,743	$88,935
Property and equipment, net	$25,743	$—	$ (14,530)	$11,213
Operating lease right-of-use assets	$—	$—	$ 8,579	$8,579
Contract liabilities: deferred revenue, gross:				
Current portion	$31,984	$(23,591)	$ —	$8,393
Long-term portion	$238,520	$(213,079)	$ —	$25,441
Operating lease liabilities:				
Other current liabilities[1]	$16,150	$—	$ 3,173	$19,323
Long-term portion of lease liabilities [2]	$14,530	$—	$ (1,206)	$13,324
Other long-term liabilities	$2,113	$—	$ (408)	$1,705
Accumulated deficit	$(1,829,172)	$258,505	$ 233	$(1,570,434)

(1) Includes deferred rent and current portion of operating lease liabilities.

(2) Long-term portion of operating lease liabilities and Financing obligation for build-to-suit lease.

The adjustments due to the adoption of Topic 606 primarily related to a reduction in deferred revenue driven by the allocation of the transaction price to our license performance obligations in the Ipsen and Takeda collaborations, which were determined to be functional intellectual property that was transferred at a point in time and as a result, revenue was recorded at a point in time. Previously under Topic 605, revenue related to the upfront payments and one non-substantive milestone payment earned in 2016 had been deferred over the estimated period of performance pursuant to the terms of the contract. Contract assets as of January 1, 2018 primarily related to estimated revenue for reimbursements for our continuing research and development services and the $10.0 million milestone from Ipsen's filing with the European Medicines Agency ("EMA") for cabozantinib, as a treatment for patients with previously-treated advanced hepatocellular carcinoma ("HCC"), that was deemed probable under Topic 606 prior to January 1, 2018. Deferred revenue as of January 1, 2018 is related to the up-front, nonrefundable, fees and milestones earned that were allocated to our research and development services performance obligation which had not been satisfied as of that date. Contract assets and liabilities are netted by collaboration agreement in our Condensed Consolidated Balance Sheets; however, for illustration purposes the above amounts are shown prior to netting.

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The adjustments due to the adoption of Topic 842 primarily related to the recognition of an operating lease right-of-use asset and operating lease liability for the Lease. In addition, the adoption of Topic 842 resulted in a change in classification of build-to-suit component of the Lease to an operating lease and as a result we derecognized the estimated fair value of the building shells that were included in Property and equipment, net as of December 31, 2017, as we had been deemed to own these buildings under Topic 840. For additional discussion of the build-to-suit property, see “Note 5 Property and Equipment” to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on February 26, 2018. For a description of the Lease, see “Note 11. Leases” in these Condensed Consolidated Financial Statements.

The impact of the adoption of Topic 606 and Topic 842 on the accompanying Condensed Consolidated Statements of Operations as of and for three and nine months ended September 30, 2018 were as follows (in thousands):

	Three Months Ended September 30, 2018			
	As Reported	Effect of Adoption of Topic 606 Higher / (Lower)	Effect of Adoption of Topic 842 Higher / (Lower)	Balances Without the Adoption of Topic 606 or 842
Collaboration revenues	$62,451	$ 32,558	$ —	$29,893
Total revenues	$225,397	$ 32,558	$ —	$192,839
Selling, general and administrative expenses	$48,120	$ —	$ 936	$47,184
Total operating expenses	$100,221	$ —	$ 936	$99,285
Interest expense	$(1)	$ —	$ (348)	$(349)
Total other income, net	$3,778	$ —	$ 348	$3,430
Income before income taxes	$128,954	$ 32,558	$ (588)	$96,984
Provision for income taxes	$2,324	$ 680	$ (2)	$1,646
Net income	$126,630	$ 31,878	$ (586)	$95,338
Net income per share, basic	$0.42	$ 0.11	$ —	$0.32
Net income per share, diluted	$0.41	$ 0.10	$ —	$0.31

	Nine Months Ended September 30, 2018			
	As Reported	Effect of Adoption of Topic 606 Higher / (Lower)	Effect of Adoption of Topic 842 Higher / (Lower)	Balances Without the Adoption of Topic 606 or 842
Collaboration revenues	$182,170	$ 9,809	$ —	$172,361
Total revenues	$625,224	$ 9,809	$ —	$615,415
Selling, general and administrative expenses	$153,989	$ —	$ 936	$153,053
Total operating expenses	$297,971	$ —	$ 936	$297,035
Interest expense	$(1)	$ —	$ (348)	$(349)
Total other income, net	$8,467	$ —	$ 348	$8,119
Income before income taxes	$335,720	$ 9,809	$ (588)	$326,499
Provision for income taxes	$5,739	$ 566	$ (2)	$5,175
Net income	$329,981	$ 9,243	$ (586)	$321,324
Net income per share, basic	$1.11	$ 0.03	$ —	$1.08
Net income per share, diluted	$1.05	$ 0.03	$ —	$1.03

Collaboration revenues for both the three and nine months ended September 30, 2018 included $36.9 million in revenue recognized in accordance with Topic 606 related to a $40.0 million milestone from Ipsen which we expect to earn in the fourth quarter of 2018 for the approval of CABOMETYX for previously-treated HCC that would not have

been recognized if we had not adopted Topic 606. If we had not adopted Topic 606, we would also have recognized a $10.0 million milestone in the first quarter of 2018 upon the validation of Ipsen's filing with the EMA for cabozantinib as a treatment for patients with previously-treated advanced HCC that was recognized under Topic 606 as part of our adoption transition adjustment on

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January 1, 2018. The adoption of Topic 606 also resulted in a reduction of previously deferred revenue that was recorded as part of our adoption transition adjustment as of January 1, 2018.

Revenue

Topic 606 supersedes all previous revenue recognition requirements in accordance with generally accepted accounting principles. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration to which the entity is entitled to in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of Topic 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer.

Net Product Revenues

We sell our products principally to specialty distributors and specialty pharmacy providers, or collectively, our Customers. These Customers subsequently resell our products to health care providers and patients. In addition to distribution agreements with Customers, we enter into arrangements with health care providers and payors that provide for government-mandated and/or privately-negotiated rebates, chargebacks and discounts with respect to the purchase of our products. Revenues from product sales are recognized when the Customer obtains control of our product, which occurs at a point in time, typically upon delivery to the Customer.

Product Sales Discounts and Allowances

Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established and that result from discounts, chargebacks, rebates, co-pay assistance, returns and other allowances that are offered within contracts between us and our Customers, health care providers, payors and other indirect customers relating to the sales of our products. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the Customer) or a current liability (if the amount is payable to a party other than a Customer). Where appropriate, these estimates take into consideration a range of possible outcomes that are probability-weighted for relevant factors such as our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted Customer buying and payment patterns. Overall, these reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. The amount of variable consideration that is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product revenues and earnings in the period such variances become known.

Chargebacks: Chargebacks are discounts that occur when contracted customers purchase directly from a specialty distributor. Contracted customers, which currently consist primarily of Public Health Service institutions, non-profit clinics, Federal government entities purchasing via the Federal Supply Schedule and Group Purchasing Organizations, and health maintenance organizations, generally purchase the product at a discounted price. The specialty distributor, in turn, charges back to us the difference between the price initially paid by the specialty distributor and the discounted price paid to the specialty distributor by the customer. The allowance for chargebacks is based on an estimate of sales to contracted customers.

Discounts for Prompt Payment: Our Customers in the U.S. receive a discount of 2% for prompt payment. We expect our Customers will earn 100% of their prompt payment discounts and, therefore, we deduct the full amount of these discounts from total product sales when revenues are recognized.

Rebates: Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program, other government programs and commercial contracts. Rebate amounts owed after the final dispensing of the product to a benefit plan participant are based upon contractual agreements or legal requirements with public sector benefit providers, such as Medicaid. The allowance for rebates is based on statutory or contractual discount rates and expected utilization. Our

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estimates for the expected utilization of rebates are based on customer and payer data received from the specialty pharmacies and distributors and historical utilization rates. Rebates are generally invoiced by the payer and paid in arrears, such that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's shipments to our customers, plus an accrual balance for known prior quarters' unpaid rebates. If actual future rebates vary from estimates, we may need to adjust our accruals, which would affect net product revenues in the period of adjustment.

Allowances for rebates also include amounts related to the Medicare Part D Coverage Gap Discount Program. In the U.S., the Medicare Part D prescription drug benefit mandates participating manufacturers to fund 50% of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients. Our estimates for expected Medicare Part D coverage gap amounts are based on customer and payer data received from specialty pharmacies and distributors and historical utilization rates. Funding of the coverage gap is invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's shipments to patients, plus an accrual balance for known prior quarters' unpaid claims. If actual future funding varies from estimates, we may need to adjust our accruals, which would affect net product revenues in the period of adjustment.

Co-payment Assistance: Patients who have commercial insurance and meet certain eligibility requirements may receive co-payment assistance. We accrue a liability for co-payment assistance based on actual program participation and estimates of program redemption using customer data provided by the specialty distributor that administers the copay program.

Other Customer Credits: We pay fees to our Customers for account management, data management and other administrative services. To the extent the services received are distinct from the sale of products to the Customer, these payments are classified in Selling, general and administrative expenses in our Condensed Consolidated Statements of Operations.

Collaboration Revenues

We enter into collaboration arrangements, under which we license certain rights to our intellectual property to third parties. The terms of these arrangements typically include payment to us for one or more of the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; product supply services; development cost reimbursements; profit sharing arrangements; and royalties on net sales of licensed products. Except for profit sharing arrangements and payments for product supply services, each of these payment types are within the scope of Topic 606. As part of the accounting for these arrangements, we must develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. These key assumptions may include forecasted revenues, clinical development timelines and costs, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

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

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

constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect Collaboration revenues and earnings in the period of adjustment.

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Product Supply Services: Arrangements that include a promise for future supply of drug product for either clinical development or commercial supply at the licensee's discretion are generally considered as options. We assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations.
Development Cost Reimbursements: Our Ipsen and Takeda arrangements include promises of future clinical development and drug safety services, as well as participation on certain joint committees. We have determined that these services collectively are distinct from the licenses provided to Ipsen and Takeda and as such, these promises are accounted for as a separate performance obligation recorded over time. We record revenue for these services as the performance obligations are satisfied, which we estimate using internal development costs incurred and projections through the term of the arrangements.
Profit Sharing Arrangements: Under the terms of our collaboration agreement with Genentech for cobimetinib, we are entitled to a share of U.S. profits and losses received in connection with commercialization of cobimetinib. We are also entitled to low double-digit royalties on ex-U.S. net sales. We account for such arrangements in accordance with ASC Topic 808: Collaborative Arrangements ("Topic 808"). We have determined that we are an agent under the agreement and therefore revenues are recorded net of costs incurred. We record U.S. profits and losses under the collaboration agreement in the period earned based on our estimate of those amounts. We expect to recognize an annual profit under the agreement for the year ending December 31, 2018 and accordingly, those profits are recognized as Collaboration revenues in the accompanying Condensed Consolidated Statements of Operations. Historically, we had not recognized a profit for any annual period from the commercialization of cobimetinib in the U.S. and accordingly, losses for periods prior to 2018 were recognized as Selling, general and administrative expenses in the accompanying Condensed Consolidated Statements of Operations.
Sales-based Milestone Payments and Royalties: For arrangements that include sales-based royalties, including milestone payments based on the volume of sales, the license is deemed to be the predominant item to which the royalties or sales-based milestones relate and we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Leases

We determine if an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use assets, other current liabilities, and operating lease liabilities in our Condensed Consolidated Balance Sheets. Right-of-use assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the present value of lease payments, we use our incremental borrowing rate based on the information available at the lease commencement date. The operating lease right-of-use assets also include any lease payments made and exclude lease incentives. Our lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise any such options. Lease expense is recognized on a straight-line basis over the expected lease term.
For lease agreements entered into after the adoption of Topic 842 that include lease and non-lease components, such components are generally accounted for separately. For our building leases, as a result of us having elected to adopt the package of practical expedients permitted under the Topic 842 transition guidance, we account for the lease and non-lease components, such as common area maintenance charges, as a single lease component.

Recent Accounting Pronouncements

In August 2018, the Financial Accounting Standards Board (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 align 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 an entity (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 Consolidated Financial Statements.

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NOTE 2. REVENUES

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Product revenues:				
Gross product revenues	$193,356	$111,148	$525,438	$289,365
Discounts and allowances	(30,410)	(14,732)	(82,384)	(36,068)
Net product revenues	162,946	96,416	443,054	253,297
Collaboration revenues:				
License revenues [1]	51,323	54,335	152,261	74,706
Research and development service revenues [2]	10,560	2,316	27,464	5,623
Other collaboration revenues [3]	568	(557)	2,445	(1,221)
Total collaboration revenues	62,451	56,094	182,170	79,108
Total revenues	$225,397	$152,510	$625,224	$332,405

(1) Upon the adoption of Topic 606, the allocation of proceeds from our collaboration partners, including upfront and milestone payments, between intellectual property licenses and research and development services as well as the resulting timing of recognition has changed. License revenues for the three and nine months ended September 30, 2018 included the immediate recognition of the portion of milestones that were allocated to the transfer of intellectual property licenses for those milestones for which it had become probable that a significant revenue reversal would not occur as well as royalty revenues from Ipsen and Genentech. License revenues for the three and nine months ended September 30, 2017 included the full recognition of substantive milestones achieved during the period, recognition of deferred revenues from upfront payments and a non-substantive milestone, which were being amortized over various periods, as well as royalty revenues from Ipsen and Genentech.

(2) Research and development service revenues for the three and nine months ended September 30, 2018 included the recognition of deferred revenue for the portion of the upfront and milestone payments that have been allocated to the research and development service performance obligations which are being amortized through early 2030, as well as development cost reimbursements earned on our collaboration agreements. As described above, we did not allocate any of our upfront payments or milestones to research and development services prior to the adoption of Topic 606; therefore, Research and development service revenues for the three and nine months ended September 30, 2017 included only development cost reimbursements earned on our collaboration agreements.

(3) Other collaboration revenues for the three and nine months ended September 30, 2018 included net losses on product supply services provided to Ipsen and Takeda and the profit on the U.S. commercialization of COTELLIC from Genentech. Other collaboration revenues for the three and nine months ended September 30, 2017 included only net losses on product supply services, since losses on the U.S. commercialization of COTELLIC for the period were instead included in Selling, general and administrative expenses.

During the three and nine months ended September 30, 2018, 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. License revenues and Research and development services revenues were recorded in accordance with Topic 606 during 2018 and Topic 605 in prior periods. 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 Topic 808 for all periods presented.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
CABOMETYX	$158,262	$90,362	$428,317	$233,582

COMETRIQ	4,684	6,054	14,737	19,715
Net product revenues	$162,946	$96,416	$443,054	$253,297

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

	Three Months Ended September 30,					
	2018			2017		
	Dollars	Percent of total		Dollars	Percent of total	
Ipsen	$57,186	25	%	$50,680	33	%
Caremark L.L.C.	30,707	14	%	20,272	13	%
Affiliates of McKesson Corporation	26,597	12	%	14,575	10	%
Diplomat Specialty Pharmacy	17,946	8	%	20,460	13	%
Accredo Health, Incorporated	20,677	9	%	13,445	9	%
Others, individually less than 10% of Total revenues for all periods presented	72,284	32	%	33,078	22	%
Total revenues	$225,397	100	%	$152,510	100	%

	Nine Months Ended September 30,					
	2018			2017		
	Dollars	Percent of total		Dollars	Percent of total	
Ipsen	$145,038	23	%	$60,704	18	%
Caremark L.L.C.	83,516	13	%	52,526	16	%
Affiliates of McKesson Corporation	71,249	11	%	38,699	12	%
Diplomat Specialty Pharmacy	56,568	9	%	62,909	19	%
Accredo Health, Incorporated	58,677	9	%	36,504	11	%
Others, individually less than 10% of Total revenues for all periods presented	210,176	35	%	81,063	24	%
Total revenues	$625,224	100	%	$332,405	100	%

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
U.S.	$166,270	$97,807	$453,342	$260,853
Europe	57,186	50,680	145,038	60,704
Rest of the world	1,941	4,023	26,844	10,848
Total revenues	$225,397	$152,510	$625,224	$332,405

Net product revenues are attributed to regions based on the ship-to location. Collaboration revenues are attributed to regions 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	Total
Balance at December 31, 2017	$ 1,928	$ 1,795	$5,770	$9,493
Provision related to sales made in:				
Current period	52,296	9,208	21,192	82,696
Prior periods	(520)	156	50	(314)
Payments and customer credits issued	(50,726)	(9,412)	(17,070)	(77,208)
Balance at September 30, 2018	$ 2,978	$ 1,747	$9,942	$14,667

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, 2017	$—	$ —	$31,984	$238,520
Adoption of Topic 606	9,588	12,247	(23,591)	(213,079)
Balance at January 1, 2018	9,588	12,247	8,393	25,441
Increases as a result of a change in transaction price and recognition of revenues as services are performed	37,744	4,037	—	—
Transfer to receivables from contract assets recognized at the beginning of the period	(9,109)	—	—	—
Increases as a result of the deferral of milestones achieved in period, excluding amounts recognized as revenue	—	—	873	3,712
Revenue recognized that was included in the contract liability balance at the beginning of the period	—	—	(6,114)	—
Other adjustments [1]	(13,734)	(16,284)	(3,152)	(26,885)
Balance at September 30, 2018	$24,489	$ —	$—	$2,268

(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 and nine months ended September 30, 2018, we recognized $48.2 million and $151.8 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 and Daiichi Sankyo Company, Limited (“Daiichi Sankyo”).

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NOTE 3. COLLABORATION AGREEMENTS

From time to time, we enter into collaborative arrangements for the development, manufacture and/or commercialization of products and/or product candidates. These collaborations generally provide for non-refundable up-front license fees, development and commercial performance milestone payments, payments for product supply services, development cost reimbursements, royalty payments and/or profit sharing. See “Note 2. Revenues” for information on collaboration revenues recognized during the three and nine months ended September 30, 2018 and 2017.

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. The parties’ efforts are governed through a joint steering committee and appropriate subcommittees established to guide and oversee the collaboration’s operation and strategic direction; provided, however, that we retain final decision-making authority with respect to cabozantinib’s ongoing development.

In consideration for the exclusive license and other rights contained in the collaboration agreement, including commercialization rights in Canada, Ipsen paid us aggregate upfront payments of $210.0 million. As of December 31, 2017 we had achieved various milestones totaling $125.0 million. During the nine months ended September 30, 2018 we achieved an additional $50.0 million milestone upon the EMA’s approval of cabozantinib as a first-line treatment of advanced RCC, a $25.0 million commercial milestone upon Ipsen’s achievement of $100.0 million of net sales cumulatively over four consecutive quarters, a $10.0 million milestone upon Ipsen’s filing with the EMA for cabozantinib as a treatment for patients with previously-treated advanced HCC and a $5.0 million milestone on the approval by Health Canada of cabozantinib for the treatment of adults with advanced RCC. The timing and amount of revenue recognized during the three and nine months ended September 30, 2018 for those milestones is described below.

We are also eligible to receive future development and regulatory milestone payments, totaling up to an additional $194.0 million, including a $40.0 million milestone upon the EMA’s approval of cabozantinib as a treatment for patients with previously-treated advanced HCC, and additional milestone payments for other future indications and/or jurisdictions. The collaboration agreement also provides that we will be eligible to receive contingent payments of up to $520.3 million associated with sales volume milestones. We will also receive royalties on net sales of cabozantinib by Ipsen outside of the U.S. and Japan. We were entitled to receive a tiered royalty of 2% to 12% on the initial $150.0 million of net sales, which was reached in the three months ended June 30, 2018. As of September 30, 2018, we are entitled to receive a tiered royalty of 22% to 26% of annual net sales, with separate tiers for Canada. These tiers reset each calendar year.

We are primarily responsible for funding cabozantinib-related development costs for those trials in existence at the time we entered into the collaboration agreement with Ipsen; global development costs for additional trials are shared between the parties, with Ipsen reimbursing us for 35% of such costs, provided Ipsen chooses to opt into such trials. In accordance with the collaboration agreement, Ipsen has opted into and is co-funding: CheckMate 9ER, the phase 3 pivotal trial evaluating the combination of cabozantinib with nivolumab versus sunitinib in patients with previously-untreated, advanced or metastatic RCC being conducted in collaboration with Bristol-Myers Squibb Company (“BMS”); CheckMate 040, the phase 1/2 study evaluating the combination of cabozantinib with nivolumab in patients with both previously-treated and previously-untreated advanced HCC being conducted in collaboration with BMS (though Ipsen will not be co-funding the triplet arm of the study evaluating cabozantinib with nivolumab and ipilimumab); and eight cohorts of the COSMIC-021 phase 1b trial evaluating cabozantinib in combination with atezolizumab in locally advanced or metastatic solid tumors being conducted in collaboration with the Roche Group.

We remain responsible for the manufacture and supply of cabozantinib for all development and commercialization activities under the collaboration agreement. In connection with the collaboration agreement, we entered into a supply agreement with Ipsen to supply finished, labeled drug product to Ipsen for distribution in the territories outside of the

U.S. and Japan for the term of the collaboration agreement. The product will be supplied at our cost, as defined in the agreement, which excludes the 3% royalty we are required to pay GlaxoSmithKline ("GSK") on Ipsen's net sales of any product incorporating cabozantinib.

Unless terminated earlier, the collaboration agreement has a term that continues, on a product-by-product and country-by-country basis, until the latter of (i) the expiration of patent claims related to cabozantinib, (ii) the expiration of

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regulatory exclusivity covering cabozantinib or (iii) ten years after the first commercial sale of cabozantinib, other than COMETRIQ. The supply agreement will continue in effect until expiration or termination of the collaboration agreement. The collaboration agreement may be terminated for cause by either party based on uncured material breach of either the collaboration agreement or the supply agreement by the other party, bankruptcy of the other party or for safety reasons. We may terminate the collaboration agreement if Ipsen challenges or opposes any patent covered by the collaboration agreement. Ipsen may terminate the collaboration agreement if the U.S. Food and Drug Administration or EMA orders or requires substantially all cabozantinib clinical trials to be terminated. Ipsen also has the right to terminate the collaboration agreement on a region-by-region basis after the first commercial sale of cabozantinib in advanced RCC in the given region. Upon termination by either party, all licenses granted by us to Ipsen will automatically terminate, and, except in the event of a termination by Ipsen for our material breach, the licenses granted by Ipsen to us shall survive such termination and shall automatically become worldwide, or, if Ipsen were to terminate only for a particular region, then for the terminated region. Following termination by us for Ipsen's material breach, or termination by Ipsen without cause or because we undergo a change of control by a party engaged in a competing program, Ipsen is prohibited from competing with us for a period of time.

We identified the following performance obligations under the collaboration agreement with Ipsen: (1) the transfer of an exclusive license for the commercialization and further development of cabozantinib, as described above; and (2) research and development services, which includes certain committed studies for the development of cabozantinib, pharmacovigilance services and participation on the joint steering and development committees (as defined in the collaboration agreement).

We evaluated the collaboration agreement with Ipsen under Topic 606 as of January 1, 2018. Based on the evaluation as of that date, the up-front, nonrefundable fees, the milestones earned and royalties earned as of December 31, 2017, the $10.0 million milestone we expected to achieve during the three months ended March 31, 2018 upon Ipsen's filing with the EMA for cabozantinib as a treatment for patients with previously-treated advanced HCC, and the estimated reimbursements for our research and development services performance obligation constituted the amount of the consideration to be included in the transaction price as of December 31, 2017. The transaction price was allocated to the performance obligations identified based on our best estimate of the relative standalone selling price: for our license, the estimate was determined using a discounted cash flow valuation utilizing forecasted revenues and costs, and a discount rate and for research and development services the estimate was determined using an adjusted market assessment approach that relies on internal and external costs and market factors. Other than the $10.0 million HCC filing milestone discussed above, variable consideration related to regulatory and development milestones not previously recognized was constrained due to the fact that it was not probable that a significant reversal of cumulative revenue would not occur, given the inherent uncertainty of success with these milestones. Any variable consideration related to sales-based milestones and royalties will be recognized when the related sales occur as these amounts have been determined to relate to the license transferred to Ipsen and therefore is recognized at the later of when the performance obligation is satisfied or the related sales occur. We re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

Revenues related to our license performance obligation are recorded immediately as our license represents functional intellectual property that was transferred at a point in time, upon execution of the collaboration agreement in February 2016. Revenues for our research and development services performance obligation are being recognized using the inputs method based on our internal development projected cost estimates through the current estimated patent expiration of cabozantinib in the European Union, which is early 2030. As of September 30, 2018, $53.4 million of the transaction price allocated to our research and development services performance obligation had not been satisfied.

Collaboration revenues for both the three and nine months ended September 30, 2018 included $36.9 million in revenue related to a $40.0 million milestone from Ipsen we expect to earn during the three months ending December 31, 2018 for the approval by the European Commission ("EC") of cabozantinib for previously-treated HCC. We determined recognition of the milestone during the three months ended September 30, 2018 was appropriate following Ipsen's receipt of the Committee for Medicinal Products for Human Use's ("CHMP") positive opinion of cabozantinib for previously-treated HCC. The positive CHMP opinion is being reviewed by the EC as part of their approval process. Our determination that we expected to earn the $40.0 million milestone resulted in a change in the overall transaction

price of the collaboration agreement, as it was probable that a significant reversal of cumulative revenue would not occur. The $36.9 million in revenue in the three months ended September 30, 2018 represents the portion of the milestone that was allocated to the previously satisfied performance obligations for the transfer of an intellectual property license and research and development services. The remainder of the milestone was allocated to research and development services which will be recognized in future periods as those services are delivered through early 2030.

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Collaboration revenues for both the three and nine months ended September 30, 2018 also included $5.0 million in revenue for a milestone from Ipsen on the approval by Health Canada of cabozantinib for the treatment of adults with advanced RCC. We have determined the milestone relates entirely to the previously satisfied performance obligations for the transfer of an intellectual property license and therefore recognized the entire milestone in the three months ended September 30, 2018 when the milestone was achieved.

Collaboration revenues for the nine months ended September 30, 2018 included $46.2 million in revenue for a $50.0 million milestone from Ipsen for the approval of cabozantinib for the first-line treatment of advanced RCC by the EC, of which $45.8 million was recognized during the three months ended March 31, 2018. We determined recognition of the milestone during the three months ended March 31, 2018 was appropriate following the CHMP positive opinion of cabozantinib for the first-line treatment of advanced RCC. The $45.8 million in revenue during the three months ended March 31, 2018 represents the portion of the milestone that was allocated to the previously satisfied performance obligations for the transfer of an intellectual property license and research and development services. The remainder of the milestone was allocated to research and development services to be recognized in future periods as those services are delivered through early 2030, which included an additional $0.2 million in revenue recognized during the three months ended September 30, 2018.

Collaboration revenues for the nine months ended September 30, 2018 also included $25.0 million in revenue for a commercial milestone from Ipsen that we earned during the three months ended June 30, 2018 upon Ipsen's achievement of $100.0 million of net sales cumulatively over four consecutive quarters. We have determined that sales-based milestones relate entirely to the previously satisfied performance obligations for the transfer of an intellectual property license and therefore recognized the entire milestone in the quarter the milestone was achieved.

As of September 30, 2018, the net contract asset for the collaboration agreement with Ipsen was $24.5 million, which was included in Unbilled collaboration revenue in the accompanying Condensed Consolidated Balance Sheets.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Ipsen collaboration revenues	$57,186	$50,679	$145,038	$60,703

Takeda Collaboration

In January 2017, we entered into a collaboration and license agreement with Takeda for the commercialization and further clinical development of cabozantinib in Japan. Pursuant to the terms of the collaboration agreement, Takeda has exclusive commercialization rights for current and potential future cabozantinib indications in Japan. The parties have also agreed to collaborate on the future clinical development of cabozantinib in Japan. The operation and strategic direction of the parties' collaboration is governed through a joint executive committee and appropriate subcommittees.

In consideration for the exclusive license and other rights contained in the collaboration agreement, we received a $50.0 million upfront nonrefundable payment from Takeda.

In May 2018, we amended the collaboration agreement to modify the milestones we are eligible to receive under the agreement. As of September 30, 2018, we were eligible to receive development, regulatory and first-sale milestone payments of up to $100.0 million related to second-line RCC, first-line RCC and second-line HCC, as well as additional development, regulatory and first-sale milestone payments for potential future indications. The collaboration agreement also provides that we are eligible to receive pre-specified payments of up to $83.0 million associated with sales volume milestones. We consider the contingent payments due to us upon the achievement of specified sales volumes to be similar to royalty payments. We will also receive royalties on net sales of cabozantinib in Japan. We are entitled to receive a tiered royalty of 15% to 24% on the initial $300.0 million of net sales, and after the initial $300.0 million of net sales, we are then entitled to receive a tiered royalty of 20% to 30% on annual net sales. These tiers will reset each calendar year.

Takeda is responsible for 20% of the costs associated with the global cabozantinib development plan's current and future trials, provided Takeda opts into such trials, and 100% of costs associated with the cabozantinib development

activities that are exclusively for the benefit of Japan. In accordance with the collaboration agreement, Takeda has opted into and is co-funding CheckMate 9ER.

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Pursuant to the terms of the collaboration agreement, we are responsible for the manufacture and supply of cabozantinib for all development and commercialization activities under the collaboration, and consequently, we entered into a clinical supply agreement covering the supply of cabozantinib to Takeda, as well as a quality agreement setting forth, in detail, the respective responsibilities pertaining to the quality requirements of the aforementioned supply to Takeda. We will record reimbursements for development costs as revenue as the development services represent a part of our ongoing major or central operations.

Unless earlier terminated, the collaboration agreement has a term that continues, on a product-by-product basis, until the earlier of (i) two years after first generic entry with respect to such product in Japan or (ii) the later of (A) the expiration of patent claims related to cabozantinib and (B) the expiration of regulatory exclusivity covering cabozantinib in Japan. The collaboration agreement may be terminated for cause by either party based on uncured material breach by the other party, bankruptcy of the other party or for safety reasons. For clarity, Takeda's failure to achieve specified levels of commercial performance, based upon sales volume and/or promotional effort, during the first six years of the collaboration shall constitute a material breach of the collaboration agreement. We may terminate the agreement if Takeda challenges or opposes any patent covered by the collaboration agreement. At any time prior to August 1, 2023, the parties may mutually agree to terminate the collaboration agreement if Japan's Pharmaceuticals and Medical Devices Agency is unlikely to grant any approval of the marketing authorization application in any cancer indication in Japan. After the commercial launch of cabozantinib in Japan, Takeda may terminate the collaboration agreement upon twelve months' prior written notice following the third anniversary of the first commercial sale of cabozantinib in Japan. Upon termination by either party, all licenses granted by us to Takeda will automatically terminate, and the licenses granted by Takeda to us shall survive such termination and shall automatically become worldwide.

We identified the following performance obligations under the collaboration agreement with Takeda: (1) the transfer of an exclusive license for the commercialization and further development of cabozantinib, as described above; and (2) research and development services, which includes certain committed studies for the development of cabozantinib, pharmacovigilance services and participation on the joint executive and development committees (as defined in the collaboration agreement).

We evaluated the collaboration agreement with Takeda under Topic 606 as of January 1, 2018. Based on the evaluation as of that date, the up-front, nonrefundable fee and the estimated reimbursements for our research and development services performance obligation constituted the amount of the consideration to be included in the transaction price as of December 31, 2017. The transaction price was allocated to the performance obligations identified based on our best estimate of the relative standalone selling price: for our license, the estimate was determined using a discounted cash flow valuation utilizing forecasted revenues and costs, and a discount rate and for research and development services the estimate was determined using an adjusted market assessment approach that relies on internal and external costs and market factors. Variable consideration related to regulatory and development milestones not previously recognized was constrained due to the fact that it was not probable that a significant reversal of cumulative revenue would not occur, given the inherent uncertainty of success with these milestones. Any variable consideration related to sales-based milestones and royalties will be recognized when the related sales occur as these amounts have been determined to relate predominantly to the license transferred to Takeda and therefore is recognized at the later of when the performance obligation is satisfied or the related sales occur. We re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

Revenues related to our license performance obligation are recorded immediately as our license represents functional intellectual property that was transferred at a point in time, upon execution of the collaboration agreement in January 2017. Revenues for our research and development services performance obligation are being recognized using the inputs method based on our internal development projected cost estimates through the current estimated patent expiration of cabozantinib in Japan, which is early 2030. As of September 30, 2018, $28.5 million of the transaction price allocated to our research and development services performance obligation had not been satisfied.

As of September 30, 2018, the net contract liability for the collaboration agreement with Takeda was $2.3 million, which was included in Long-term portion of deferred revenue in the accompanying Condensed Consolidated Balance Sheets.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Takeda collaboration revenues	$1,940	$4,023	$6,843	$10,848

Genentech Collaboration

Royalty revenues on ex-U.S. sales and our share of the profits and losses recognized in connection with COTELLIC's commercialization in the U.S. were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Royalty revenues on ex-U.S. sales	$1,390	$1,392	$4,285	$5,057
Profits and losses on U.S. commercialization	$1,935	$(891)	$6,004	$(2,298)

The royalty revenues on ex-U.S. sales were included in Collaboration revenues. Prior to 2017, royalty revenues from the collaboration agreement with Genentech were based on amounts reported to us by our collaboration partner and were recorded when such information becomes available to us; beginning in the first quarter of 2017 such information became available in the current quarter and for 2016 such information was not available until the following quarter, meaning that through December 31, 2016 we recorded royalty revenues on a one quarter lag. As a result of this change, royalty revenues for the nine months ended September 30, 2017 included $1.1 million in royalty revenues for sales in the fourth quarter of 2016 in addition to the royalty revenues for sales for the nine months ended September 30, 2017.

Losses on the U.S. commercialization of COTELLIC for the three and nine months ended September 30, 2017 were included in Selling, general and administrative expenses in the accompanying Condensed Consolidated Statements of Operations. We expect an overall profit on the U.S. commercialization of COTELLIC for the year ending December 31, 2018 and therefore we have included the profit for the three and nine months ended September 30, 2018 in Collaboration revenues.

GSK Collaboration

Royalties accruing to GSK in connection with the sales of COMETRIQ and CABOMETYX are included in Cost of goods sold for net sales by us and as a reduction of Collaboration revenues for net sales by Ipsen in the accompanying Condensed Consolidated Statements of Operations. Such royalties were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Royalties accruing to GSK	$6,268	$3,446	$17,021	$8,809

StemSynergy Collaboration

In January 2018, we entered into an exclusive collaboration and license agreement with StemSynergy Therapeutics, Inc. ("StemSynergy") for the discovery and development of novel oncology compounds targeting Casein Kinase 1 alpha ("CK1 ") a component of the Wnt signaling pathway implicated in key oncogenic processes. Under the terms of the agreement, we will partner with StemSynergy to conduct preclinical and clinical studies with compounds targeting CK1 . We paid StemSynergy an upfront payment of $3.0 million in initial research and development funding. As of September 30, 2018, we have accrued $0.6 million to fund additional research and development under the agreement and StemSynergy is eligible for an additional $2.9 million of such funding. The funding costs incurred to date, including the $3.0 million initial payment, was included in Research and development expenses in the accompanying Condensed Consolidated Statements of Operations. StemSynergy will also be eligible for up to $56.5 million in milestones for the first product to emerge from the collaboration, including preclinical and clinical development and regulatory milestone payments, commercial milestones, as well as single-digit royalties on worldwide sales. We will

be solely responsible for the commercialization of products that arise from the collaboration.

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Invenra Collaboration

In May 2018, we entered into a collaboration and license agreement with Invenra, Inc. ("Invenra"), which is focused on developing next-generation biologics, to discover and develop multispecific antibodies for the treatment of cancer. Invenra is responsible for antibody lead discovery and generation while we will lead Investigational New Drug enabling studies, manufacturing, clinical development in single-agent and combination therapy regimens, and future regulatory and commercialization activities. The collaboration agreement also provides that we will receive an exclusive, worldwide license to one preclinical asset (the "lead preclinical asset"), and that we and Invenra will pursue up to six additional discovery projects during the term of the collaboration, which in total are directed to three discovery programs.

In consideration for the exclusive worldwide license and other rights contained in the collaboration agreement, we paid Invenra an upfront payment of $2.0 million and second project initiation fee of $2.0 million. The $4.0 million of total payments we made during the nine months ended September 30, 2018 are included in Research and development expenses in the accompanying Condensed Consolidated Statements of Operations. Invenra is eligible to receive payments of up to $131.5 million based on the achievement of specific development and regulatory milestones for a product containing the lead preclinical asset in the first indication. Upon successful commercialization of a product, Invenra is eligible to receive global milestone payments up to $325.0 million if certain sales thresholds are achieved as well as single digit tiered royalties on net sales of the approved product. We also have the right to initiate five additional discovery projects for development subject to an upfront payment of $2.0 million for each project as well as additional global milestone payments and royalties for any products that arise from these discovery efforts.

Unless earlier terminated, the collaboration agreement has a term that continues, on a product-by-product and country-by-country basis, until the later of (i) ten years after the first commercial sale of such product in such country or (ii) expiration of patent claims covering the product in such country. We may terminate the collaboration agreement in its entirety or on a project-by-project basis at any time prior to commercialization, for any or no reason, upon thirty days' written notice to Invenra. The collaboration agreement also may be terminated by either party for a material breach by the other, subject to notice and cure provisions.

Other Collaborations

For a description of our other existing collaboration agreements, see "Note 2. Collaboration Agreements" to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on February 26, 2018.

We have determined that each of our other existing collaboration agreements have one performance obligation, the delivery of an intellectual property license to each collaboration partner, which was satisfied for all such agreements prior to the adoption of Topic 606. As a result, any consideration earned and received from these collaborations will be recognized immediately as the licenses we provided represent functional intellectual property that was transferred at a point in time prior to the adoption of Topic 606, when the agreements were executed. Potential variable consideration for these collaborations related to regulatory and development milestones was constrained due to the fact that it was not probable that a significant reversal of cumulative revenue would not occur, given the inherent uncertainty of success with these milestones. Any variable consideration related to sales-based milestones, including royalties, will be recognized when the related sales occur as these amounts have been determined to relate predominantly to the licenses transferred and therefore are recognized at the later of when the performance obligation is satisfied or the related sales occur.

In February 2018, upon Daiichi Sankyo's submission of a regulatory application to the Japanese Pharmaceutical and Medical Devices Agency for esaxerenone as a treatment for patients with essential hypertension, we earned a $20.0 million milestone, which is included in Collaboration revenues during the nine months ended September 30, 2018.

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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):

	September 30, 2018	December 31, 2017	September 30, 2017	December 31, 2016
Cash and cash equivalents	$ 353,623	$ 183,164	$ 149,357	$ 151,686
Restricted cash included in short-term restricted cash and investments	504	504	—	—
Restricted cash included in long-term restricted cash and investments	1,100	4,646	4,650	4,150
Cash, cash equivalents, and restricted cash as reported within the accompanying Condensed Consolidated Statements of Cash Flows	$ 355,227	$ 188,314	$ 154,007	$ 155,836

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

Investments Available-for-sale

Investments by security type were as follows; the amounts presented exclude cash, but include investments classified as cash equivalents (in thousands):

	September 30, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$ 62,325	$ —	$ —	$ 62,325
Certificates of deposit	19,098	—	—	19,098
Commercial paper	355,720	—	—	355,720
Corporate bonds	262,050	93	(549)	261,594
U.S. Treasury and government sponsored enterprises	50,621	1	(58)	50,564
Total	$ 749,814	$ 94	$ (607)	$ 749,301

	December 31, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$ 45,478	$ —	$ —	$ 45,478
Commercial paper	199,647	—	—	199,647
Corporate bonds	179,336	18	(332)	179,022
U.S. Treasury and government sponsored enterprises	16,295	—	(32)	16,263
Total	$ 440,756	$ 18	$ (364)	$ 440,410

Gains and losses on the sales of investments available-for-sale were nominal during the three and nine months ended September 30, 2018 and 2017.

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

	September 30, 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	$175,380	$ (507)	$11,211	$ (42)	$186,591	$ (549)
U.S. Treasury and government sponsored enterprises	42,669	(58)	—	—	42,669	(58)
Total	$218,049	$ (565)	$11,211	$ (42)	$229,260	$ (607)

	December 31, 2017					
	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	$140,746	$ (296)	$20,047	$ (36)	$160,793	$ (332)
U.S. Treasury and government sponsored enterprises	13,611	(23)	2,651	(9)	16,262	(32)
Total	$154,357	$ (319)	$22,698	$ (45)	$177,055	$ (364)

There were 151 and 134 investments in an unrealized loss position as of September 30, 2018 and December 31, 2017, respectively. During the three and nine months ended September 30, 2018 and 2017 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 cash equivalents and investments by contractual maturity were as follows (in thousands):

	September 30, 2018	December 31, 2017
Maturing in one year or less	$ 635,208	$ 377,155
Maturing after one year through five years	114,093	63,255
Total	$ 749,301	$ 440,410

Related Party Transactions

During the three months ended September 30, 2018, BlackRock, Inc. (“BlackRock”), a global provider of investment, advisory and risk management solutions, reported that their beneficial ownership increased to more than 10% of our outstanding common stock. BlackRock manages a portion of our cash and investments portfolio. As of September 30, 2018 and December 31, 2017, respectively, the fair value of cash and investments managed by BlackRock was $263.5 million and $141.0 million, which included $21.3 million and $1.1 million invested in the BlackRock Liquidity Money Market Fund. We paid BlackRock $0.1 million in fees for advisory services during the nine months periods ended September 30, 2018.

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NOTE 5. INVENTORY

Inventory consisted of the following (in thousands):

	September 30, 2018	December 31, 2017
Raw materials	$ 2,344	$ 498
Work in process	5,203	3,997
Finished goods	4,082	2,854
Total	$ 11,629	$ 7,349
Balance Sheet classification:		
Inventory	$ 10,433	$ 6,657
Other long-term assets	1,196	692
Total	$ 11,629	$ 7,349

Write-downs related to excess and expiring inventory are charged to either Cost of goods sold or the cost of supplied product included in Collaboration revenues. Such write-downs were $0.8 million and $1.2 million for the nine months ended September 30, 2018 and September 30, 2017, respectively.

Inventory expected to be used in production or sold in periods more than 12 months from the date presented is classified as Other long-term assets in the accompanying Condensed Consolidated Balance Sheets. As of both September 30, 2018 and December 31, 2017, the non-current portion of inventory consisted of a portion of our finished goods.

NOTE 6. PROPERTY AND EQUIPMENT

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

	September 30, 2018	December 31, 2017
Leasehold improvements	$ 42,581	$4,715
Computer equipment and software	15,533	14,146
Furniture and fixtures	3,780	1,609
Laboratory equipment	2,936	5,959
Construction in progress	2,071	22,114
	66,901	48,543
Less: accumulated depreciation and amortization	(15,855)	(22,800)
Property and equipment, net	$ 51,046	$25,743

Depreciation expense was $1.7 million and $2.9 million for the three and nine months ended September 30, 2018, respectively, as compared to $0.3 million and $0.8 million for the comparable periods in 2017.

In May 2017, we entered into the Lease for office and research facilities located at 1851, 1801, and 1751 Harbor Bay Parkway, Alameda, California (the “Premises”). The Lease was amended in October 2017 and June 2018 to increase the space leased to an aggregate of 134,765 square feet. For a description of the Lease, see “Note 11. Leases.” In June 2018, we relocated our offices and research facilities to the Premises. Accordingly, we placed into service $46.3 million in related Leasehold improvements, Furniture and fixtures and Computer equipment and software, portions of which were included in Construction in progress at prior period ends. We are continuing to review the allocation of these additions between Leasehold improvements and Furniture and fixtures.

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NOTE 7. STOCK-BASED COMPENSATION

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development	$3,169	$1,663	$9,102	$4,741
Selling, general and administrative	6,573	3,626	19,228	10,288
Total stock-based compensation	$9,742	$5,289	$28,330	$15,029

We have several equity incentive plans under which we have granted stock options and restricted stock units ("RSUs") to employees and directors. At September 30, 2018, 14,408,816 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Stock options	$8.67	$11.75	$9.13	$10.32
ESPP	$6.19	$6.85	$6.96	$5.29

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Stock options:				
Risk-free interest rate	2.91 %	1.70 %	2.83 %	1.68 %
Dividend yield	— %	— %	— %	— %
Volatility	55 %	58 %	55 %	61 %
Expected life	4.4 years	4.0 years	4.4 years	4.1 years
ESPP:				
Risk-free interest rate	2.11 %	1.14 %	1.74 %	0.88 %
Dividend yield	— %	— %	— %	— %
Volatility	51 %	55 %	52 %	61 %
Expected life	6 months	6 months	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 fair value of RSUs was based on the closing price of the underlying common stock on the date of grant.

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Activity for stock options during the nine months ended September 30, 2018 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, 2017	22,208,446	$ 6.83		
Granted	3,022,113	$ 19.52		
Exercised	(2,083,457)	$ 5.01		
Forfeited	(216,522)	$ 14.40		
Expired	(5,548)	$ 18.62		
Options outstanding at September 30, 2018	22,925,032	$ 8.59	3.9 years	$ 226,821
Exercisable at September 30, 2018	15,896,370	$ 5.03	3.1 years	$ 203,118

In September 2018, in connection with our long-term incentive compensation program, we granted 308,365 stock options to our President and Chief Executive Officer that have a market vesting condition ("PSOs"). In addition to the standard service conditions included in our other stock options, these PSOs may not be exercised unless, at any time after the grant date, the fair market value of a share of our Common Stock is at least 125% of the per share exercise price of the PSOs over a period of at least 30 consecutive calendar days.

As of September 30, 2018, there was $52.8 million of unrecognized compensation expense related to our unvested stock options that will be recognized over a weighted-average period of 2.6 years.

Activity for RSUs during the nine months ended September 30, 2018 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, 2017	3,762,990	$ 17.76		
Awarded	2,411,245	$ 18.50		
Vested and released	(374,992)	$ 8.18		
Forfeited	(249,362)	$ 18.64		
RSUs outstanding at September 30, 2018	5,549,881	$ 18.69	2.1 years	$ 98,344

In September 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. We have not recognized any compensation expense related to these PSUs. As of September 30, 2018, the total unrecognized compensation expense related to the unvested PSUs was $12.7 million.

As of September 30, 2018, there was $87.6 million of unrecognized compensation expense related to our unvested RSUs, including the PSUs described above. The RSUs will be recognized over a weighted-average period of 3.2 years.

NOTE 8. INCOME TAXES

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

	Three Months Ended September 30,	Nine Months Ended September 30,

	2018	2017	2018	2017
Provision for income taxes	$2,324	$3,206	$5,739	$3,921

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Provision for income taxes for the three and nine months ended September 30, 2018 and 2017 primarily relates to state taxes for which we do not have net operating loss carry-forwards due to a limited operating history. Our historical losses are sufficient to fully offset our federal taxable income.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 was signed into law. The Tax Cuts and Jobs Act contained significant changes to corporate taxation, including among other items, a reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%. Further guidance may be forthcoming from the FASB and the SEC, as well as regulations, interpretations and rulings from federal and state tax agencies, which could result in additional impacts. The Provision for income taxes for the three and nine months ended September 30, 2018 did not reflect any adjustment to the impact of the Tax Cuts and Jobs Act enactment that we recorded during the year ended December 31, 2017.

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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Numerator:				
Net income	$126,630	$81,382	$329,981	$115,738
Net income allocated to participating securities	—	(221)	—	(368)
Net income allocable to common stock for basic net income per share	126,630	81,161	329,981	115,370
Adjustment to net income allocated to participating securities	—	14	—	23
Net income allocable to common stock for diluted net income per share	$126,630	$81,175	$329,981	$115,393
Denominator:				
Weighted-average shares of common stock outstanding used in computing basic net income per share	298,416	294,269	297,700	292,776
Dilutive securities:				
Outstanding stock options, unvested RSUs and ESPP contributions	13,930	18,671	15,500	18,779
Weighted-average shares of common stock outstanding and dilutive securities used in computing diluted net income per share	312,346	312,940	313,200	311,555
Net income per share, basic	$0.42	$0.28	$1.11	$0.39
Net income per share, diluted	$0.41	$0.26	$1.05	$0.37

The two-year warrants to purchase an aggregate of 1,000,000 shares of our common stock issued in January 2014 (“2014 Warrants”) were participating securities. The warrant holders did not have a contractual obligation to share in our losses. The 2014 Warrants were fully exercised in September 2017. For a description of the 2014 Warrants, see “Note 7. Common Stock and Warrants” to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on February 26, 2018.

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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Outstanding stock options, unvested RSUs and ESPP contributions	5,687	583	2,938	1,108
Total	5,687	583	2,938	1,108

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NOTE 10. FAIR VALUE MEASUREMENTS

The classification of our financial assets within the fair value hierarchy that were measured and recorded at fair value on a recurring basis was as follows; the amounts presented exclude cash, but include investments classified as cash equivalents (in thousands):

	September 30, 2018		
	Level 1	Level 2	Total
Money market funds	$62,325	$—	$62,325
Certificates of deposit	—	19,098	19,098
Commercial paper	—	355,720	355,720
Corporate bonds	—	261,594	261,594
U.S. Treasury and government sponsored enterprises	—	50,564	50,564
Total financial assets	$62,325	$686,976	$749,301
	December 31, 2017		
	Level 1	Level 2	Total
Money market funds	$45,478	$—	$45,478
Commercial paper	—	199,647	199,647
Corporate bonds	—	179,022	179,022
U.S. Treasury and government sponsored enterprises	—	16,263	16,263
Total financial assets	$45,478	$394,932	$440,410

We did not have any financial liabilities measured and recorded at fair value on a recurring basis as of those dates. We did not have any financial assets or liabilities classified as Level 3 in the fair value hierarchy as of September 30, 2018 or December 31, 2017 and there were no transfers of financial assets or liabilities classified as Level 3 during the nine months ended September 30, 2018 or 2017.

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.

Our remaining financial assets and liabilities include Cash, Trade and other receivables, Unbilled collaboration revenue, 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.

NOTE 11. LEASES

In May 2017, we entered into the Lease with Ascentris for office and research facilities located at the Premises in Alameda, California. The Lease was amended in October 2017 and June 2018 to increase the space leased to an aggregate of 134,765 square feet. We have the right to make certain tenant improvements to the space leased on the Premises. The Lease has an initial term through January 31, 2028. Rent payments began February 1, 2018, following the conclusion of a partial twelve-month rent abatement period. We have two five-year options to extend the Lease and a one-time option to terminate the Lease without cause on the last day of the 8th year of the initial term; none of these optional periods have been considered in the determination of the right-of-use asset or the lease liability for the Lease as we did not consider it reasonably certain that we would exercise any such options. The Lease further provides that we are obligated to pay to Ascentris certain costs, including taxes and operating expenses. We also have a right of first offer to lease certain additional space, in the aggregate of approximately 170,000 square feet of space, as that additional space becomes available at 1601, 1701 and 1751 Harbor Bay Parkway, Alameda, California over the remainder of the initial term of the Lease at a market rate determined according to the Lease.

We had a lease for two buildings in South San Francisco, California with a total area of 116,063 square feet which expired in July 2018.

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We have evaluated our facility leases and determined that, effective upon the adoption of Topic 842, they were all operating leases.

In April 2018, we entered into a three-year financing lease for office equipment that commenced in May 2018. We will be required to make cash payments totaling $0.2 million during the term of the lease.

We have performed an evaluation of our other contracts with customers and suppliers in accordance with Topic 842 and have determined that, except for the facility and equipment leases described above, none of our contracts contain a lease.

The balance sheet classification of our lease liabilities was as follows (in thousands):

	September 30, 2018	December 31, 2017
Operating lease liabilities:		
Current portion included in Other current liabilities	$ 2,315	$ —
Long-term portion of lease liabilities	12,529	—
Total operating lease liabilities	14,844	—
Financing lease liabilities:		
Financing obligation for build-to-suit lease	—	14,530
Current portion included in Other current liabilities	49	—
Long-term portion of lease liabilities	90	—
Total financing lease liabilities	139	14,530
Total lease liabilities	$ 14,983	$ 14,530

The components of lease costs, which were included in Operating expenses in our Condensed Consolidated Statements of Operations, were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Operating lease cost	$1,614	$986	$3,587	$4,292
Variable lease cost	363	229	1,366	705
Sublease income	—	—	—	(1,225)
Total lease costs	$1,977	$1,215	$4,953	$3,772

Cash paid for amounts included in the measurement of lease liabilities for the nine months ended September 30, 2018 was $3.3 million and was included in Net cash provided by operating activities in our Condensed Consolidated Statements of Cash Flows

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As of September 30, 2018, the maturities of our operating lease liabilities were as follows (in thousands):

	Operating leases
Remainder of 2018	$403
Years ending December 31,	
2019	2,654
2020	2,823
2021	2,904
2022	3,000
Thereafter	16,665
Total lease payments	28,449
Less:	
Imputed interest	(5,435)
Tenant improvement reimbursements	(8,170)
Operating lease liabilities	$14,844

As of September 30, 2018, the weighted average remaining lease term is 9.3 years and the weighted average operating discount rate used to determine the operating lease liability was 4.50%.

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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 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. Words such as "expect," "potential," "will," "goal," "would," "intend," "continues," "objective," "anticipate," "initiate," "believe," "plan," "trend," or the negative of such terms or other similar expressions identify 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 Part II, Item 1A of this Form 10-Q, as well as those discussed elsewhere in this report. 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 financial statements and accompanying notes included in this report and the financial statements and accompanying notes thereto included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 filed with the Securities and Exchange Commission, or SEC, on February 26, 2018.

Overview

We are a biotechnology company committed to the discovery, development and commercialization of new medicines to improve care and outcomes for people with cancer. Since our founding in 1994, three products discovered at Exelixis have progressed through clinical development, received regulatory approval, and entered the marketplace. Two are derived from cabozantinib, an inhibitor of multiple tyrosine kinases including MET, AXL, VEGF receptors, and RET: CABOMETYX® (cabozantinib) tablets approved for advanced renal cell carcinoma, or RCC; and COMETRIQ® (cabozantinib) capsules approved for progressive, metastatic medullary thyroid cancer, or MTC. The third product, COTELLIC® (cobimetinib) tablets, is an inhibitor of MEK, marketed under a collaboration agreement with Genentech, Inc. (a member of the Roche Group), or Genentech, and is approved as part of a combination regimen to treat advanced melanoma. Both cabozantinib and cobimetinib have shown potential in a variety of forms of cancer and are the subject of broad clinical development programs for multiple potential oncology indications.

CABOMETYX was approved by the U.S. Food and Drug Administration, or FDA, for previously-treated patients with advanced RCC in April 2016, and then on December 19, 2017, approximately two months ahead of the assigned Prescription Drug User Fee Act, or PDUFA, action date, the FDA expanded CABOMETYX's approval in this indication to include previously-untreated patients with advanced RCC. We continue to be highly focused on optimizing the execution of this commercial launch 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, or Ipsen, and Takeda Pharmaceutical Company Ltd., or 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. Ipsen and Takeda also contribute financially and operationally to the further global development and commercialization of cabozantinib in other potential indications, and we continue to work closely with them on these activities.

In addition to our commercialization efforts, we are also focused on the next wave of cabozantinib's clinical development program, pursuing other indications that have the potential to expand the number of cancer patients who could benefit from this medicine. Furthest advanced is our effort to secure regulatory approval of CABOMETYX as a treatment for patients with previously-treated advanced hepatocellular carcinoma, or HCC. In September 2018, our partner Ipsen received a positive opinion from the Committee for Medicinal Products for Human Use, or CHMP, for CABOMETYX as a treatment in the European Union, or EU, for adult patients who have been treated with sorafenib. In the U.S., on May 29, 2018, the FDA accepted our supplemental New Drug Application, or sNDA, for cabozantinib in this indication, assigning a PDUFA action date of January 14, 2019. The data in support of these filings are derived from CELESTIAL, our company-sponsored, global phase 3 trial comparing cabozantinib to placebo in patients with advanced HCC who had previously progressed on or were intolerant to sorafenib and up to one additional therapy. On

October 16, 2017, we announced that at the time of the second planned interim analysis, the study's independent data monitoring committee had recommended that CELESTIAL be stopped because it had met its primary endpoint, with cabozantinib providing a statistically significant and clinically meaningful improvement in overall survival, or OS, compared to placebo. Safety data from the study were consistent with the established profile of cabozantinib. The results of the CELESTIAL trial were published in the New England Journal of Medicine, or NEJM, in early July 2018.

We are also evaluating cabozantinib, both as a single agent and in combination with other compounds, 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 clinicians conduct the remaining trials through our Cooperative Research and Development Agreement, or CRADA, with the National Cancer Institute's Cancer Therapy Evaluation Program, or 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 of late is COSMIC-311, a phase 3 trial evaluating cabozantinib in patients with radioiodine refractory differentiated thyroid cancer, or 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 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 immune checkpoint inhibitors in multiple clinical trials. The most advanced of these combination studies include a phase 3 pivotal trial evaluating cabozantinib in combination with nivolumab in previously-untreated advanced or metastatic RCC, and a phase 1/2 trial evaluating cabozantinib in combination with nivolumab and in combination with both nivolumab and ipilimumab in patients with both previously-treated and previously-untreated advanced HCC. Both trials are in collaboration with Bristol-Myers Squibb Company, or BMS. As a further part of our clinical collaboration with BMS, we also plan to evaluate cabozantinib and nivolumab with or without ipilimumab in various other tumor types, including in urothelial cancer, or UC. Diversifying our exploration of combinations with immune checkpoint inhibitors, we have also initiated COSMIC-021, a phase 1b dose escalation study evaluating the safety and tolerability of cabozantinib in combination with the Roche Group's, or Roche's immune checkpoint inhibitor, atezolizumab, in patients with locally advanced or metastatic solid tumors. The study comprises eighteen tumor expansion cohorts, including multiple therapeutic settings of RCC, UC, and non-small cell lung cancer and single therapeutic settings of HCC, castration-resistant prostate cancer, or CRPC, triple-negative breast cancer, epithelial ovarian cancer, endometrial cancer, gastric or gastroesophageal junction cancer, colorectal adenocarcinoma, DTC and head and neck cancer of squamous cell histology, and is currently enrolling. Findings from the dose escalation stage of the study were presented at the European Society for Medical Oncology, or ESMO, 2018 Congress and demonstrate encouraging clinical activity of the combination, including in patients with previously-untreated advanced RCC.

Genentech also continues to make progress with respect to the phase 3 clinical development program for our second approved cancer agent, cobimetinib. In December 2006, we licensed cobimetinib to Genentech and Genentech has been, and is, solely responsible for the product's clinical development. Genentech is currently conducting two phase 3 pivotal trials exploring the combination of cobimetinib with atezolizumab in BRAF wild type melanoma (IMspire170), and the combination of cobimetinib with atezolizumab and vemurafenib in BRAF V600 mutant melanoma (IMspire150). The first patient for IMspire170 was enrolled in December 2017, and enrollment for IMspire150 was completed in April 2018. Additionally, although IMblaze370, a third phase 3 pivotal trial conducted by Genentech evaluating the combination of cobimetinib with atezolizumab in colorectal carcinoma, or CRC, did not meet its primary endpoint as announced in May 2018, Genentech continues to pursue the cobimetinib development program and is conducting a series of early-stage clinical trials investigating the combination of cobimetinib and atezolizumab in multiple tumor settings. Should these trials prove positive and Genentech obtain regulatory approvals based on such positive results, we believe that cobimetinib could provide us with a potentially meaningful source of revenue in the future.

As we continue to work to maximize the clinical, therapeutic and commercial potential of cabozantinib and cobimetinib, we also remain committed to building our product pipeline by discovering and developing new cancer

therapies for patients. In this regard, we have resumed 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 we have discovered, many of which are in earlier stages of clinical and regulatory development pursuant to our collaborations with Daiichi Sankyo Company, Limited, or Daiichi Sankyo, Merck & Co., Inc., or Merck, (known as MSD outside of the U.S. and Canada), BMS and Sanofi. Using our expertise in biology, chemistry and biotherapeutics, we are advancing drug candidates toward and through preclinical development.

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, in January 2018, we entered into an exclusive global collaboration and license agreement with StemSynergy Therapeutics, Inc., or StemSynergy, for the discovery and development of novel oncology compounds aimed to inhibit tumor growth by targeting Casein Kinase 1 alpha, or CK1 , a component of the Wnt signaling pathway implicated in key oncogenic processes. Under the terms of this agreement, we have partnered with StemSynergy to conduct preclinical and clinical studies with compounds targeting CK1 . Additionally, in May 2018, we entered into a collaboration and license agreement with Invenra, Inc., or Invenra, which is focused on developing next-generation biologics, to discover and develop multispecific antibodies for the treatment of cancer. Invenra is responsible for antibody lead discovery and generation while we will lead Investigational New Drug enabling studies, manufacturing, clinical development in single-agent and combination therapy regimens, and future regulatory and commercialization activities. The collaboration agreement also provides that we will receive an exclusive, worldwide license to one preclinical asset, and that we will pursue up to six additional discovery projects during the term of the collaboration, which in total are directed to three discovery programs.

Third Quarter 2018 Business Updates and Financial Highlights

During the third quarter of 2018, we continued to execute on our commercial, development and financial objectives, generating significant revenue from operations and positioning the business to be able to maximize the clinical and commercial potential of CABOMETYX, COMETRIQ and COTELLIC and to expand the product pipeline. Significant business updates and financial highlights for the quarter and subsequent to quarter end include:

Business Updates

- In July 2018, we were added to Standard & Poor's, or S&P's, MidCap 400 index and are classified under S&P's Global Industry Classification Standard Biotechnology Sub-Industry index.
- In July 2018, the NEJM published results from CELESTIAL, our company-sponsored, global phase 3 pivotal trial comparing cabozantinib to placebo in patients with advanced HCC who had previously progressed on or were intolerant to sorafenib and up to one additional therapy. The data demonstrate that cabozantinib provided a statistically significant and clinically meaningful improvement in OS versus placebo.
- In September 2018, we announced that the National Comprehensive Cancer Network, or NCCN, updated its Clinical Practice Guidelines to include favorable new recommendations for CABOMETYX as a treatment for patients with advanced RCC, regardless of patient risk status. In particular, NCCN designated CABOMETYX as the only preferred tyrosine kinase inhibitor treatment option for previously-untreated patients with poor- or intermediate-risk and for previously-treated patients.
- In September 2018, Ipsen received regulatory approval from Health Canada for CABOMETYX as a treatment in Canada for adult patients with advanced RCC who have received prior VEGF targeted therapy.
- In September 2018, Ipsen received a positive CHMP opinion for CABOMETYX as a treatment in the EU for adult patients with HCC who have been previously treated with sorafenib.
- In October 2018, we announced the initiation of COSMIC-311, a phase 3 pivotal trial evaluating cabozantinib in patients with radioiodine refractory DTC who have progressed after up to two VEGFR-targeted therapies.
- In October 2018, clinical data from cabozantinib were the subject of thirteen presentations at ESMO, including a poster presentation covering the results from the dose escalation stage of COSMIC-021, our phase 1b study evaluating the safety and tolerability of cabozantinib in combination with Roche's atezolizumab in patients with locally advanced or metastatic solid tumors. Findings from the dose escalation phase of the trial demonstrate that the combination was well-tolerated and showed encouraging anti-tumor activity, including in patients with previously untreated advanced RCC. In another poster presentation at ESMO, data were presented from an analysis that evaluated the effect of

PD-L1 expression on clinical outcomes with cabozantinib in advanced RCC from the CABOSUN and METEOR trials. This analysis showed that cabozantinib's activity was independent of PD-L1 expression. Additionally, a separate retrospective analysis of RCC patients found that cabozantinib was active following prior treatment with immune checkpoint inhibitor therapy either alone or in combination with VEGF-targeted or other prior therapy.

- In October 2018, Ipsen received approvals from both the Agencia Nacional de Vigilancia Sanitaria in Brazil for CABOMETYX as a treatment for both previously-treated and previously-untreated advanced RCC and from the Taiwan Food and Drug Administration for CABOMETYX as a treatment for patients with advanced RCC who have received prior anti-angiogenic therapy.

Financial Highlights

- Net income for the third quarter of 2018 was $126.6 million, or $0.42 per share, basic and $0.41 per share, diluted, compared to $81.4 million, or $0.28 per share, basic and $0.26 per share diluted, for the third quarter of 2017.
- Total revenues for the third quarter of 2018 increased to $225.4 million, compared to $152.5 million for the third quarter of 2017.
- Net product revenues for the third quarter of 2018 increased to $162.9 million, compared to $96.4 million for the third quarter of 2017.
- Research and development expenses for the third quarter of 2018 increased to $44.7 million, compared to $28.5 million for the third quarter of 2017.
- Selling, general and administrative expenses for the third quarter of 2018 increased to $48.1 million, compared to $38.1 million for the third quarter of 2017.
- Cash and investments increased to $750.3 million at September 30, 2018, compared to $457.2 million at December 31, 2017.

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 a number of challenges and risks to our business that may impact our ability to execute on our 2018 business objectives. In particular, we anticipate that for the foreseeable future our ability to maintain or meaningfully increase unrestricted cash to fund our commercial operations and our development and discovery programs will be dependent upon the successful commercialization of CABOMETYX for the treatment of advanced RCC in territories where it has been or may soon be approved and in potential other indications for which we are in late-stage development or intend to seek regulatory review, such as previously-treated advanced HCC and previously-treated radioiodine refractory DTC. The commercial opportunity for CABOMETYX as a treatment for advanced RCC remains subject to a variety of factors, most importantly, CABOMETYX's perceived benefit/risk profile as compared to the benefit/risk profiles of other treatments available or currently in development for the treatment of advanced RCC. Our ability to maintain or meaningfully increase product revenues from CABOMETYX is also affected by a number of other factors, including the highly competitive markets for which we intend to pursue regulatory approval of cabozantinib and the prospect for new competitive therapies and generic competition, and the extent to which coverage and reimbursement for CABOMETYX is available from government and other third-party payers. Obtaining and maintaining appropriate coverage and reimbursement for CABOMETYX is increasingly challenging due to, among other things, the attention being paid to healthcare cost containment and other potential austerity measures being discussed in the U.S. and worldwide, as well as increasing interest amongst legislators and policymakers in the U.S. in restricting drug prices through the imposition of pharmaceutical drug price controls. Our ability to fulfill the commercial potential of cabozantinib also depends on whether data generated by our clinical development activities will support regulatory approval of cabozantinib in additional indications. Achievement of our 2018 business objectives will also depend on our ability to adapt our development and commercialization strategy to navigate increased competition, including that from, but not limited to, immune checkpoint inhibitors, as well as the use of combination therapy to treat cancer. Furthermore, our research and development objectives may be impeded as we work to scale 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 an extensive 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 2018 will end on December 28, 2018 and fiscal year 2017 ended on December 29, 2017. For convenience, references in this report as of and for the fiscal periods ended September 28, 2018, June 29, 2018, March 30, 2018 and September 29, 2017, and as of and for the fiscal years ended December 28, 2018 and December 29, 2017, are indicated as being as of and for the periods ended September 30, 2018, June 30, 2018, March 31, 2018 and September 30, 2017, and the years ended December 31, 2018 and December 31, 2017, respectively. Similarly, references in this report to the first day of the fiscal year ended December 28, 2018 are indicated as being as of January 1, 2018.

Results of Operations

Revenues

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

	Three Months Ended September 30,		Percentage Change - Q3 2018 v. Q3 2017	Nine Months Ended September 30,		Percentage Change - Year to Date 2018 v. 2017
	2018	2017		2018	2017	
Net product revenues	$162,946	$96,416	69 %	$443,054	$253,297	75 %
Collaboration revenues	62,451	56,094	11 %	182,170	79,108	130 %
Total revenues	$225,397	$152,510	48 %	$625,224	$332,405	88 %

Total revenues for the three and nine months ended September 30, 2018 were impacted by our adoption of Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers (Topic 606), or Topic 606. For additional information on our adoption of Topic 606, see “Note 1. Organization and Summary of Significant Accounting Policies - Recently Adopted Accounting Pronouncements,” “Note 2. Revenues” and “Note 3. Collaboration Agreements” in our “Notes to Condensed Consolidated Financial Statements” contained in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Net Product Revenues

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

	Three Months Ended September 30,		Percentage Change - Q3 2018 v. Q3 2017	Nine Months Ended September 30,		Percentage Change - Year to Date 2018 v. 2017
	2018	2017		2018	2017	
CABOMETYX	$158,262	$90,362	75 %	$428,317	$233,582	83 %
COMETRIQ	4,684	6,054	(23)%	14,737	19,715	(25)%
Net product revenues	$162,946	$96,416	69 %	$443,054	$253,297	75 %

The increases in net product revenues for CABOMETYX for the three and nine months ended September 30, 2018, as compared to the comparable periods in 2017, were primarily due to a 59% and 70% increase, respectively, in the number of units of CABOMETYX sold, and to a lesser extent, increases in the average selling price of the product. The increase in CABOMETYX sales volume reflects the continued growth of CABOMETYX in advanced RCC. The decreases in net product revenues for COMETRIQ for the three and nine months ended September 30, 2018, as compared to the comparable periods in 2017, were primarily due to a 28% decline in the number of units of COMETRIQ sold for both comparable periods. COMETRIQ sales volume has continued to decrease since the launch of CABOMETYX in April 2016. The adoption of Topic 606 did not impact our net product revenues.

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 Condensed Consolidated Financial Statements” contained in Part I, Item 1 of this Quarterly Report on Form 10-Q. We expect our discounts and allowances as a percentage of gross product revenues to increase during the remainder of 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.

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Collaboration Revenues

Collaboration revenues were as follows (dollars in thousands):

	Three Months Ended September 30,		Percentage Change - Q3 2018 v. Q3 2017	Nine Months Ended September 30,		Percentage Change - Year to Date 2018 v. 2017
	2018	2017		2018	2017	
Collaboration revenues:						
License revenues [1]	$51,323	$54,335	(6)%	$152,261	$74,706	104 %
Research and development service revenues [2]	10,560	2,316	356 %	27,464	5,623	388 %
Other collaboration revenues [3]	568	(557)	n/m	2,445	(1,221)	n/m
Total collaboration revenues	$62,451	$56,094	11 %	$182,170	$79,108	130 %

(1) Upon the adoption of Topic 606, the allocation of proceeds from our collaboration partners, including upfront and milestone payments, between intellectual property licenses and research and development services as well as the resulting timing of recognition has changed. License revenues for the three and nine months ended September 30, 2018 included the immediate recognition of the portion of milestones that were allocated to the transfer of intellectual property licenses for those milestones for which it had become probable that a significant revenue reversal would not occur as well as royalty revenues from Ipsen and Genentech. License revenues for the three and nine months ended September 30, 2017 included the full recognition of substantive milestones achieved during the period, recognition of deferred revenues from upfront payments and a non-substantive milestone, which were being amortized over various periods, as well as royalty revenues from Ipsen and Genentech.

(2) Research and development service revenues for the three and nine months ended September 30, 2018 included the recognition of deferred revenue for the portion of the upfront and milestone payments that have been allocated to the research and development service performance obligations which are being amortized through early 2030, as well as development cost reimbursements earned on our collaboration agreements. As described above, we did not allocate any of our upfront payments or milestones to research and development services prior to the adoption of Topic 606; therefore, Research and development service revenues for the three and nine months ended September 30, 2017 included only development cost reimbursements earned on our collaboration agreements.

(3) Other collaboration revenues for the three and nine months ended September 30, 2018 included net losses on product supply services provided to Ipsen and Takeda and the profit on the U.S. commercialization of COTELLIC from Genentech. Other collaboration revenues for the three and nine months ended September 30, 2017 included only net losses on product supply services, since losses on the U.S. commercialization of COTELLIC for the period were instead included in Selling, general and administrative expenses.

Collaboration revenues increased to $62.5 million and $182.2 million for the three and nine months ended September 30, 2018, respectively, as compared to $56.1 million and $79.1 million for the comparable periods in 2017. The increases in collaboration revenues were primarily the result of increases in milestones revenues, as well as increases in royalties under our collaboration agreement with Ipsen, development cost reimbursement revenues and profit sharing under our collaboration agreement with Genentech; those increases were partially offset by decreases in the recognition of deferred revenue due to the adoption of Topic 606 and increases in the losses on product supply services.

Milestone revenues for both the three and nine months ended September 30, 2018 included $36.9 million in revenue related to a $40.0 million milestone from Ipsen we expect to earn in the fourth quarter of 2018 for the approval by the European Commission, or EC, of cabozantinib for previously-treated HCC and $5.0 million in revenue for a milestone from Ipsen on the approval by Health Canada of cabozantinib for the treatment of adults with advanced RCC. Milestone revenues for the nine months ended September 30, 2018 also included $46.2 million in revenue for a $50.0 million milestone from Ipsen for the approval of cabozantinib for first-line advanced RCC by the EC, including $0.2 million that was recognized during the three months ended September 30, 2018, $25.0 million in revenue for a commercial milestone from Ipsen that we earned in the second quarter of 2018 upon Ipsen’s achievement of $100.0

million of net sales cumulatively over four consecutive quarters and $20.0 million in revenue for a milestone earned in February 2018 upon Daiichi Sankyo's submission of a regulatory application to the Japanese Pharmaceutical and Medical Devices Agency for esaxerenone as a treatment for patients with essential hypertension. See "Note 3. Collaboration Agreements" for additional information about the timing and amounts of revenue associated with the achievement of these milestones. Milestone revenues for the three and nine months ended September 30, 2017 reflect recognition of two milestones from Ipsen totaling $45.0 million. Milestone revenues for the nine months ended September 30, 2017 also reflect recognition of a $2.5 million milestone earned from the ROR collaboration agreement with BMS.

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Royalties on net sales of cabozantinib by Ipsen outside of the U.S. and Japan increased to $10.3 million and $20.0 million for the three and nine months ended September 30, 2018, respectively as compared to $0.4 million and $0.8 million for the comparable periods in 2017. Ipsen's net sales of cabozantinib has continued to grow since their first commercial sale of the product in the fourth quarter of 2016. During the three months ended June 30, 2018, Ipsen reached $150.0 million in cumulative net sales of cabozantinib, which resulted in an increase in royalty rate earned by us to 22% of net sales by Ipsen. Previously we had been entitled to receive a tiered royalty of 2% to 12%. Moving forward, we are now entitled to receive a tiered royalty of 22% to 26% on annual net sales, with separate tiers for Canada. These tiers reset each calendar year.

Development cost reimbursements in connection with our collaboration arrangements with Ipsen and Takeda increased to $6.9 million and $17.7 million for the three and nine months ended September 30, 2018, respectively, as compared to $2.3 million and $5.6 million for the comparable periods in 2017. The increases were primarily the result of Ipsen's and Takeda's participation in 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 $3.3 million and $10.3 million for the three and nine months ended September 30, 2018, respectively, as compared to losses of $1.4 million and $5.1 million for the comparable periods in 2017. We expect an overall profit on the U.S. commercialization of COTELLIC for the year ending December 31, 2018 and have therefore included the profit in Collaboration revenues for the three and nine months ended September 30, 2018; losses on the U.S. commercialization of COTELLIC for the three and nine months ended September 30, 2017 were included in Selling, general and administrative expenses. Royalty revenues on ex-U.S. net sales of COTELLIC for the nine months ended September 30, 2017 included $1.1 million in royalty revenues for sales in the fourth quarter of 2016 in addition to the royalty revenues for sales in the nine months ended September 30, 2017 as a result of a change in the timing of when we receive sales information from Genentech in the first quarter of 2017. Following a commercial review, commencing in January 2018 we and Genentech scaled back the personal promotion of COTELLIC as a treatment for patients with BRAF V600E or V600K mutation-positive advanced melanoma in the U.S. This decision is not indicative of any change in our intention to promote COTELLIC for other therapeutic indications for which it may be approved in the future.

During the three and nine months ended September 30, 2018, we recognized $3.7 million and $7.2 million, respectively, in revenues from the amortization of deferred revenue, including revenue deferred for the upfront payments received in 2016 and 2017 in connection with our collaboration arrangements with Ipsen and Takeda. Revenues from the amortization of deferred revenue were $7.6 million and $21.3 million during the comparable periods in 2017. The decrease in the recognition of such revenues was a result of the adoption of Topic 606; Upon adopting Topic 606 on January 1, 2018, we recorded a $236.7 million reduction of the unrecognized upfront and non-substantive milestone payments previously received from our collaboration partners that had been included in deferred revenue at December 31, 2017.

The net losses on product supply services increased to $1.4 million and $3.6 million for the three and nine months ended September 30, 2018, respectively, as compared to $0.6 million and $1.2 million for the comparable periods in 2017. As part of the collaboration agreement with Ipsen, we entered into a supply agreement pursuant to which we supply finished, labeled product to Ipsen at our cost, as defined in the agreement, which excludes the 3% royalty we are required to pay GlaxoSmithKline, or GSK, on Ipsen's net sales of any product incorporating cabozantinib. As a result, as royalty generating sales of cabozantinib by Ipsen have increased as described above, our losses on the related product supply agreement have also increased.

Cost of Goods Sold

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

	Three Months Ended September 30,		Percentage Change - Q3 2018 v. Q3 2017	Nine Months Ended September 30,		Percentage Change - Year to Date 2018 v. 2017
	2018	2017		2018	2017	
Cost of goods sold	$7,360	$4,658	58 %	$18,996	$10,875	75 %

Gross margin	95	%	95	%	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, indirect labor costs, the cost of manufacturing the product, write-downs related to expiring and excess inventory, and other third-party logistics costs. Portions of the manufacturing costs for inventory were incurred prior to the regulatory approval of CABOMETYX and COMETRIQ and, therefore, were expensed as research and development costs when incurred, rather than capitalized as inventory. Cost of goods sold included a 2%

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reduction related to materials that had been previously expensed during the nine months ended September 30, 2018, respectively, as compared to a 6% reduction during the comparable period in 2017. There were no amounts remaining related to previously expensed materials in our inventory balances as of June 30, 2018. Write-downs related to excess and expiring inventory were $0.8 million and $1.1 million for the nine months ended September 30, 2018 and September 30, 2017, respectively.

The increases in Cost of goods sold for the three and nine months ended September 30, 2018, as compared to the comparable periods in 2017, were primarily related to the growth in sales of CABOMETYX. We do not expect our gross margin to change significantly during the remainder of 2018.

Research and Development Expenses

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

	Three Months Ended September 30,		Percentage Change - Q3 2018 v. Q3 2017		Nine Months Ended September 30,		Percentage Change - 2018 v. 2017	
	2018	2017			2018	2017		
Research and development expenses	$44,741	$28,543	57	%	$124,986	$79,967	56	%

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

The increases in research and development expenses for the three and nine months ended September 30, 2018, as compared to the comparable periods in 2017, were primarily related to increases in personnel expenses, clinical trial costs, license costs and stock-based compensation. Personnel expenses increased $5.8 million and $14.9 million for the three and nine months ended September 30, 2018, respectively, as compared to the comparable periods in 2017, primarily due to increases in headcount to support our development and discovery efforts. The increase in clinical trial costs, which includes services performed by third-party contract research organizations and other vendors who support our clinical trials, was $7.5 million and $12.5 million for the three and nine months ended September 30, 2018, respectively, as compared to the comparable periods in 2017. The increase in clinical trial costs was primarily due to increases in costs associated with CheckMate 9ER, COSMIC-021, COSMIC-311 and preparation for further pivotal phase 3 trials that are expected to be initiated in the coming months; those increases were partially offset by decreases in costs related to METEOR, our completed phase 3 pivotal trial of cabozantinib in patients with previously treated advanced RCC and CELESTIAL. License costs increased $0.4 million and $7.7 million for the three and nine months ended September 30, 2018, respectively, as compared to the comparable periods in 2017, primarily as a result of the collaboration agreements we entered into with Invenra and StemSynergy. Stock-based compensation increased $1.5 million and $4.4 million for the three and nine months ended September 30, 2018, respectively, as compared to the comparable periods in 2017, primarily due to increases in headcount.

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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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development expenses:				
Development:				
Clinical trial costs	$17,242	$9,754	$40,482	$27,966
Personnel expenses	12,316	7,437	34,182	21,649
Consulting and outside services	1,943	2,464	6,969	6,370
Other development costs	2,925	3,771	10,257	10,318
Total development	34,426	23,426	91,890	66,303
Drug discovery [(1)]	4,073	1,743	17,354	3,986
Other [(2)]	6,242	3,374	15,742	9,678
Total research and development expenses	$44,741	$28,543	$124,986	$79,967

(1) Primarily includes personnel expenses, consulting and outside services, laboratory supplies and license costs for our exclusive 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, which includes the pursuit of commercial collaborations with major pharmaceutical and biotechnology companies for the development of our drug candidates.

We are focusing our development and commercialization 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, COSMIC-021 being conducted in collaboration with Roche 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 have resumed internal drug discovery efforts 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, 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 September 30,		Percentage Change - Q3 2018 v. Q3 2017	Nine Months Ended September 30,		Percentage Change - 2018 v. 2017
	2018	2017		2018	2017	
Selling, general and administrative expenses	$48,120	$38,129	26 %	$153,989	$113,084	36 %

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

The increases in Selling, general and administrative expenses for the three and nine months ended September 30, 2018, as compared to the comparable periods in 2017, were primarily related to increases in corporate giving, personnel expenses, consulting and outside services, stock-based compensation and marketing costs; those increases with respect to the nine months ended September 30, 2018 were partially offset by a decrease in legal and accounting costs, as compared to the comparable period in 2017. Corporate giving, consisting predominantly of donations to independent patient support foundations, increased $2.3 million and $11.4 million for the three and nine months ended September 30, 2018, respectively, as compared to the comparable periods in 2017. Personnel expenses increased $3.0 million and $10.8 million for the three and nine months ended September 30, 2018, respectively, as compared to the comparable periods in 2017, primarily due to increases in general and administrative headcount to support our commercial and research and development organizations. Consulting and outside services increased $1.5 million and $9.3 million and marketing costs increased $0.9 million and $4.0 million for the three and nine months ended September 30, 2018, respectively, as compared to the comparable periods in 2017, primarily due to increases in marketing activities, partially offset by a $0.9 million and $2.3 million decrease in the losses on the U.S. commercialization of COTELLIC; for the three and nine months ended September 30, 2017 such losses were included in Selling, general and administrative expenses in the accompanying Condensed Consolidated Statements of Operations; we expect an overall profit on the U.S. commercialization of COTELLIC for the year ending December 31, 2018 and have therefore included the profit for the three and nine months ended September 30, 2018 in Collaboration revenues for those periods. Stock-based compensation increased $2.9 million and $8.9 million for the three and nine months ended September 30, 2018, respectively, as compared to the comparable periods in 2017, primarily due to increases in headcount. Legal and accounting costs decreased by $3.5 million for the nine months ended September 30, 2018, as compared to the comparable period in 2017, primarily due to legal costs incurred in

2017 related to the resolution of our dispute with Genentech.

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Other Income (Expenses), Net

Other income (expenses), net, were as follows (dollars in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Interest income	$3,507	$1,133	$8,099	$3,497
Interest expense	(1)	—	(1)	(8,679)
Other, net	272	2,275	369	(3,638)
Total other income (expenses), net	$3,778	$3,408	$8,467	$(8,820)

Interest income increased 210% and 132% during the three and nine months ended September 30, 2018, respectively, as compared to the comparable periods in 2017, as a result of both an increase in our investment balances and an increase in the yield earned on those investments.

The decreases in Interest expense during the nine months ended September 30, 2018, as compared to the comparable periods in 2017, were primarily due to the June 2017 repayment of our Secured Convertible Notes due 2018, or the Deerfield Notes, and the March 2017 repayment of our term loan with Silicon Valley Bank.

The changes in Other, net during the three and nine months ended September 30, 2018, as compared to the comparable periods in 2017, were primarily due to a loss on extinguishment of debt and gains on the sale of other equity investments that both occurred in 2017 that did not reoccur in 2018. During the nine months ended September 30, 2017, we incurred a $6.2 million loss on extinguishment of debt as a result of the prepayment penalty associated with the early repayment of the Deerfield Notes in June 2017. For more information on the repayment of these debt instruments, see “Note 6. Debt” in our “Notes to Consolidated Financial Statements” contained in Part II, Item 8 of our Annual Report on Form 10-K filed with the SEC on February 26, 2018. During the three and nine months ended September 30, 2017 we also recognized gains of $2.3 million and $3.0 million, respectively, resulting from the resolution of contingencies related to the August 2016 sale of our 9% interest in Akarna Therapeutics, Ltd. to Allergan Holdco UK Limited.

Provision for Income Taxes

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

	Three Months Ended September 30,		Percentage Change - Q3 2018 v. Q3 2017	Nine Months Ended September 30,		Percentage Change - 2018 v. 2017
	2018	2017		2018	2017	
Provision for income taxes	$2,324	$3,206	(28)%	$5,739	$3,921	46 %

Provision for income taxes for the three and nine months ended September 30, 2018 and 2017 primarily relates to state taxes for which we do not have net operating loss carry-forwards due to a limited operating history. Our historical losses are sufficient to fully offset our federal taxable income.

We have historically recorded a valuation allowance for our deferred tax assets as we believe the ability to realize those deferred tax assets is currently not more likely than not (as defined in Accounting Standards Codification, or ASC, Topic 740: Income Taxes) as a result of weighing all available positive and negative evidence, which includes but is not limited to our history of annual operating losses for most years from inception through December 31, 2016. Because of our more recent history of recognizing an operating income, we are continually reassessing the likelihood of realizing the deferred tax assets. Should we determine in a future period that the realization of those assets is more likely than not based on all available evidence, both positive and negative, that change in assessment would result in a reversal of some or all of our recorded valuation allowance which would have a significant impact to that period’s provision for income taxes and net income.

Liquidity and Capital Resources

Although we reported net income of $330.0 million and $154.2 million for the nine months ended September 30, 2018 and the year ended December 31, 2017, 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

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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; our share of the net profits and losses for the commercialization of COTELLIC in the U.S. under our collaboration with Genentech; the amount of royalties from COTELLIC sales outside the U.S. under our collaboration with Genentech; other license and contract revenues; and the level of our expenses, including development and commercialization activities for cabozantinib and any pipeline expansion efforts. We have limited commercialization experience and expect to continue to spend significant additional amounts to fund the continued development and commercialization of cabozantinib. In addition, we will continue to expand our product pipeline through our drug discovery efforts and the evaluation of in-licensing and acquisition opportunities that align with our oncology drug expertise, which efforts could involve substantial costs.

As of September 30, 2018, we had $750.3 million in cash and investments, which included $748.7 million available for operations, as compared to $457.2 million in cash and investments, which included $452.0 million available for operations, as of December 31, 2017. 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 and Financial Results,” in Part II, Item 1A of this Quarterly Report on Form 10-Q. 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. In addition, we may choose to raise additional funds through the issuance of equity or debt due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current and future operating plans. For example, we may choose to raise additional capital to fund in-licensing or product acquisition opportunities.

Sources and Uses of Cash

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

	Nine Months Ended September 30,	
	2018	2017
Net cash provided by operating activities:		
Net income	$ 329,981	$ 115,738
Adjustments to reconcile net income to net cash provided by operating activities	32,806	9,017
Changes in operating assets and liabilities	(51,658)	(12,497)
Net cash provided by operating activities	311,129	112,258
Net cash (used in) provided by investing activities	(155,051)	55,128
Net cash provided by (used in) financing activities	10,835	(169,215)
Net increase (decrease) in cash, cash equivalents and restricted cash	166,913	(1,829)

Cash, cash equivalents and restricted cash at beginning of period	188,314		155,836	
Cash, cash equivalents and restricted cash at end of period	$	355,227	$	154,007

Operating Activities

Our operating activities provided cash of $311.1 million for nine months ended September 30, 2018, compared to $112.3 million of cash provided in 2017.

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 depreciation and amortization and share-based compensation charges; 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 Results of Operations. The most significant of those timing differences are related to our Collaboration revenues; during the nine months ended September 30, 2018, we recognized $41.9 million in revenues related to two milestones from Ipsen that will be received in a future period.

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The most significant factors that contributed to the increase in cash provided by operating activities for the nine months ended September 30, 2018, as compared to the comparable period in 2017, was a $189.8 million increase in net product revenues and $130.0 million in milestone payments received from Ipsen and Daiichi Sankyo. This was partially offset by a $94.0 million increase in operating expenses for the nine months ended September 30, 2018, as compared to the comparable period in 2017, and by the impact of the upfront nonrefundable payment of $50.0 million received from Takeda in 2017 in consideration for the exclusive license and other rights contained in our collaboration agreement with Takeda.

Investing Activities

Our investing activities used cash of $155.1 million for the nine months ended September 30, 2018, as compared to $55.1 million of cash provided during the comparable period in 2017.

Cash used in investing activities for the nine months ended September 30, 2018 was primarily due to investment purchases of $368.3 million and Property and equipment purchases of $30.4 million, less cash provided by the maturity and sale of investments of $231.2 million and $11.9 million, respectively.

Cash provided by investing activities for the nine months ended September 30, 2017 was primarily due to cash provided by the maturity of investments of $266.3 million and the sale of investments of $37.3 million, less cash used for investment purchases of $248.0 million.

Financing Activities

Cash provided by financing activities was $10.8 million for the nine months ended September 30, 2018, as compared to $169.2 million cash used during the comparable period in 2017.

Cash provided by financing activities for the nine months ended September 30, 2018 was primarily a result of $14.0 million in proceeds from the issuance of common stock under our equity incentive plans, partially offset by $3.2 million of taxes paid related to net share settlements.

Cash used in financing activities for the nine months ended September 30, 2017 was primarily a result of $185.8 million paid for all amounts outstanding under the Deerfield Notes and our term loan with Silicon Valley Bank.

Contractual Obligations

Except as follows, there were no material changes outside of the ordinary course of business in our contractual obligations from those as of December 31, 2017.

In January 2018, we entered into an exclusive collaboration and license agreement with StemSynergy. We may be required to pay StemSynergy up to $2.9 million in additional research and development funding. StemSynergy will be eligible for up to $56.5 million in milestones for the first product to emerge from the collaboration, including preclinical and clinical development and regulatory milestone payments, commercial milestones, as well as single-digit royalties on worldwide sales.

In May 2018, we entered into a collaboration and license agreement with Invenra. Invenra is eligible to receive payments of up to $131.5 million based on the achievement of specific development and regulatory milestones for a product containing the lead preclinical asset in the first indication. Upon successful commercialization of a product, Invenra is eligible to receive global milestone payments up to $325.0 million if certain sales thresholds are achieved as well as single digit tiered royalties on net sales of the approved product. We also have the right to initiate five additional discovery projects for development subject to an upfront payment of $2.0 million for each project as well as additional global milestone payments and royalties for any products that arise from these discovery efforts.

For more information on the collaboration and license agreements with StemSynergy and Invenra, see “Note 3. Collaboration Agreements” in our “Notes to Condensed Consolidated Financial Statements” contained in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Off-Balance Sheet Arrangements

As of September 30, 2018, we did not have any material off-balance-sheet arrangements, as defined by applicable SEC regulations.

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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 and sales allowances as well as milestones included in collaboration arrangements; the amounts of revenues and expenses under our profit and loss sharing agreement; recoverability of inventory; operating lease assets and liabilities; the accrual for certain liabilities including accrued clinical trial liability; and valuations of equity awards used to determine stock-based compensation. We base our estimates on historical experience and on various other market-specific and other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our senior management has discussed the development, selection and disclosure of these estimates with the Audit Committee of our Board of Directors. Actual results could differ materially from those estimates.

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

We adopted Topic 606 and ASC Topic 842: Leases, or Topic 842, on January 1, 2018, resulting in changes to our accounting policies for revenue recognition and leases. Except with respect to revenue recognition, there have been no changes in significant estimates and judgments for our critical accounting policies during the nine months ended September 30, 2018, 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, 2017 filed with the SEC on February 26, 2018.

Revenue Recognition - Collaboration Revenues

We enter into collaboration arrangements, under which we license certain rights to our intellectual property to third parties. The terms of these arrangements typically include payment to us for one or more of the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; product supply services; development cost reimbursements; profit sharing arrangements; and royalties on net sales of licensed products. As part of the accounting for these arrangements, we must develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. We use key assumptions to determine the standalone selling price, which may include forecast revenues and costs, clinical development timelines and costs, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success. At the inception of each arrangement that includes development milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. At the end of each subsequent reporting period, we re-evaluate the probability of earning of such development milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. In addition, in recording revenues for our research and development services performance obligation, we use internal development projected cost estimates to determine the amount of revenue to record as we satisfy this performance obligation, known as the inputs method.

We record royalty revenues and U.S. profits and losses under the collaboration agreement with Genentech based on estimates of the sales that occurred during the period. The relevant period estimates of sales are based on interim data provided by licensees and analysis of historical activity, adjusted for any changes in facts and circumstances, as appropriate. We base our estimates on the best information available at the time provided to us by our collaboration partners. However, additional information may subsequently become available to us, which may allow us to make a

more accurate estimate in future periods. In this event, we are required to record adjustments in future periods when the actual level of activity becomes more certain. Such increases or decreases are generally considered to be changes in estimates and will be reflected in our Condensed Consolidated Statements of Operations in the period they become known.

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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 September 30, 2018 have not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on February 26, 2018.

Our exposure to market risk for changes in interest rates relates to our investment portfolio. As of September 30, 2018, 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 $2.5 million as compared to $1.6 million as of December 31, 2017.

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. During the quarter ended September 30, 2018, we implemented certain internal controls in connection with our adoption of Topic 842. There were no other 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.

We have marked with an asterisk (*) those risk factors below that reflect substantive changes in risks facing us from the risk factors included in our Annual Report on Form 10-K for the fiscal year ended December 29, 2017 filed with the SEC on February 26, 2018.

Risks Related to Our Business and Industry

Our future prospects are 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 cobimetinib, 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 commercial operations and our development and discovery programs is dependent upon the successful commercialization of CABOMETYX for the treatment of advanced RCC in territories where it has been or may soon be approved and in potential other indications for which we are in late-stage development or for which we have sought regulatory review. The commercial opportunity for CABOMETYX as a treatment for advanced RCC remains subject to a variety of factors, most importantly, CABOMETYX's perceived benefit/risk profile as compared to the benefit/risk profiles of other treatments available or currently in development for the treatment of advanced RCC. 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 plan, which may have a material adverse effect on our business and financial condition, results of operations and growth prospects. 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. 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 may be 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.

Following the approval of CABOMETYX for the treatment of advanced RCC in the U.S., the EU, Canada and other territories, our success remains contingent upon, among other things, successful clinical development, regulatory approval and market acceptance of cabozantinib, the active pharmaceutical ingredient in CABOMETYX, in potential additional indications, such as advanced HCC. 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 to receive regulatory approval. Should we prove unsuccessful in advancing the further clinical development and commercialization of cabozantinib beyond its approved indications, we may be unable to execute our business plan, and our financial results and condition could be materially adversely affected. 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. Our ability to grow CABOMETYX product sales in future periods is also dependent on price increases, and we periodically increase the price of

CABOMETYX. Proposed government regulations, negative publicity regarding drug pricing and price increases generally, whether for CABOMETYX or products distributed by other

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pharmaceutical companies, could negatively affect market acceptance of, and sales of, CABOMETYX. In any event, we cannot assure that price increases we have taken or may take in the future will not negatively affect CABOMETYX sales.

The commercial success of CABOMETYX will depend upon the degree of market acceptance among physicians, patients, health care payers, and the medical community.

Our ability to successfully commercialize CABOMETYX for its approved indications is, and if approved for additional indications will be, highly dependent upon the extent to which CABOMETYX gains market acceptance among physicians, patients, government health care payers such as Medicare and Medicaid, commercial health care plans and the medical community. If CABOMETYX does not achieve an adequate level of acceptance, we may not generate significant future 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 and any new government initiatives affecting pharmaceutical pricing;
- the strength of CABOMETYX sales efforts, marketing, market access and product distribution support;
- the sufficiency of commercial and government insurance coverage and adequacy of reimbursement for CABOMETYX; and
- our ability to enforce our intellectual property rights with respect to CABOMETYX.

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 technologies and products that would render our technologies and 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 or cobimetinib for the treatment of additional tumor types, for example, could allow our competitors to bring products to market before us.

Specifically, the advanced RCC 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 immunotherapy. CABOMETYX in particular may become less marketable if we are unable to successfully adapt our development strategy to address the fact that this recent approach to treating cancer with immune checkpoint inhibitors has and will continue to become more prevalent in indications for which our products are approved, most notably advanced RCC, and in additional indications for which our products are under regulatory review, such as previously-treated advanced HCC. Furthermore, the complexities of such a strategy has and may continue to require collaboration with some of our competitors.

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We also may in the future face competition from manufacturers of generic versions of our marketed products. In this regard, in February 2018, the FDA published draft guidance containing product-specific bioequivalence recommendations for drug products containing cabozantinib, the active pharmaceutical ingredient in CABOMETYX and COMETRIQ. The FDA regularly issues product specific bioequivalence guidance for products following their approval. The February 2018 draft guidance for drug products containing cabozantinib could have been issued by the FDA as a matter of its own standard practice; it could also indicate that a generic drug manufacturer is investigating whether to submit an Abbreviated New Drug Application, or ANDA, for cabozantinib. The ANDA process is discussed in more detail under "Item I. Business—Government Regulation—The Hatch-Waxman Act" in our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on February 26, 2018. Generic competition often results in decreases in the 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 CABOMETYX and COMETRIQ or enter into or maintain agreements with third parties to do so, we may be unable to maximize product revenues and our business, financial condition, results of operations and prospects may be adversely affected.

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-stage oncology-focused biotech 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 the commercialization teams or the scale of distribution necessary to market and sell CABOMETYX successfully. If we are unable to maintain or scale our organization appropriately, we may not be able to maximize product revenues, and our business, financial condition, results of operations and prospects may be adversely affected.

Our ability to successfully commercialize CABOMETYX and COMETRIQ 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 to handle storage and distribution for our commercial supplies of both CABOMETYX and COMETRIQ in the U.S. Furthermore, we rely on our collaboration partners for the 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, results of operations and prospects.

We are subject to certain healthcare laws, regulation and enforcement; our failure to comply with those laws could have a material adverse effect on our results of operations and financial condition.*

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, or 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,

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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, or FDCA, and its 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, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, 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 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;
- federal and state government price reporting laws, which require us to calculate and report complex pricing metrics to government agencies, where such reported prices are used in the calculation of reimbursement and/or discounts on our marketed drugs, as well as certain state and municipal government price reporting and transparency laws that require us to report certain information and/or provide justifications where drug prices exceed a certain price increase threshold. The landscape surrounding these state price reporting and transparency laws continues to evolve, and existing or future requirements may subject us to potentially significant discounts on our products, increased infrastructure costs, and could potentially affect our ability to offer certain marketplace discounts; and
- state financial and drug pricing transparency laws, which generally require that we track, and in certain cases, publicly report certain types of expenditures in the U.S.

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. Such 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

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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.

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, that govern the collection, use and disclosure of personal information. For example, in June 2018, California Governor Jerry Brown signed the California Consumer Privacy Act of 2018, or CCPA, which takes effect on January 1, 2020 and will broadly define personal information, give California residents expanded privacy rights and protections and provide for civil penalties for violations and a private right of action for data breaches. 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 obtain individually identifiable health information from a HIPAA-covered entity in a manner that is 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 Data Privacy Directive (95/46/EC) and implementing legislation in the various national Member States of the EU was replaced on May 25, 2018 by the more restrictive General Data Protection Regulation (Regulation (EU) 2016/679), or GDPR, which now regulates the processing of personal data within the EU and between countries in the EU and countries outside of the EU, including the U.S. 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 processing of personal data to the extent necessary given our operations and commensurate with similar companies in our industry, and we will continue to review all future privacy and other regulations implemented pursuant to these new laws to assess whether additional procedural safeguards are warranted. Failure to provide adequate privacy protections and maintain compliance with these laws and regulations could jeopardize business transactions across borders, create liability for us, including the imposition of sanctions or other penalties, and/or could increase our cost of doing business.

If we are unable to obtain both sufficient coverage and adequate reimbursement from third-party payers for CABOMETYX or COMETRIQ, our revenues and prospects for profitability will suffer.*

Our ability to commercialize CABOMETYX or COMETRIQ successfully is highly dependent on the extent to which 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 may not be capable of paying for CABOMETYX or COMETRIQ themselves and may 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 prospects for profitability 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 the prices charged for pharmaceutical products and services, and many also limit reimbursement for newly-approved products and indications.

Current healthcare laws and regulations and future legislative or regulatory reforms to the healthcare system may affect our ability to sell CABOMETYX and COMETRIQ 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 sell 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.

Since its enactment, there have been judicial and Congressional challenges to numerous provisions of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (and other legislation), or the PPACA, as well as recent efforts by the Trump Administration and Congress to repeal or replace certain aspects of the PPACA. Since January 2017, President Trump has signed two Executive Orders as well as other directives designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health

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insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been enacted. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” Additionally, on January 23, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018 among other things, amends the PPACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole.” It is expected that Congress will continue to consider legislation to repeal and replace other elements of the PPACA.

Moreover, certain politicians, including the President, have announced plans to regulate the prices of pharmaceutical products. On May 11, 2018, President Trump’s administration released a “Blueprint” describing strategies for reducing drug prices and patient out-of-pocket costs. The Blueprint describes four "challenges" in the U.S. drug market: (i) "high list prices for drugs"; (ii) "seniors and government programs overpaying for drugs due to lack of the latest negotiation tools"; (iii) "high and rising out-of-pocket costs for consumers"; and (iv) "foreign governments free-riding off of American investments in innovation." The Blueprint describes two "phases" for addressing these challenges: (i) "actions the President may direct [the U.S. Department of Health and Human Services, or HHS,] to take immediately" and "actions HHS is actively considering, on which feedback is being solicited." While the Blueprint provides broad proposals for reform, we cannot know what form these proposals may take, when and if they are finalized. More recently, President Trump announced a new initiative to contain drug costs. Specifically, on October 25, 2018, the Centers for Medicare & Medicaid Services, or CMS, issued an Advance Notice of Proposed Rulemaking for the Medicare Program that would seek to reduce drug spending in part based on the prices that are charged by manufacturers in foreign countries. Although this proposal would target physician-administered drugs, it is possible that similar proposals could affect reimbursement for our products in the future, and we cannot know the impact that such initiatives would have on our ability to commercialize our drugs.

Congress has also signaled an intent to address pharmaceutical pricing, with Senate hearings to examine the cost of prescription drugs, which were held on June 13, October 17 and December 12, 2017. Federal legislators previously proposed legislation that would require pharmaceutical manufacturers to report price increases and provide a public justification for increases that exceed given benchmarks and authorize HHS to negotiate the price of Part D prescription drugs. More recently, in September 2018, both the U.S. House of Representatives and Senate passed legislation that would prohibit pharmaceutical benefit managers for private and public health plans from enforcing “gag clauses” that forbid pharmacies from telling customers about cheaper ways to buy drugs. President Trump has signaled support for these bills, although they have not yet been signed into law.

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. We cannot know what form any such measures may take or the market’s perception of how such proposals and provisions would affect us. Any reduction in reimbursement from government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may limit our ability to generate revenue or commercialize our current products and/or those for which we may receive regulatory approval in the future.

In August 2017, President Trump signed the FDA Reauthorization Act of 2017, which will reauthorize the FDA user fee programs for prescription drugs, generic drugs, medical devices, and biosimilars, under which manufacturers of such products partially pay for the FDA’s pre-market review of their product candidates. 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. In January 2018, the FDA took steps to implement the Drug Competition Action Plan, among other steps, and released guidance to streamline aspects of the submission and review of ANDAs for generic drugs, as well as generics' participation in shared Risk Evaluation and Mitigation strategies, or REMS. The FDA is also seeking to sharply curtail the use of Citizen Petitions that could delay the entry of generic competition, and along with the U.S. Federal Trade Commission has been focused on brand companies'

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denial of drug supply to potential generic competitors for testing (despite legitimate liability concerns), and alleged misuse of REMS. Although such scrutiny has not resulted in successful enforcement against companies, Congress has been considering whether to create a private right of action under which generic companies could bring suit against companies who refuse access to product for bioequivalence testing and obtain very substantial damages. We cannot currently predict the specific outcome or impact on our business of such regulatory actions or legislation.

As a result of the overall trend towards cost-effectiveness criteria and 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. Such policy actions could have a material adverse impact on our revenues and profitability.

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, such findings could further harm our business, reputation and/or prospects. It is possible that such 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 and proposed and enacted federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the price of drugs under Medicare, reform government program reimbursement methodologies for drugs, and facilitate value-based arrangements between manufacturers and payers. For example, the Trump Administration’s budget proposal for fiscal year 2019 contains drug price control measures that could be enacted during the 2019 budget 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 for low-income patients. While any 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, CMS just proposed a rule that would require drug manufacturers to disclose drug prices in television advertisements. In addition, the HHS Office of Inspector General has solicited input for proposed rulemaking related to the potential addition of “safe harbor” regulations for the AKS. This solicitation aims, among other things, at changes to pharmaceutical contracting and discounting (including potentially encouraging value-based contracting). We cannot know what form any final regulations promulgated by the HHS Office of Inspector General might look like or how they could affect our business

At the state and local level, governments continue to consider prescription drug pricing transparency proposals. For example, in October 2017, California Governor Jerry Brown signed legislation requiring pharmaceutical manufacturers to disclose and provide justification for certain price increases. The legislation will also require

additional disclosures regarding new high-cost specialty products beginning in January 2019; however, the final regulations under which we will be required to operate have not yet been promulgated, and the legislation is currently being challenged in court. While we have taken and will continue to take appropriate actions to ensure compliance with this new law, without knowing the final regulations applicable to us or the outcome of the court case, we cannot comprehensively assess the potential impact on our business. Additionally, in March 2018, Oregon Governor Kate Brown signed legislation requiring manufacturers to report an increase in the wholesale acquisition cost of a drug if the wholesale acquisition cost is $100 or more for a one-month supply, or for a course of treatment lasting less than one month and there is a net increase of 10 percent or more in the wholesale

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acquisition cost of the drug over the course of the previous calendar year. This law will go into effect in January 2019; additional requirements to provide notice and information about the launch of new high cost specialty products will go into effect in March 2019.

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.

We are heavily dependent on our partner, Genentech, for the successful development, regulatory approval and commercialization of cobimetinib, marketed as COTELLIC.*

The terms of our collaboration agreement with Genentech provide Genentech with exclusive authority over the global development and commercialization plans for cobimetinib and the execution of those plans. We have limited effective influence over those plans and are heavily dependent on Genentech's decision making. Any significant changes to Genentech's business strategy and priorities, over which we have no control, could adversely affect Genentech's willingness or ability to complete their obligations under our collaboration agreement and result in harm to our business and operations. Subject to contractual diligence obligations, Genentech has complete control over and financial responsibility for cobimetinib's development program, as well as over regulatory and commercial strategy and execution, and we are not able to control the amount or timing of resources that Genentech will devote to the product. Of particular significance are Genentech's development efforts with respect to the combination of cobimetinib with immune checkpoint inhibitors, a competitive area of clinical research. Regardless of Genentech's efforts and expenditures for the further development of cobimetinib, the results of such additional clinical investigation may not prove positive and may not produce label expansions or approval in additional indications, which could have a material adverse impact on our long-term revenue prospects. For instance, we announced in May 2018 that IMblaze370, Genentech's phase 3 pivotal trial evaluating the combination of cobimetinib and atezolizumab versus regorafenib, in unresectable locally advanced or metastatic CRC patients who have received at least two lines of prior cytotoxic chemotherapy, did not meet its primary endpoint; should Genentech obtain negative or inconclusive results in either of the other two phase 3 pivotal trials evaluating cobimetinib in combination with other therapies, cobimetinib's prospects, and its ability to contribute meaningfully to our business, will be substantially impaired.

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 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. In this regard, in February 2018, the FDA published draft guidance containing product-specific bioequivalence recommendations for drug products containing cabozantinib, the active pharmaceutical ingredient in CABOMETYX and COMETRIQ. The FDA regularly issues product specific bioequivalence guidance for products following their approval. The February 2018 draft guidance for drug products containing cabozantinib could have been issued by the FDA as a matter of its own standard practice; it could also indicate that a generic drug manufacturer is investigating whether to submit an ANDA for cabozantinib. The FDA can also approve a 505(b)(2) New Drug Application, or NDA, that relies on the agency's findings of safety and/or effectiveness for a previously approved drug. In either case, we will have to engage in litigation with a 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 patents covering cabozantinib were held to be invalid (or if any such competing generic versions of cabozantinib were found not to infringe our patents), the resulting generic competition would negatively affect our business, financial condition and results of operations. In

this regard, generic equivalents, which must meet the same quality standards as the branded drugs, would be significantly less costly than ours to bring to market. Companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, regardless of the regulatory approval pathway, the introduction of a generic version of any of our marketed products could result in a significant decrease in the sales of these marketed products and materially harm our business and financial condition.

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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 an effective safety profile;
- negative or inconclusive clinical trial results may 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 on a timely basis with an adequate 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
- regulators or institutional review boards may withhold authorization to commence or conduct clinical trials of cabozantinib or another product candidate, or delay, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or their determination 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 business plan, and our financial results could be materially adversely affected.

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;
- 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.

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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 adversely affect our business.

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. We have only limited experience in preparing and submitting the applications necessary to gain regulatory approvals. 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 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 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 and MTC, or one of our other product candidates, the 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, 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.

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

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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 effort or if we are unable to successfully obtain rights to suitable product candidates, our business, financial condition 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 rules, there is risk that the unauthorized use of social media by us or our employees to communicate about our products or business, or 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 an adverse effect on our business. Furthermore, negative posts or comments about us or our products in social media could seriously damage our reputation, brand image, and goodwill.

Risks Related to Our Capital Requirements and Financial Results

We may be unable to maintain or increase profitability.*

Although we reported net income of $330.0 million and $154.2 million for the nine months ended September 30, 2018 and the year ended December 31, 2017, 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; our share of the net profits and losses for the commercialization of COTELLIC in the U.S. under our collaboration with Genentech; the amount of royalties from COTELLIC sales outside the U.S. under our collaboration with Genentech; 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 evaluation and execution of potential additional in-licensing and acquisition opportunities 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.

If additional capital is not available to us when we need it, we may be forced to limit the expansion of our product development programs or commercialization efforts.*

As of September 30, 2018, we had $750.3 million in cash and investments, which included $748.7 million available for operations, as compared to $457.2 million in cash and investments, which included $452.0 million available for

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operations, as of December 31, 2017. Our business operations grew substantially during 2017 and experienced further expansion during the nine months ended September 30, 2018. In order to maintain business growth and maximize the clinical and commercial opportunities for cabozantinib, we plan to continue to execute on the U.S. commercialization plans for CABOMETYX, while reinvesting in our product pipeline through the continued development of cabozantinib, both alone and in combination with other therapies, research and development activities, as well as through in-licensing and acquisition efforts. Our ability to execute on 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 under our collaboration agreements with Ipsen and Takeda;
- the commercial success of COTELLIC and the revenues generated through our share of related profits and losses for the commercialization of COTELLIC in the U.S. and royalties from COTELLIC sales outside the U.S. under our collaboration with Genentech;
- the potential regulatory approval of cabozantinib as a treatment for patients with previously-treated advanced HCC, and in other indications, both in the U.S. and abroad;
- future clinical trial results;
- our future investments in the expansion of our pipeline through drug discovery and corporate development activities;
- our ability to control costs;
- the cost of clinical drug supply for our clinical trials;
- 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 in-licensing and acquisition efforts, 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 may adversely impact the availability and cost of credit, as well as our ability to raise money in the capital markets. Economic 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 required to limit the expansion of our product development programs or commercialization efforts, which could have a material adverse effect on our business and growth prospects.

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 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 ability to maintain profitability or our current financial position. For example, during 2018, we adopted Topic 606 and Topic 842 which have replaced prior revenue recognition and lease accounting guidance in U.S. generally accepted accounting principles. For a detailed description of the impact that Topic 606 and Topic 842 have had on our reported results, see "Note 1. Organization and Summary of Significant Accounting Policies" to our "Notes to Condensed Consolidated Financial Statements" contained in Part I, Item I of this Quarterly Report on Form 10-Q.

Risks Related to Our Relationships with Third Parties

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

We have established collaborations with leading pharmaceutical and biotechnology companies, including, Ipsen, Takeda, Genentech, Daiichi Sankyo, Merck, BMS and Sanofi 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:

- we are not able 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;
- we are not able 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;
- 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;
- disputes 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;
- collaborators may experience financial difficulties;
- collaborators may not be successful in their efforts to obtain regulatory approvals in a timely manner, or at all;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- collaborators may not comply with applicable healthcare regulatory laws;
- 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;
- a collaborator could independently move forward with a competing drug candidate developed either independently or in collaboration with others, including our competitors;

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- we may be precluded from entering into additional collaboration arrangements with other parties in an area or field of exclusivity;
- future collaborators may require us to relinquish some important rights, such as marketing and distribution rights; and
- 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, our product development efforts could be delayed and our business, operating results and financial condition could be adversely affected.

If third parties upon which we rely to perform clinical trials for cabozantinib do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize cabozantinib for the treatment of additional indications beyond advanced RCC and MTC.

We do not have the ability to conduct clinical trials for cabozantinib 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 beyond its 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 product candidates.

We lack internal manufacturing capabilities necessary for us to produce cabozantinib 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 or distribution facilities for clinical or commercial production and distribution of CABOMETYX and COMETRIQ. 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 development and commercial progress, we expect to enter into new agreements with additional third-party contract manufacturers and suppliers. This will continue for the foreseeable future for our potential product candidates, as well as for 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 our business, operating results and financial condition could be adversely affected. As part of our collaboration agreements with Ipsen and Takeda, we are responsible for the manufacturing and supply of cabozantinib products 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 cabozantinib and generate revenues to which we are entitled under the collaborations.

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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. These advisors and collaborators are not our employees and may have other commitments 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. In such a circumstance, we may lose work performed by them, and our development efforts with respect to the matters on which they were working 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.

Risks Related to Our 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 sensitive business information. 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 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,

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including our patent position, are generally uncertain and involve complex legal and factual questions. We will be able to protect our intellectual property rights from unauthorized use by third parties only to the extent that our technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. We will continue to apply for patents covering our technologies and products as, where and when we deem lawful and appropriate. However, these applications may be challenged or may fail to result in issued patents. Our issued patents have been and may in the future be challenged by third parties as invalid or unenforceable under U.S. or foreign laws, or they may be infringed by third parties, and we are from time to time involved in the defense and enforcement of our patents or other intellectual property rights in a court of law, U.S. Patent and Trademark Office inter partes review or reexamination proceeding, foreign opposition proceeding or related legal and administrative proceeding in the U.S. and elsewhere. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings and litigation can be substantial and the outcome can be uncertain. An adverse outcome may allow third parties to use our intellectual property without a license and/or allow third parties to introduce generic and other competing products, any of which would negatively impact our business. Third parties may also attempt to invalidate or design around our patents, or assert that they are invalid or otherwise unenforceable, and seek to introduce generic versions of cabozantinib. 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.

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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.

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 money claims, 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 commercialize certain product candidates, which could severely harm our business.

Risks Related to Employees and Location

We have moved our headquarters and may face disruption and turnover of employees.*

In the second quarter of 2018, we moved our corporate headquarters from South San Francisco, California to Alameda, California. As a result, we have incurred additional expenses, including those related to tenant improvements, furniture and equipment for the new corporate headquarters, as well as moving and exit costs. In addition, relocation of our corporate headquarters 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.

If we are unable to manage our growth, our business, financial condition, results of operations and 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. In addition, the physical expansion of our operations and change of location of our corporate headquarters may lead to significant costs and may divert our management and capital resources. If we are unable to manage our growth effectively, or are unsuccessful in recruiting qualified management personnel, our business, financial condition, results of operations and 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 plan. 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.

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Our headquarters are located near known earthquake fault zones, and the occurrence of an earthquake or other disaster could damage our facilities and equipment, which could harm our operations.

Our current headquarters in Alameda is located in the San Francisco Bay Area, California 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 fire, floods, power loss, communications failures, terrorism and similar events since any insurance we may maintain may not be adequate 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, the unique nature of our research activities could cause significant delays in our programs and make it difficult for us to recover from a disaster. Accordingly, an earthquake or other disaster could materially and adversely harm our ability to conduct business.

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, operating results and financial condition.

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.

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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;
- 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;
- the commercial success of COTELLIC and the revenues generated through our share of related profits and losses for the commercialization of COTELLIC in the U.S. and royalties from COTELLIC sales outside the U.S. under our collaboration with Genentech;
- 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, COMETRIQ and COTELLIC;
- our ability to obtain regulatory approval for cabozantinib as a treatment for patients with previously-treated advanced HCC;
- the achievement of stated regulatory and commercial milestones under our collaboration agreements;
- 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;
- additions and departures of key personnel;
- significant fluctuations in interest rates or foreign currency exchange rates;

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- 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.

Due to the possibility of 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:

- adverse or inconclusive results or announcements in 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 at earlier stages of clinical development or with lesser developed data sets and the speed with which the FDA is conducting regulatory 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;
- failure to achieve operating results projected by securities analysts;
- changes in earnings estimates or recommendations 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;
- 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.

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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 United Kingdom's pending withdrawal from the EU 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 the repeal of the individual mandate and the potential repeal and/or replacement of other portions or all of the PPACA, or greater restrictions on free trade stemming from Trump Administration policies, 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.

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 and adverse effect on our business.

Future sales of our common stock or the perception that such sales or conversions may occur, may depress our stock price.

A substantial number of shares of our common stock are reserved for issuance upon the exercise of stock options, upon vesting of restricted stock unit awards and upon a purchase under our employee stock purchase plan. The issuance and sale of substantial amounts of our common stock or the perception that such issuances and sales may occur, could adversely affect the market price of our common stock and impair our ability to raise capital through the sale of additional equity or equity-related securities in the future at a time and price that we deem appropriate.

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.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act of 2017 that significantly reforms the Internal Revenue Code of 1986, as amended, or the Code. The Tax Cuts and Jobs Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction of future net operating losses to 80% of current year

taxable income and elimination of net operating loss carry-backs, one-time taxation of offshore earnings at reduced rates regardless of whether

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they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new capital investments instead of deductions for depreciation expense over time, and modifying, reducing or repealing many business deductions and credits (including reducing the business tax credit for certain clinical trial expenses incurred in the testing of certain drugs for rare diseases or conditions). Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Cuts and Jobs Act is uncertain and our business and financial condition could be adversely affected. 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, 2017 and September 30, 2018, or are expected to be recorded in future periods. Additionally, further guidance may be forthcoming from the Financial Accounting Standards Board and SEC, as well as regulations, interpretations and rulings from federal and state tax agencies, which could result in additional impacts. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

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

We are subject to taxation in numerous U.S. states and territories. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Our effective tax rate, however, may be different than experienced in the past due to numerous factors, including the passage of the Tax Cuts and Jobs Act, changes in the mix of our profitability from state to state, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, our utilization of federal and state net operating losses, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

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

As of December 31, 2017, we had federal and state net operating loss carry-forwards of approximately $1.5 billion. The federal and state net operating loss carry-forwards will begin to expire, if not utilized, beginning in 2024 for federal income tax purposes and 2028 for California state income tax purposes. These net operating loss carry-forwards could expire unused and be unavailable to offset future income tax liabilities. While the Tax Cuts and Jobs Act allows for federal net operating losses incurred in 2018 and in future years to be carried forward indefinitely, the deductibility of such federal net operating losses incurred in 2018 and in future years will be limited. In addition, under 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 carry-forwards 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 carry-forwards before utilization. Based on our review and analysis, we concluded, as of December 31, 2017, 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. We do not know whether or when we will generate the U.S. federal taxable income necessary to utilize our remaining net operating losses. A full valuation allowance has been provided for the entire amount of our remaining net operating losses.

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.

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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	
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	12/5/2011	
4.1	Specimen Common Stock Certificate	S-1, as amended	333-96335	4.1	4/7/2000	
10.1*	First Amendment dated July 6, 2018 to the Supplement to the Clinical Trial Collaboration Agreement dated February 24, 2017, by and among Exelixis, Inc., Bristol-Meyers Squibb Company and Ipsen Pharma SAS					X
10.2*	Supplement dated July 6, 2018 to the Clinical Trial Collaboration Agreement dated February 24, 2017, by and among Exelixis, Inc., Bristol-Meyers Squibb Company and Takeda Pharmaceutical Company Limited					X
10.3*	Ono Territorial Supplemental Agreement to the Clinical Trial Collaboration Agreement dated February 24, 2017, by and among Exelixis, Inc., Ono Pharmaceutical Co., Ltd. and Bristol-Meyers Squibb Company					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

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

* Confidential treatment requested for certain portions of this exhibit.

‡ 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.

November 1, 2018 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)