EXELIXIS, INC.
Form 10-Q
November 01, 2017
Table of Contents

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 29, 2017
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)

210 East Grand Ave.
South San Francisco, CA 94080
(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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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	¨ (Do not check if a smaller reporting company)	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 7(a)(2)(B) 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 24, 2017, there were 295,853,210 shares of the registrant's common stock outstanding.

Table of Contents

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

Table of Contents

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, 2017	December 31, 2016*
ASSETS		
Current assets:		
Cash and cash equivalents	$ 149,357	$151,686
Short-term investments	217,741	268,117
Trade and other receivables	90,005	40,444
Inventory, net	5,806	3,338
Prepaid expenses and other current assets	8,012	5,416
Total current assets	470,921	469,001
Long-term investments	50,569	55,601
Long-term restricted cash and investments	4,650	4,150
Property and equipment, net	19,256	2,071
Goodwill	63,684	63,684
Other long-term assets	692	1,232
Total assets	$ 609,772	$595,739
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,988	$6,565
Accrued compensation and benefits	19,914	20,334
Accrued clinical trial liabilities	16,181	14,131
Accrued collaboration liabilities	9,137	2,046
Current portion of deferred revenue	31,377	19,665
Convertible notes	—	109,122
Term loan payable	—	80,000
Other current liabilities	26,356	16,923
Total current liabilities	108,953	268,786
Long-term portion of deferred revenue	246,092	237,094
Other long-term liabilities	16,012	541
Total liabilities	371,057	506,421
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: 295,700,576 and 289,923,798 at September 30, 2017 and December 31, 2016, respectively	296	290
Additional paid-in capital	2,106,132	2,072,591
Accumulated other comprehensive loss	(52)	(416)
Accumulated deficit	(1,867,661)	(1,983,147)
Total stockholders' equity	238,715	89,318
Total liabilities and stockholders' equity	$ 609,772	$595,739

* The condensed consolidated balance sheet as of December 31, 2016 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.

3

Table of Contents

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenues:				
Net product revenues	$96,416	$42,742	$253,297	$83,459
Collaboration revenues	56,094	19,452	79,108	30,414
Total revenues	152,510	62,194	332,405	113,873
Operating expenses:				
Cost of goods sold	4,658	2,455	10,875	4,700
Research and development	28,543	20,256	79,967	72,166
Selling, general and administrative	38,129	32,463	113,116	103,143
Restructuring (recovery) charge	—	(244)	(32)	871
Total operating expenses	71,330	54,930	203,926	180,880
Income (loss) from operations	81,180	7,264	128,479	(67,007)
Other income (expense), net:				
Interest income and other, net	3,408	3,059	6,098	4,010
Interest expense	—	(7,834)	(8,679)	(28,575)
Loss on extinguishment of debt	—	(13,773)	(6,239)	(13,773)
Total other income (expense), net	3,408	(18,548)	(8,820)	(38,338)
Income (loss) before income taxes	84,588	(11,284)	119,659	(105,345)
Income tax expense	3,206	—	3,921	—
Net income (loss)	$81,382	$(11,284)	$115,738	$(105,345)
Net income (loss) per share, basic	$0.28	$(0.04)	$0.39	$(0.44)
Net income (loss) per share, diluted	$0.26	$(0.04)	$0.37	$(0.44)
Shares used in computing net income (loss) per share, basic	294,269	256,319	292,776	238,024
Shares used in computing net income (loss) per share, diluted	312,940	256,319	311,555	238,024

The accompanying notes are an integral part of these condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Net income (loss)	$81,382	$(11,284)	$115,738	$(105,345)
Other comprehensive income (loss) [1]	67	(209)	364	152
Comprehensive income (loss)	$81,449	$(11,493)	$116,102	$(105,193)

(1) Other comprehensive income (loss) consisted solely of unrealized gains or losses, net, on available-for-sale securities arising during the periods presented. There were nominal or no reclassification adjustments to net income (loss) resulting from realized gains or losses on the sale of securities 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.

4

Table of Contents

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

	Nine Months Ended September 30,	
	2017	2016
Net income (loss)	$115,738	$(105,345)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	842	754
Stock-based compensation expense	15,029	18,346
Loss on extinguishment of debt	6,239	13,773
Amortization of debt discounts and debt issuance costs	182	8,295
Interest paid in kind	(11,825)	5,939
Gain on other equity investments	(2,980)	(2,494)
Other	1,530	1,332
Changes in assets and liabilities:		
Trade and other receivables	(49,241)	(85,026)
Inventory, net	(2,468)	(676)
Prepaid expenses and other current assets	(2,530)	(3,342)
Other long-term assets	689	535
Accounts payable	(577)	(2,436)
Accrued compensation and benefits	(420)	12,357
Accrued clinical trial liabilities	2,050	(3,184)
Accrued collaboration liabilities	7,091	7,772
Deferred revenue	20,710	251,512
Other current and long-term liabilities	12,199	7,183
Net cash provided by operating activities	112,258	125,295
Cash flows from investing activities:		
Purchases of property and equipment	(3,449)	(1,116)
Proceeds from sale of property and equipment	14	92
Purchases of investments	(248,046)	(258,509)
Proceeds from maturities of investments	266,335	100,635
Proceeds from sale of investments	37,294	2,266
Purchase of restricted cash and investments	(11,150)	(4,150)
Proceeds from maturities of restricted cash and investments	10,650	2,650
Proceeds from other equity investments	2,980	2,494
Net cash provided by (used in) investing activities	54,628	(155,638)
Cash flows from financing activities:		
Repayment of convertible notes and term loan payable	(185,788)	—
Payment on conversion of convertible notes	—	(7,134)
Proceeds from exercise of stock options	16,532	9,296
Proceeds from employee stock purchase plan	3,053	479
Taxes paid related to net share settlement of equity awards	(3,012)	(2,713)
Net cash used in financing activities	(169,215)	(72)
Net decrease in cash and cash equivalents	(2,329)	(30,415)
Cash and cash equivalents at beginning of period	151,686	141,634
Cash and cash equivalents at end of period	$149,357	$111,219
Supplemental cash flow disclosure - non-cash investing and financing activity:		

Construction-in-progress deemed to have been acquired under build-to-suit lease	$14,530	$—
Issuance of common stock in settlement of convertible notes	$—	$285,308

The accompanying notes are an integral part of these condensed consolidated financial statements.

Table of Contents

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 VEGF, MET, AXL and RET receptors: CABOMETYX® (cabozantinib) tablets approved for previously treated advanced renal cell carcinoma ("RCC") and COMETRIQ® (cabozantinib) capsules approved for progressive, metastatic medullary thyroid cancer. The third product, COTELLIC® (cobimetinib) tablets, is a reversible inhibitor of MEK, marketed under a collaboration with Genentech (a member of the Roche Group), and is approved as part of a combination regimen to treat advanced melanoma.

Basis of Consolidation

The condensed consolidated financial statements include the accounts of Exelixis and those of our wholly-owned subsidiaries. These entities' functional currency is the United States ("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 2017 will end on December 29, 2017 and fiscal year 2016 ended on December 30, 2016. For convenience, references in this report as of and for the fiscal periods ended September 29, 2017 and September 30, 2016, and as of and for the fiscal years ended December 29, 2017 and December 30, 2016, are indicated as being as of and for the periods ended September 30, 2017 and September 30, 2016, and the years ended December 31, 2017 and December 31, 2016, respectively.

Operating results for the nine months ended September 30, 2017 are not necessarily indicative of the results that may be expected for the year ending December 31, 2017 or for any future period. These financial statements and notes should be read in conjunction with the consolidated financial statements and notes thereto for the year ended December 31, 2016, included in our Annual Report on Form 10-K filed with the SEC on February 27, 2017.

Use of 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, revenue and expenses, and related disclosures. On an ongoing basis, management evaluates its estimates including, but not limited to, those related to revenue recognition, including deductions from revenues (such as rebates, chargebacks, sales returns and sales allowances), the period of performance, identification of deliverables and evaluation of milestones with respect to our collaborations, the amounts of revenues and expenses under our profit and loss sharing agreement, recoverability of inventory, certain accrued liabilities including accrued clinical trial liability, and 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.

6

Table of Contents

Reclassifications

Certain prior period amounts in the condensed consolidated financial statements have been reclassified to conform to current period presentation. We reclassified $1.8 million in payable to our customers from Other current liabilities to Trade and other receivables in the accompanying December 31, 2016 Condensed Consolidated Balance Sheet. We have also reclassified the related balances between line items in Changes in assets and liabilities in the accompanying Condensed Consolidated Statement of Cash Flows for the nine months ended September 30, 2016 to conform the presentation of those line items to the corresponding presentation of assets and liabilities in our accompanying Condensed Consolidated Balance Sheets.

Segment Information

We operate as a single reportable segment.

Stock-Based Compensation

In January 2017, we adopted Accounting Standards Update ("ASU") No. 2016-09, Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting, ("ASU 2016-09"). ASU 2016-09 is aimed at the simplification of several aspects of the accounting for employee share-based payment transactions, including accounting for forfeitures, income tax consequences and classification on the statement of cash flows.

Pursuant to the adoption of ASU 2016-09, we have made an election to record forfeitures when they occur. Previously, stock-based compensation was based on the number of awards expected to vest after considering estimated forfeitures. The change in accounting principle with regards to forfeitures was adopted using a modified retrospective approach, with a cumulative adjustment of $0.3 million to accumulated deficit and additional paid-in-capital as of January 1, 2017. No prior periods were restated as a result of this change in accounting principle.

As a result of the adoption of ASU 2016-09, as of January 1, 2017 we also recorded an increase to the federal and state net operating losses of $56.9 million for excess tax benefits previously not included. The resulting increase to the deferred tax assets of approximately $21.2 million was offset by a corresponding increase to the valuation allowance, resulting in a net zero impact to both our income tax expense in our Condensed Consolidated Statements of Operations and our deferred tax assets and liabilities in our Condensed Consolidated Balance Sheets.

ASU 2016-09 also requires that cash paid to taxing authorities when directly withholding shares for tax withholding purposes be classified as a financing activity on our Condensed Consolidated Statement of Cash Flows. Previously, we classified such payments as operating cash flows. The change in accounting principle with regards to such cash flows was adopted using a retrospective approach. Accordingly, we recorded a reclassification that resulted in an increase in cash provided by operating activities by $2.7 million along with a corresponding increase in cash used in financing activities in our Condensed Consolidated Statement of Cash Flows for the nine months ended September 30, 2016.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASU 2014-09"). In August 2015, the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, which delayed the effective date of ASU 2014-09 by one year. ASU 2014-09, as amended, becomes effective for us in the first quarter of fiscal year 2018, which is when we will adopt the standard. ASU 2014-09 also permits two methods of adoption: retrospectively to each prior reporting period presented (full retrospective method), or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (the modified retrospective method). We will adopt ASU 2014-09 using the modified retrospective method.

The core principle of ASU 2014-09 is that an entity should recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, has created the possibility that more judgment and estimates may be required within the revenue recognition process than required under existing U.S. generally accepted accounting pronouncements. We have substantially completed our analysis on the adoption of ASU 2014-09 and have determined the adoption will not have a material impact on the recognition of revenue from product sales. ASU 2014-09 will impact the timing of recognition of revenue for our collaboration arrangements with Ipsen Pharma SAS ("Ipsen") and Takeda Pharmaceutical Company

Ltd. (“Takeda”). We expect to reclassify deferred revenue

Table of Contents

to accumulated deficit (a concept known as “lost revenue”) for amounts associated with these collaboration arrangements upon recording our transition adjustment in the first quarter of 2018, primarily due to the timing of recognition of revenue related to intellectual property licenses that we have transferred for development and commercialization of our products. Additionally, for all of our collaboration arrangements, the timing of recognition of certain of our development and regulatory milestones could change as a result of the variable consideration guidance included in ASU 2014-09. ASU 2014-09 will also require additional disclosures regarding our revenue transactions.

NOTE 2: COLLABORATION AGREEMENTS

Ipsen Collaboration

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

In consideration for the exclusive license and other rights contained in the Ipsen Collaboration Agreement, Ipsen paid us an upfront nonrefundable payment of $200.0 million in March 2016. Additionally, as a result of the Amendment, we received a $10.0 million upfront nonrefundable payment from Ipsen in December 2016 and, as a result of the approval of cabozantinib in second-line RCC by the European Commission (“EC”) in September 2016, we received a $60.0 million milestone in November 2016. We are receiving a 2% royalty on the initial $50.0 million of net sales by Ipsen, and are entitled to receive a 12% royalty on the next $100.0 million of net sales by Ipsen. After the initial $150.0 million of sales, we are entitled to receive a tiered royalty of 22% to 26% on annual net sales by Ipsen; these tiers will 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 Ipsen Collaboration Agreement; global development costs for additional trials are shared between the parties, with Ipsen reimbursing us for 35% of such costs, provided Ipsen opts in to participate in such additional trials. Pursuant to the terms of the Ipsen Collaboration Agreement, we will remain responsible for the manufacture and supply of cabozantinib for all development and commercialization activities. As part of the collaboration agreement, we entered into a supply agreement pursuant to which we will supply finished, labeled drug product to Ipsen for distribution in the Ipsen Territories 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.

The Ipsen Collaboration Agreement contains multiple deliverables consisting of intellectual property licenses, delivery of products and/or materials containing cabozantinib to Ipsen for all development and commercial activities, research and development services, and participation on the joint steering, development and commercialization committees (as defined in the Ipsen Collaboration Agreement). We determined that these deliverables do not have stand-alone value and accordingly, combined these deliverables into a single unit of accounting and allocated the entire arrangement consideration to that combined unit of accounting. As a result, the upfront payment of $200.0 million, received in the first quarter of 2016 and the $10.0 million upfront payment received in December 2016 in consideration for the development and commercialization rights in Canada are being recognized ratably over the term of the Ipsen Collaboration Agreement, through early 2030, which is the current estimated patent expiration of cabozantinib in the European Union. At the time we entered into the Ipsen Collaboration Agreement, we also determined that the $60.0 million milestone we achieved upon the approval of cabozantinib by the EC in second-line RCC was not substantive due to the relatively low degree of uncertainty and relatively low amount of effort required on our part to achieve the milestone as of the date of the collaboration agreement; the $60.0 million was deferred entirely until the date of the European Medicines Agency’s (the “EMA”) approval of cabozantinib in second-line RCC in September 2016 and has been and will continue to be recognized ratably over the remainder of the term of the Ipsen Collaboration Agreement. The two $10.0 million milestones for the first commercial sales of CABOMETYX in Germany and the United Kingdom were determined to be substantive at the time we entered into the Ipsen

Collaboration Agreement and were recognized as collaboration revenues in the fourth quarter of 2016. We determined that the remaining development and regulatory milestones are substantive and will be recognized as revenue in the periods in which they are achieved. We consider the contingent payments due to us upon the achievement of specified sales volumes to be similar to royalty payments. Reimbursements for development costs are classified as revenue as the development services represent our ongoing major or central operations.

Table of Contents

During the three months ended March 31, 2017, we reclassified $9.0 million of deferred revenue to Accrued collaboration liabilities and Other long-term liabilities, and accordingly adjusted our amortization of the upfront payment of $200.0 million as a result of a change in operational responsibilities for certain clinical programs in the Ipsen Territory. As of September 30, 2017, we had paid $2.1 million toward the $9.0 million of reimbursements due to Ipsen for these clinical programs.

In September 2017, we recognized two milestones totaling $45.0 million resulting from Ipsen's receipt of the validation from the EMA for the application for variation to the CABOMETYX marketing authorization for the addition of a new indication in first-line treatment of advanced RCC in adults. The two milestones were determined to be substantive at the time we entered into the Ipsen Collaboration Agreement and were recognized as collaboration revenues in the third quarter of 2017. Payment for the first milestone of $20.0 million is due in the fourth quarter of 2017 and payment for the second milestone of $25.0 million is due in the first quarter of 2018.

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, 2016 filed with the SEC on February 27, 2017 for additional description of our collaboration agreement with Ipsen.

During the three and nine months ended September 30, 2017 and 2016, collaboration revenues under the Ipsen Collaboration Agreement were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Milestones achieved	$45,000	$—	$45,000	$—
Amortization of upfront payments and deferred milestone	4,742	3,780	13,788	8,570
Royalty revenue	371	—	814	—
Development cost reimbursements	1,123	—	2,322	—
Product supply agreement revenue	1,681	—	3,483	—
Cost of supplied product	(1,681)	—	(3,483)	—
Royalty payable to GSK on net sales by Ipsen	(557)	—	(1,221)	—
Collaboration revenues under the Ipsen Collaboration Agreement	$50,679	$3,780	$60,703	$8,570

As of September 30, 2017, short-term and long-term deferred revenue relating to the Ipsen Collaboration Agreement was $19.0 million and $215.0 million, respectively.

Genentech Collaboration

In December 2006, we out-licensed the further development and commercialization of cobimetinib to Genentech pursuant to a worldwide collaboration agreement (the "Genentech Collaboration Agreement"). Under the terms of the Genentech Collaboration Agreement for cobimetinib, we are entitled to a share of profits and losses received in connection with cobimetinib's commercialization in the U.S. This profit and loss share has multiple tiers: we are entitled to 50% of profits and losses from the first $200.0 million of U.S. actual sales, decreasing to 30% of profits and losses from U.S. actual sales in excess of $400.0 million. Separately, we are entitled to low double-digit royalties on net sales outside the U.S. In November 2013, we exercised an option under the Genentech Collaboration Agreement to co-promote COTELLIC in the U.S., which allows for us to provide up to 25% of the total sales force for approved cobimetinib indications in the U.S. In 2015, we began fielding 25% of the sales force promoting COTELLIC in combination with Zelboraf® as a treatment for patients with BRAF mutation-positive advanced melanoma.

On June 3, 2016, we filed a Demand for Arbitration before JAMS in San Francisco, California asserting claims against Genentech related to its clinical development, pricing and commercialization of COTELLIC, and cost and revenue allocations arising from COTELLIC's commercialization in the U.S. Our arbitration demand asserted that Genentech breached the Genentech Collaboration Agreement by, amongst other breaches, failing to meet its diligence and good faith obligations.

On July 13, 2016, Genentech asserted a counterclaim for breach of contract seeking monetary damages and interest related to the cost allocations under the Genentech Collaboration Agreement. On December 29, 2016, however, Genentech withdrew its counterclaim against us and stated that it would unilaterally change its approach to the

allocation

9

Table of Contents

of promotional expenses arising from commercialization of the COTELLIC plus Zelboraf combination therapy, both retrospectively and prospectively. The revised allocation approach substantially reduced our exposure to costs associated with promotion of the COTELLIC plus Zelboraf combination in the U.S. However, other significant issues remained in dispute between the parties. Genentech's action did not address the claims in our demand for arbitration related to Genentech's clinical development of cobimetinib, or pricing or promotional costs for COTELLIC in the U.S. and it did not fully resolve claims over revenue allocation. In addition, Genentech's unilateral action did not clarify how it intended to allocate promotional costs incurred with respect to the promotion of other combination therapies that include COTELLIC for other indications that may be developed or are in development and may be approved. As a result, we continued to press our position before the arbitral panel to obtain a just resolution of these claims.

On June 8, 2017, the parties settled the arbitration, which was dismissed with prejudice. The settlement was memorialized in a settlement agreement dated July 19, 2017, that included a mutual release of all claims arising out of or related in any way to the causes of actions and/or claims that were asserted or could have been asserted based on the facts alleged in the arbitration. The settlement does not provide for payments in settlement of the asserted claims; as part of the settlement, on July 19, 2017, the parties entered into an amendment to the Genentech Collaboration Agreement. Pursuant to the terms of the amendment, we continue to be entitled to a share of U.S. profits and losses received in connection with the commercialization of COTELLIC in accordance with the profit share tiers as originally set forth in the collaboration agreement, which share continues to decrease as sales of COTELLIC increase. However, effective as of July 1, 2017, the revenue for each sale of COTELLIC applied to the profit and loss statement for the collaboration agreement (the "Collaboration P&L") is being calculated using the average of the quarterly net selling prices of COTELLIC and any additional branded Genentech product(s) prescribed with COTELLIC in such sale. While we also continue to share U.S. commercialization costs for COTELLIC, the amendment expressly sets forth that the amount of commercialization costs Genentech is entitled to allocate to the Collaboration P&L is to be reduced based on the number of Genentech products in any given combination including COTELLIC. In addition, the amendment also sets forth the parties' confirmation and agreement that we have exercised our co-promotion option and that, as such, we have the option to co-promote current and future Genentech combinations that include COTELLIC in the U.S.

During the three and nine months ended September 30, 2017 and 2016, ex-U.S. royalty revenues and U.S. losses under the Genentech Collaboration Agreement were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Royalty revenues on ex-U.S. sales of COTELLIC included in Collaboration revenues	$1,392	$672	$5,057	$1,844
U.S. losses included in Selling, general and administrative expenses [1]	$(891)	$(2,922)	$(2,298)	$(14,845)

(1) A portion of the accrual for losses for the three and nine months ended September 30, 2016 were reversed in December 2016 when we were relieved of our obligation to pay certain disputed costs as a result of Genentech's unilateral change to its approach to the allocation of promotional expenses arising from commercialization of the COTELLIC plus Zelboraf combination therapy.

The U.S. losses under the Genentech Collaboration Agreement include our share of the net loss from the collaboration, as well as personnel and other costs we have incurred to co-promote COTELLIC plus Zelboraf in the U.S.

Royalty revenues from the Genentech Collaboration Agreement are based on amounts reported to us by Genentech and are recorded when such information becomes available to us. For prior periods, from the launch of COTELLIC through December 31, 2016, such information was not available until the following quarter, meaning that historically we recorded royalty revenues on a one quarter lag. Beginning in 2017, such information became available to us in the current quarter. As a result of this change, during the nine months ended September 30, 2017, in addition to the royalties reported to us for that period we also recorded $1.1 million in royalties for the sales activity related to the

three months ended December 31, 2016.

Takeda Collaboration

On January 30, 2017, we entered into a collaboration and license agreement (the “Takeda Collaboration Agreement”) with Takeda for the commercialization and further clinical development of cabozantinib in Japan. Pursuant to the terms of the Takeda Collaboration Agreement, Takeda will have exclusive commercialization rights for current and potential future cabozantinib indications in Japan. The companies have also agreed to collaborate on the clinical

Table of Contents

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 Takeda Collaboration Agreement, Takeda paid us an upfront nonrefundable payment of $50.0 million in February 2017. We will be eligible to receive development, regulatory and first-sales milestones of up to $95.0 million related to second-line RCC, first-line RCC and second-line hepatocellular carcinoma ("HCC"), as well as additional development, regulatory and first-sale milestone payments for potential future indications. The Takeda Collaboration Agreement also provides that we will be eligible to receive pre-specified payments of up to $83.0 million associated with potential sales milestones. We will also receive royalties on net sales of cabozantinib in Japan at an initial tiered rate of 15% to 24% on net sales for the first $300.0 million of cumulative net sales. Thereafter, the royalty rate will be adjusted to 20% to 30% on annual net sales.

Takeda will be responsible for 20% of the costs associated with the global cabozantinib development plan's current and future trials, provided Takeda opts to participate in such future trials, and 100% of costs associated with cabozantinib development activities that are exclusively for the benefit of Japan. Pursuant to the terms of the Takeda Collaboration Agreement, we will remain responsible for the manufacture and supply of cabozantinib for all development and commercialization activities under the collaboration. As part of the collaboration, the parties will enter into appropriate supply agreements for the manufacture and supply of cabozantinib for Takeda's territory.

During the three and nine months ended September 30, 2017, collaboration revenues under the Takeda Collaboration Agreement were as follows (in thousands):

	Three Months Ended September 30,	Nine Months Ended September 30,
Amortization of upfront payment	$ 2,830	$ 7,547
Development cost reimbursements	1,193	3,301
Collaboration revenues under the Takeda Collaboration Agreement	$ 4,023	$ 10,848

There was no such revenue during the comparable periods in 2016. As of September 30, 2017, short-term and long-term deferred revenue relating to the Takeda Collaboration Agreement was $11.3 million and $31.1 million, respectively.

The Takeda 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 following the first commercial sale of cabozantinib in Japan shall constitute a material breach of the Takeda Collaboration Agreement. We may terminate the agreement if Takeda challenges or opposes any patent covered by the Takeda Collaboration Agreement. At any time prior to August 1, 2023, the parties may mutually agree to terminate the Takeda Collaboration Agreement if Japan's Pharmaceuticals and Medical Devices Agency is unlikely to grant approval of the marketing authorization application in any cancer indication in Japan. After the commercial launch of cabozantinib in Japan, Takeda may terminate the Takeda 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.

The Takeda Collaboration Agreement contains multiple deliverables consisting of intellectual property licenses, delivery of products and/or materials containing cabozantinib to Takeda for all development and commercial activities, research and development services, and participation on the joint executive, development and commercialization committees (as defined in the Takeda Collaboration Agreement). We determined that these deliverables, other than the commercial supply and joint commercialization committee participation, are non-contingent in nature. The commercial supply deliverable was deemed contingent, primarily due to the fact that there is uncertainty around approval in Japan, which is dependent on successful clinical trial results from a study in

Japanese patients. We also determined that the non-contingent deliverables do not have stand-alone value, because each one of them has value only if we meet our obligation as a whole to provide Takeda with research and development services, including clinical supply of cabozantinib under the Takeda Collaboration Agreement. Accordingly, we combined the non-contingent deliverables into a single unit of accounting and allocated the $50.0 million upfront fee to that combined unit of accounting. We also determined that the level of effort required of us to meet our obligations under the Takeda Collaboration Agreement is not expected to vary significantly over

Table of Contents

the development period of the Takeda Collaboration Agreement. As a result, the upfront payment of $50.0 million, received in the first quarter of 2017, will be recognized ratably over the development period of the Takeda Collaboration Agreement of approximately four years. We determined that the development and regulatory milestones are substantive and will be recognized as revenue in the periods in which they are achieved. We consider the contingent payments due to us upon the achievement of specified sales volumes to be similar to royalty payments. We will record reimbursements for development costs as revenue as the development services represent a part of our ongoing major or central operations.

Bristol-Myers Squibb Collaboration - First-Line Advanced RCC, Bladder Cancer and HCC Combination Studies

In February 2017, we entered into a clinical trial collaboration agreement with Bristol-Myers Squibb Company (the "BMS Collaboration Agreement") for the purpose of evaluating the combination of cabozantinib and nivolumab with or without ipilimumab in various tumor types, including, in RCC, HCC and bladder cancer. To date, a phase 3 trial in first-line advanced RCC and a phase 2 trial in HCC evaluating these combinations has been initiated. Pursuant to the terms of the BMS Collaboration Agreement, each party will grant to the other a non-exclusive, worldwide (within the collaboration territory as defined in the BMS Collaboration Agreement), non-transferable, royalty-free license to use the other party's compounds in the conduct of each clinical trial. The parties' efforts are governed through a joint development committee established to guide and oversee the collaboration's operation. Each trial will be conducted under a combination Investigational New Drug Application, unless otherwise required by a regulatory authority. Each party will be responsible for supplying drug product for the applicable clinical trial in accordance with the terms of the supply agreement entered into between the parties in April 2017, and costs for each such trial will be shared equally between the parties, unless two Bristol-Myers Squibb Company ("BMS") compounds will be utilized in such trial, in which case BMS will bear two-thirds of the costs and we will bear one-third of the costs for such study treatment arms. Unless earlier terminated, the BMS Collaboration Agreement will remain in effect until the completion of all clinical trials under the collaboration, all related trial data has been delivered to both parties and the completion of any then agreed upon analysis. Ipsen has opted in to participate in the phase 3 pivotal trial in first-line advanced RCC and will have access to the results to support potential future regulatory submissions. Ipsen may also participate in future studies at its choosing.

The Roche Group Collaboration

In February 2017, we established a clinical trial collaboration with The Roche Group ("Roche") for the purpose of evaluating the safety and tolerability of cabozantinib in combination with Roche's atezolizumab in patients with locally advanced or metastatic solid tumors. Each party is responsible for supplying drug product for the applicable clinical trial in accordance with the terms of the clinical supply agreement entered into by the parties in February 2017. Based on the dose-escalation results, the trial has the potential to enroll up to four expansion cohorts, including a cohort of patients with previously untreated advanced clear cell RCC and three cohorts of urothelial carcinoma, namely platinum eligible first-line patients, first or second-line platinum ineligible patients and patients previously treated with platinum-containing chemotherapy. The trial was initiated in June 2017 and is open for enrollment. We are the sponsor of the trial, and Roche is responsible for supplying atezolizumab to us. Ipsen has opted to participate in the study and will have access to the results to support potential future development in its territories.

GlaxoSmithKline Collaboration

In October 2002, we established a collaboration with GSK to discover and develop novel therapeutics in the areas of vascular biology, inflammatory disease and oncology. Under the terms of the product development and commercialization agreement, GSK had the right to choose cabozantinib for further development and commercialization, but notified us in October 2008 that it had waived its right to select the compound for such activities. As a result, we retained the rights to develop, commercialize, and license cabozantinib, subject to payment to GSK of a 3% royalty on net sales of any product incorporating cabozantinib. The product development and commercialization agreement was terminated during 2014, although GSK will continue to be entitled to a 3% royalty on net sales by us or our collaboration partners of any product incorporating cabozantinib, including COMETRIQ and CABOMETYX.

During the three and nine months ended September 30, 2017 and 2016, royalties owed to GSK in connection with the sales of COMETRIQ and CABOMETYX were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Royalties owed to GSK	$3,446	$1,277	$8,809	$2,495

Table of Contents

Royalties owed to GSK are included in Cost of goods sold for sales by us and as a reduction of Collaboration revenues for sales by Ipsen in the accompanying Condensed Consolidated Statements of Operations.

Other Collaborations

During the nine months ended September 30, 2017, we recognized $2.5 million in contract revenues from a milestone payment received from BMS related to its ROR gamma program.

During the three and nine months ended September 30, 2016, we recognized $15.0 million in contract revenues from a milestone payment earned from Daiichi Sankyo Company, Limited ("Daiichi Sankyo") related to its worldwide license of our compounds that modulate the mineralocorticoid receptor ("MR"), including CS-3150 (an isomer of XL550). During the nine months ended September 30, 2016, we also recognized $5.0 million in contract revenues from a milestone payment earned from Merck related to its worldwide license of our phosphoinositide-3 kinase-delta program.

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, 2016 filed with the SEC on February 27, 2017 for a description of our existing collaboration agreements.

NOTE 3: CASH AND INVESTMENTS

All of our cash equivalents and investments are classified as available-for-sale. The following tables summarize cash and cash equivalents, investments, and restricted cash and investments by balance sheet line item as of September 30, 2017 and December 31, 2016 (in thousands):

	September 30, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents	$149,357	$ —	$ —	$149,357
Short-term investments	217,805	17	(81)	217,741
Long-term investments	50,557	41	(29)	50,569
Long-term restricted cash and investments	4,650	—	—	4,650
Total cash and investments	$422,369	$ 58	$ (110)	$422,317

	December 31, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents	$151,686	$ —	$ —	$151,686
Short-term investments	268,234	13	(130)	268,117
Long-term investments	55,792	1	(192)	55,601
Long-term restricted cash and investments	4,150	—	—	4,150
Total cash and investments	$479,862	$ 14	$ (322)	$479,554

Under our loan and security agreement with Silicon Valley Bank, we were required to maintain compensating balances on deposit in one or more investment accounts with Silicon Valley Bank or one of its affiliates. The total collateral balance of $81.6 million as of December 31, 2016 is reflected in our Condensed Consolidated Balance Sheet in short-term investments; as a result of our repayment of the term loan with Silicon Valley Bank, the compensating balance requirement was terminated as of March 29, 2017. See "Note 7 - Debt" to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2016 filed with the SEC on February 27, 2017 for more information regarding the collateral balance requirements under our Silicon Valley Bank loan and security agreement.

Table of Contents

The following tables summarize our cash equivalents and investments by security type as of September 30, 2017 and December 31, 2016. The amounts presented exclude cash, but include investments classified as cash equivalents (in thousands):

	September 30, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$42,797	$ —	$ —	$42,797
Commercial paper	168,738	—	—	168,738
Corporate bonds	187,197	58	(95)	187,160
U.S. Treasury and government sponsored enterprises	14,659	—	(15)	14,644
Total investments	$413,391	$ 58	$ (110)	$413,339

	December 31, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$71,457	$ —	$ —	$71,457
Commercial paper	165,375	—	—	165,375
Corporate bonds	152,712	3	(308)	152,407
U.S. Treasury and government sponsored enterprises	70,730	11	(14)	70,727
Total investments	$460,274	$ 14	$ (322)	$459,966

Gains and losses on the sales of investments available-for-sale were nominal or zero during the three and nine months ended September 30, 2017 and 2016.

All of our investments are subject to a quarterly impairment review. During the nine months ended September 30, 2017 and 2016 we did not record any other-than-temporary impairment charges on our available-for-sale securities. As of September 30, 2017, there were 84 investments in an unrealized loss position with gross unrealized losses of $0.1 million and an aggregate fair value of $134.9 million. The investments in an unrealized loss position comprise corporate bonds with an aggregate fair value of $124.9 million and securities issued by U.S. Treasury and government sponsored enterprises with an aggregate fair value of $10.0 million. The unrealized losses were not attributed to credit risk, but rather associated with the changes in interest rates. Based on the scheduled maturities of our investments, we concluded that the unrealized losses in our investment securities are not other-than-temporary, as it is more likely than not that we will hold these investments for a period of time sufficient for a recovery of our cost basis.

The following table summarizes the fair value of securities classified as available-for-sale by contractual maturity as of September 30, 2017 (in thousands):

	Mature within One Year	After One Year through Five Years	Fair Value
Money market funds	$42,797	$—	$42,797
Commercial paper	168,738	—	168,738
Corporate bonds	136,592	50,568	187,160
U.S. Treasury and government sponsored enterprises	14,644	—	14,644
Total investments	$362,771	$50,568	$413,339

Cash is excluded from the table above. The classification of certain restricted investments is dependent upon the term of the underlying restriction on the asset and not the maturity date of the investment. Therefore, certain long-term restricted cash and investments have contractual maturities within one year.

14

Table of Contents

NOTE 4. INVENTORY

Inventory consists of the following (in thousands):

	September 30, 2017	December 31, 2016
Raw materials	$ 378	$ 863
Work in process	2,951	2,343
Finished goods	2,856	738
Total	6,185	3,944
Less: non-current portion included in Other long-term assets	(379)	(606)
Inventory, net	$ 5,806	$ 3,338

We generally relieve inventory on a first-expiry, first-out basis. A portion of the manufacturing costs for inventory was incurred prior to regulatory approval of CABOMETYX and COMETRIQ and therefore was expensed as research and development costs when those costs were incurred, rather than capitalized as inventory. 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 $1.2 million for the nine months ended September 30, 2017 and $0.4 million for the comparable period in 2016. The non-current portion of inventory is expected to be used or sold in future periods more than 12 months from the date presented. As of September 30, 2017, the non-current portion of inventory consists of finished goods. As of December 31, 2016, the non-current portion of inventory consists of raw materials and a portion of the active pharmaceutical ingredient that is included in work in process inventories.

NOTE 5. PROPERTY AND EQUIPMENT

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

	September 30, 2017	December 31, 2016
Computer equipment and software	$ 14,242	$ 13,738
Leasehold improvements	4,715	6,646
Laboratory equipment	5,836	4,310
Furniture and fixtures	1,954	2,240
Construction-in-progress	15,627	19
	42,374	26,953
Less: accumulated depreciation and amortization	(23,118)	(24,882)
Property and equipment, net	$ 19,256	$ 2,071

Depreciation expense was $0.8 million during both the nine months ended September 30, 2017 and 2016.

Build-to-Suit Lease

On May 2, 2017, we entered into a Lease Agreement (the “Lease”) with Ascentris 105, LLC (“Ascentris”), to lease 110,783 square feet of space in office and research facilities located at 1851, 1801, and 1751 Harbor Bay Parkway, Alameda, California (the “Premises”). On October 16, 2017, we executed an amendment to the Lease for 19,778 square feet of additional space located at the Premises with terms consistent with the original Lease. See “Note 12. Commitments” for a description of the Lease.

In connection with the Lease, we received a tenant improvement allowance of $6.7 million from Ascentris, for the costs associated with the design, development and construction of tenant improvements for the Premises. We are obligated to fund all costs incurred in excess of the tenant improvement allowance and to certain indemnification obligations related to the construction activities. We evaluated our involvement during the construction period and determined the scope of the tenant improvements on portions of the Premises including the building shells did not qualify as “normal tenant improvements” under Accounting Standards Codification topic 840, Leases. Accordingly, for accounting purposes, we are the deemed owner of such portions of the Premises during the construction period. As such, we will capitalize the construction costs as a build-to-suit property within property and equipment, net, including the estimated fair value of the

Table of Contents

building shells that we are deemed to own at the lease inception date, as determined using a third-party appraisal. The capitalized construction costs will also include the estimated tenant improvements incurred by Ascentris. Accordingly, we capitalized $14.5 million of costs related to the Lease in construction-in-progress as of May 2, 2017, with a corresponding build-to-suit lease obligation in Other long-term liabilities. As of September 30, 2017, we have capitalized an additional $0.5 million to construction in progress for improvements to the Premises.

Once the construction is complete, we will consider the requirements for sale-leaseback accounting treatment, including evaluating whether all risks of ownership have been transferred back to Ascentris, as evidenced by a lack of continuing involvement in the leased property. If the arrangement does not qualify for sale-leaseback accounting treatment, the building assets will remain on our consolidated balance sheets at their historical cost.

NOTE 6. DEBT

The amortized carrying amount of our debt consists of the following (in thousands):

	September 30, 2017	December 31, 2016
Secured Convertible Notes due 2018 ("Deerfield Notes")	$ —	$ 109,122
Term loan payable	—	80,000
Total debt	$ —	$ 189,122

See "Note 7 - Debt" to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2016 filed with the SEC on February 27, 2017 for additional information on the terms of our debt, including a description of the material features of the Deerfield Notes.

Deerfield Notes

On June 28, 2017, we repaid all amounts outstanding under the Deerfield Notes. The repayment amount totaled $123.8 million which comprised $113.9 million in principal, including $13.9 million of interest paid in kind paid through the repayment date, a $5.8 million prepayment penalty associated with the early repayment of the notes and $4.2 million in accrued and unpaid interest. As a result of the early repayment, there was a $6.2 million loss on the extinguishment of the debt which comprised the prepayment penalty and the unamortized fees and costs on the date of the repayment.

Prior to our early repayment of the notes, the outstanding principal amount of the Deerfield Notes bore interest at the rate of 7.5% per annum to be paid in cash, quarterly in arrears, and 7.5% per annum to be paid in kind, quarterly in arrears, for a total interest rate of 15% per annum. The following is a summary of interest expense for the Deerfield Notes (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Stated coupon interest	$ —	$ 2,031	$ 4,151	$ 5,939
Interest paid in kind	—	2,031	4,151	5,939
Amortization of debt discount and debt issuance costs	—	121	182	327
Total interest expense	$ —	$ 4,183	$ 8,484	$ 12,205

The balance of unamortized fees and costs was $0.4 million as of December 31, 2016, which was recorded as a reduction of the carrying amount of the Deerfield Notes on the accompanying Condensed Consolidated Balance Sheet.

Silicon Valley Bank Loan and Security Agreement

On March 29, 2017, we repaid all amounts outstanding under our term loan with Silicon Valley Bank. The repayment included $80.0 million in principal plus $0.1 million in accrued and unpaid interest. There was no gain or loss on the extinguishment of debt as a result of the repayment of the term loan. Prior to our early repayment of the term loan, the principal amount outstanding under the term loan had accrued interest at 1.0% per annum, which was due and payable monthly.

In accordance with the terms of the loan and security agreement, we were required to maintain an amount equal to at least 100%, but not to exceed 107%, of the outstanding principal balance of the term loan on deposit in one or more

Table of Contents

investment accounts with Silicon Valley Bank or one of its affiliates as support for our obligations under the loan and security agreement. We were entitled to retain income earned on the amounts maintained in such accounts. The total collateral balance as of December 31, 2016 was $81.6 million and was reflected in our Condensed Consolidated Balance Sheet in Short-term investments as the amounts were not restricted as to withdrawal. As a result of our repayment of the term loan, the compensating balance requirement was terminated as of March 29, 2017.

NOTE 7. 2014 WARRANTS

In connection with an amendment to the note purchase agreement for the Secured Convertible Notes due 2015, (the "Original Deerfield Notes"), in January 2014 we issued two-year warrants to purchase an aggregate of 1,000,000 shares of our common stock at an exercise price of $9.70 per share (the "2014 Warrants"). Subsequent to our March 2015 notification of our election to extend the maturity date of the Deerfield Notes, the exercise price of the 2014 Warrants was reset to $3.445 per share, the term was extended by two years to January 22, 2018, and the 2014 Warrants were transferred to Additional paid-in capital as of that date at their then estimated fair value of $1.5 million as their terms had become fixed.

On September 11, 2017, we issued an aggregate of 877,451 shares of common stock pursuant to the cashless exercises of the 2014 Warrants issued to an accredited investor transferee. The number of shares issued upon exercise was net of 122,549 shares withheld to effect the cashless exercise of the 2014 Warrants in accordance with their terms.

NOTE 8. STOCK-BASED COMPENSATION

We recorded and allocated employee 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,	
	2017	2016	2017	2016
Research and development expense	$1,663	$1,165	$4,741	$7,894
Selling, general and administrative expense	3,626	2,438	10,288	10,452
Total stock-based compensation expense	$5,289	$3,603	$15,029	$18,346

We use the Black-Scholes Merton option pricing model to value our stock options and ESPP purchases. The weighted average grant-date fair value per share of our stock options and ESPP purchases was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Stock options	$11.75	$8.59	$10.32	$4.31
ESPP	$6.85	$1.51	$5.29	$1.65

The fair value of stock options and ESPP purchases was estimated using the following assumptions:

	Stock Options			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Risk-free interest rate	1.70 %	1.07 %	1.68 %	1.09 %
Dividend yield	— %	— %	— %	— %
Expected volatility	58 %	76 %	61 %	76 %
Expected life	4.0 years	4.5 years	4.1 years	4.4 years

Table of Contents

	ESPP			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Risk-free interest rate	1.14 %	0.37 %	0.88 %	0.39 %
Dividend yield	— %	— %	— %	— %
Expected volatility	55 %	63 %	61 %	66 %
Expected life	6 months	6 months	6 months	6 months

We considered implied volatility as well as our historical volatility in developing our estimate of expected volatility. The expected life computation is based on historical exercise patterns and post-vesting termination behavior.

A summary of stock option activity for the nine months ended September 30, 2017 is presented below (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, 2016	24,999,665	$ 4.91		
Granted	821,260	$ 21.60		
Exercised	(4,282,847)	$ 3.94		
Forfeited	(204,525)	$ 8.14		
Options outstanding at September 30, 2017	21,333,553	$ 5.72	4.08 years	$ 395,212
Exercisable at September 30, 2017	15,961,685	$ 4.41	3.59 years	$ 316,415

As of September 30, 2017, a total of 24,037,291 shares were available for grant under our stock option plans.

A summary of restricted stock unit (“RSU”) activity for the nine months ended September 30, 2017 is presented below (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, 2016	2,469,791	$ 8.69		
Awarded	331,847	$ 22.03		
Vested and released	(348,294)	$ 4.63		
Forfeited	(111,603)	$ 10.89		
RSUs outstanding at September 30, 2017	2,341,741	$ 11.08	1.55 years	$ 56,740

NOTE 9. INCOME TAXES

Income tax expense consists of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Income tax expense	$ 3,206	$ —	$ 3,921	$ —

During the nine months ended September 30, 2017, we recorded income tax expense of $3.9 million, which primarily comprises our computed income tax expense of $5.2 million reduced by $1.2 million of excess benefits associated with equity compensation. The income tax expense for the three and nine months ended September 30, 2017 primarily relates to state taxes in jurisdictions outside of California, for which we do not have net operating loss carry-forwards due to a limited operating history.

18

Table of Contents

NOTE 10. NET INCOME (LOSS) PER SHARE

The following table sets forth a reconciliation of basic and diluted net income (loss) per share (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Net income (loss)	$81,382	$(11,284)	$115,738	$(105,345)
Net income allocated to participating securities	(221)	—	(368)	—
Net income allocable to common stock for basic net income (loss) per share	81,161	(11,284)	115,370	(105,345)
Adjustment to net income allocated to participating securities	14	—	23	—
Net income allocable to common stock for diluted net income (loss) per share	$81,175	$(11,284)	$115,393	$(105,345)
Weighted-average shares of common stock outstanding	294,269	256,319	292,776	238,024
Dilutive securities:				
Outstanding stock options, unvested RSUs and ESPP contributions	18,671	—	18,779	—
Weighted-average shares of common stock outstanding and dilutive securities	312,940	256,319	311,555	238,024
Net income (loss) per share, basic	$0.28	$(0.04)	$0.39	$(0.44)
Net income (loss) per share, diluted	$0.26	$(0.04)	$0.37	$(0.44)

The 2014 Warrants were participating securities and the warrant holders did not have a contractual obligation to share in our losses. See “Note 7 - 2014 Warrants” for a description of the 2014 Warrants.

The following table sets forth potentially dilutive shares of common stock that are not included in the computation of diluted net income (loss) per share because to do so would be anti-dilutive (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Outstanding stock options, unvested RSUs and ESPP contributions	583	30,474	1,108	30,474
Deerfield Notes	—	33,890	—	33,890
4.25% convertible senior subordinated notes due 2019 (the “2019 Notes”)	—	413	—	413
2014 Warrants	—	1,000	—	1,000
Total potentially dilutive shares	583	65,777	1,108	65,777

The 2014 Warrants were exercised in September 2017. The Deerfield Notes were repaid in June 2017. The 2019 Notes were converted and redeemed between August and November 2016.

Table of Contents

NOTE 11. FAIR VALUE MEASUREMENTS

The following table sets forth the classification of our financial assets within the fair value hierarchy that were measured and recorded at fair value on a recurring basis as of September 30, 2017 and December 31, 2016. We did not have any financial liabilities measured and recorded at fair value on a recurring basis as of those dates. The amounts presented exclude cash, but include investments classified as cash equivalents (in thousands):

	September 30, 2017		
	Level 1	Level 2	Total
Money market funds	$42,797	$—	$42,797
Commercial paper	—	168,738	168,738
Corporate bonds	—	187,160	187,160
U.S. Treasury and government sponsored enterprises	—	14,644	14,644
Total financial assets	$42,797	$370,542	$413,339
	December 31, 2016		
	Level 1	Level 2	Total
Money market funds	$71,457	$—	$71,457
Commercial paper	—	165,375	165,375
Corporate bonds	—	152,407	152,407
U.S. Treasury and government sponsored enterprises	—	70,727	70,727
Total financial assets	$71,457	$388,509	$459,966

We did not have any financial assets or liabilities classified as Level 3 in the fair value hierarchy as of September 30, 2017 or December 31, 2016 and there were no transfers of financial assets or liabilities classified as Level 3 during the nine months ended September 30, 2017 or the year ended December 31, 2016.

The carrying amounts of cash, trade and other receivables, accounts payable, accrued clinical trial liabilities, accrued compensation and benefits, and other liabilities approximate their fair values and are excluded from the tables above. 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 of similar assets as observable inputs for pricing, which are Level 2 inputs.

NOTE 12. COMMITMENTS

Leases

On May 2, 2017, we entered into the Lease with Ascentris for an aggregate of 110,783 square feet of space in office and research facilities located at the Premises in Alameda, California. We also have the right to make certain tenant improvements to the space leased on the Premises. The Lease has an initial term of 10 years with a target commencement date of February 1, 2018, and, subject to a partial twelve-month rent abatement period, rent payments will begin upon the target commencement date. 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. We are obligated to make lease payments totaling $24.1 million over the Lease term. 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 over the remainder of the initial term at 1601, 1701, 1751, and 1801 Harbor Bay Parkway, Alameda, California at a market rate determined according to the Lease.

We are deemed, for accounting purposes only, to be the owner of portions of the Premises, including two building shells, even though we are not the legal owner. See “Note 5. Property and Equipment - Build-to-Suit Lease” for a further description of the accounting for that portion of the Premises.

Table of Contents

On May 2, 2017, we also entered into an Agreement for Conditional Option to Amend Lease (the "Optional Amendment Agreement") with Ascentris. Under the terms of the Optional Amendment Agreement, a current tenant (the "Tenant") occupying approximately 16,343 square feet of the facility located at 1801 Harbor Bay Parkway was given the option to relocate to another building on the premises or terminate their current lease early, requiring them to relocate within six months from the termination date. Under the terms of the Optional Amendment Agreement, we would reimburse Ascentris for the first $1.5 million of costs incurred to induce the Tenant to relocate. In August 2017, the Tenant communicated to Ascentris that they were terminating their lease early. As of September 30, 2017, we have accrued $1.4 million for our anticipated reimbursement of costs to Ascentris for the Tenant's relocation. On October 16, 2017, we executed an amendment to the Lease for an additional 19,778 square feet of space located on the Premises, which includes the space vacated by the Tenant, with terms consistent with the original Lease.

As of September 30, 2017, the aggregate future minimum lease payments under our leases are as follows (in thousands):

	Operating leases	Other financing obligations [1]
Remainder of 2017	$ 1,006	$ —
Year Ending December 31,		
2018	2,802	566
2019	605	1,477
2020	630	1,685
2021	637	1,745
2022	646	1,814
Thereafter	3,465	10,441
	$ 9,791	$ 17,728

(1) Other financing obligations includes payments related to our build-to-suit lease.

Rent expense and sublease income were as follows for the periods presented (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Gross rental expense	$1,215	$1,972	$4,986	$7,424
less: Sublease income	—	(908)	(1,225)	(2,637)
Net rental expense	$1,215	$1,064	$3,761	$4,787

Letter of Credit

We obtained a standby letter of credit in May 2017 in the amount of $0.5 million, which may be drawn down by Ascentris in the event we fail to fully and faithfully perform all of our obligations under the Lease and to compensate Ascentris for all losses and damages Ascentris may suffer as a result of the occurrence of any default on our part not cured within the applicable cure period. As of September 30, 2017, none of the standby letter of credit amount has been used.

See "Note 13 - Commitments" to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2016 filed with the SEC on February 27, 2017 for a description of additional letters of credits that were entered into prior to December 31, 2016.

NOTE 13. CONCENTRATIONS OF CREDIT RISK

Financial instruments that potentially subject us to concentrations of credit risk are primarily trade and other receivables and investments. Investments consist of money market funds, commercial paper, corporate bonds with high credit quality, and securities issued by the U.S. Treasury and other government sponsored enterprises. All investments are maintained with financial institutions that management believes are creditworthy.

Trade and other receivables are unsecured and are concentrated in the pharmaceutical and biotechnology industries. Accordingly, we may be exposed to credit risk generally associated with pharmaceutical and biotechnology

Table of Contents

companies. We have incurred no bad debt expense since inception. As of September 30, 2017, 55% of our trade receivables are with Ipsen, which include the amounts due from two milestones totaling $45.0 million resulting from Ipsen's receipt of the validation from the EMA for the application for variation to the CABOMETYX marketing authorization for the addition of a new indication in first-line treatment of advanced RCC in adults. Payment for the first milestone of $20.0 million is due in the fourth quarter of 2017 and payment for the second milestone of $25.0 million is due in the first quarter of 2018. Ipsen historically has paid promptly.

The percentage of total revenues recognized by customer that represent 10% or more of total revenues was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Diplomat Specialty Pharmacy	13%	31%	19%	41%
Ipsen	33%	6%	18%	8%
Caremark L.L.C.	13%	9%	16%	8%
Affiliates of McKesson Corporation	10%	6%	12%	5%
Accredo Health, Incorporated	9%	9%	11%	7%
Daiichi Sankyo	—%	24%	—%	13%

All of our long-lived assets are located in the U.S. We have operations solely in the U.S., while some of our collaboration partners have headquarters outside of the U.S. and some of our clinical trials for cabozantinib are also conducted outside of the U.S.

The following table shows the revenues earned by geographic region. Net product revenues are attributed to regions based on the delivery location. Collaboration revenues are attributed to regions based on the location of our collaboration partner's headquarters (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
U.S.	$97,807	$41,971	$260,853	$87,757
Europe	50,680	5,223	60,704	11,116
Japan	4,023	15,000	10,848	15,000

We recorded losses of $0.2 million relating to foreign exchange fluctuations for both the nine months ended September 30, 2017 and 2016.

Table of Contents

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

The following discussion and analysis 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.

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, 2016, filed with the Securities and Exchange Commission, or SEC, on February 27, 2017. Operating results are not necessarily indicative of results that may occur in future periods. We undertake no obligation to update any forward-looking statement to reflect events after the date of this report.

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 VEGF, MET, AXL and RET receptors: CABOMETYX® (cabozantinib) tablets approved for previously treated 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 a reversible inhibitor of MEK, marketed under a collaboration with Genentech (a member of the Roche Group), 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 oncology indications.

While our commercialization efforts for CABOMETYX and COMETRIQ are focused in the United States, or U.S., we have licensed development and commercialization rights to cabozantinib outside of the U.S. to 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 are working closely with them on these activities.

Beyond our currently approved indications for RCC and MTC, we are pursuing other indications that have the potential to expand the number of cancer patients that could benefit from cabozantinib. Most advanced in the cabozantinib development program is our evaluation of CABOMETYX as a treatment for patients with previously untreated advanced RCC. On August 15, 2017, we submitted a supplemental New Drug Application, or sNDA, for cabozantinib in this indication to the U.S. Food and Drug Administration, or FDA, and on October 16, 2017, we announced that the FDA had accepted this filing and granted it Priority Review, assigning a Prescription Drug User Fee Act, or PDUFA, action date of February 15, 2018. The data in support of this filing are derived from CABOSUN, a randomized phase 2 trial comparing cabozantinib to sunitinib in the first-line treatment of patients with intermediate- or poor-risk RCC that was conducted by The Alliance for Clinical Trials in Oncology, or The Alliance, through our Cooperative Research and Development Agreement, or CRADA, with the National Cancer Institute's Cancer Therapy Evaluation Program, or NCI-CTEP. In May 2016, The Alliance informed us that CABOSUN met its primary endpoint demonstrating a statistically significant and clinically meaningful improvement of progression-free survival, or PFS, compared with sunitinib. The CABOSUN primary efficacy endpoint results were later confirmed by a blinded independent radiology review committee, or IRRC, in June 2017.

Closely behind our FDA filing for first-line RCC is our investigation of CABOMETYX as a treatment for patients with advanced hepatocellular carcinoma, or HCC, who have previously been treated with sorafenib. 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, our company-sponsored, global phase 3 trial of cabozantinib versus placebo in patients with advanced HCC who have been previously treated with sorafenib, 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. Based on the results of CELESTIAL, we plan to submit an sNDA to the FDA in the first quarter of 2018, for cabozantinib as a second-line treatment for patients with advanced HCC. We will discuss the trial results with regulatory authorities and determine next steps for the trial, including offering patients currently receiving placebo the opportunity to cross over to cabozantinib.

We believe that the available clinical data demonstrate that cabozantinib has the potential to be a broadly active anti-cancer agent that can make a meaningful difference in the lives of patients. Accordingly, we are engaged in a broad development program composed of over 50 ongoing or planned clinical trials to explore the clinical potential of cabozantinib in additional tumor types. This program includes Exelixis sponsored trials and trials conducted through our CRADA with NCI-CTEP or our investigator sponsored trial program. We are particularly interested in examining cabozantinib's potential in combination with immunotherapies to determine if such combinations further improve outcomes for patients. Building on preclinical and clinical observations that cabozantinib creates a more immune-permissive tumor environment potentially resulting in the 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 includes a phase 3 trial evaluating cabozantinib with nivolumab (Opdivo®) or with nivolumab and ipilimumab (Yervoy®) in first-line advanced RCC and a phase 2 evaluation of the same combinations in HCC, each 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 bladder cancer. Diversifying our exploration of immunotherapy combinations, we have also initiated a phase 1b dose escalation study evaluating the safety and tolerability of cabozantinib in combination with The Roche Group's, or Roche's, atezolizumab (Tecentriq®) in patients with locally advanced or metastatic solid tumors.

Significant progress also continues to be made under our December 2006 worldwide collaboration agreement with Genentech, or the Genentech Collaboration Agreement, with respect to the phase 3 clinical development program for our second approved cancer agent, cobimetinib. Genentech is now conducting three phase 3 pivotal trials exploring the combination of cobimetinib with atezolizumab in colorectal carcinoma (IMblaze370) and BRAF wild type melanoma population (IMspire170), and the combination of cobimetinib with atezolizumab and vemurafenib in BRAF V600 mutant melanoma (IMspire150 TRILOGY). Enrollment for IMblaze370 was completed in the first quarter of 2017, and Genentech has announced that top line results for the trial are expected during the first half of 2018. Should these trials prove positive, we believe that cobimetinib will have the potential to provide us with a second meaningful source of revenue. With respect to COTELLIC commercialization in the U.S. under the Genentech Collaboration Agreement, we have been fielding 25% of the sales force promoting COTELLIC in combination with Zelboraf® as a treatment for patients with BRAF mutation-positive advanced melanoma. However, following a recent commercial review, commencing in January 2018, we and Genentech will scale back the personal promotion of COTELLIC in combination with Zelboraf as a treatment for patients with BRAF 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.

As we continue to maximize the clinical, therapeutic and commercial potential of cabozantinib and cobimetinib, we remain steadfast in our commitment to discover and develop 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 Exelixis compounds that are in earlier stages of clinical and regulatory development pursuant to our collaborations with Daiichi Sankyo Company, Limited, or Daiichi Sankyo, Merck and BMS.

Third Quarter 2017 Business Development Updates and Financial Highlights

During the third quarter of 2017, we continued to build infrastructure intended to support our anticipated growth and evolution beyond our current product pipeline. Significant business development updates and financial highlights for

the quarter include:

Business Development Updates

- In July 2017, BMS initiated a phase 3 trial, CheckMate 9ER, to evaluate cabozantinib in combination with nivolumab with or without ipilimumab, versus sunitinib in patients with previously untreated, advanced or metastatic RCC. The primary endpoint for the trial is PFS.
- In July 2017, we entered into an amendment to our collaboration agreement with Genentech in connection with the settlement of our arbitration concerning claims asserted by us against Genentech related to the development, pricing and commercialization of COTELLIC. The amendment resolves our concerns outlined in the arbitration demand and provides for a favorably revised revenue and cost-sharing arrangement, effective as of July 1, 2017, that is applicable to current and potential future commercial uses of COTELLIC.
- In August 2017, we completed the submission of an sNDA with the FDA for cabozantinib as a treatment for patients with previously untreated advanced RCC.
- In September 2017, Ipsen received validation from the European Medicines Agency, or EMA, for the application for variation to the CABOMETYX marketing authorization for the addition of a new indication in first-line treatment of advanced RCC in adults.
- In September 2017, at the 2017 European Society for Medical Oncology Congress, we announced updated results from CABOSUN, including the IRRC analysis that confirmed the primary efficacy endpoint results of investigator-assessed PFS. Per the IRRC analysis, cabozantinib demonstrated a clinically meaningful and statistically significant 52% reduction in the rate of disease progression or death (HR 0.48, 95% CI 0.31-0.74, two-sided P=0.0008). The median PFS for cabozantinib was 8.6 months versus 5.3 months for sunitinib, corresponding to a 3.3 month (62%) improvement favoring cabozantinib over sunitinib.
- In September 2017, we announced that our partner Daiichi Sankyo reported positive top-line results from ESAX-HTN, a phase 3 pivotal trial of esaxerenone, a product of the companies' prior research collaboration, in patients with essential hypertension in Japan. With the trial achieving its primary endpoint, Daiichi Sankyo communicated its intention to submit a Japanese regulatory application for esaxerenone for an essential hypertension indication in the first quarter of 2018.
- In October 2017, we announced that BMS filed a Clinical Trial Authorization in Europe for a first-in-human study of a ROR t inverse agonist, which will trigger a $10.0 million milestone payment to us in the fourth quarter of 2017 under the terms of the parties' worldwide collaboration for compounds targeting retinoic acid-related orphan receptor, a family of nuclear hormone receptors implicated in inflammatory conditions.
- In October 2017, we announced that the FDA determined that our sNDA for cabozantinib for patients with previously untreated advanced RCC was sufficiently complete to permit a substantive review. The FDA granted Priority Review of the filing and assigned a PDUFA action date of February 15, 2018.
- In October 2017, we announced that CELESTIAL met its primary endpoint of OS, with cabozantinib providing a statistically significant and clinically meaningful improvement in OS compared to placebo in patients with advanced HCC. Based on these results, we plan to submit an sNDA to the FDA in the first quarter of 2018.

Financial Highlights

- Net income for the third quarter of 2017 was $81.4 million, or $0.28 per share, basic and $0.26 per share, diluted, compared to a net loss of $(11.3) million, or $(0.04) per share, basic and fully diluted, for the third quarter of 2016.
- Total revenues for the third quarter of 2017 increased to $152.5 million, compared to $62.2 million for the third quarter of 2016.
- Cost of goods sold for the third quarter of 2017 increased to $4.7 million, compared to $2.5 million for the third quarter of 2016.
- Research and development expenses for the third quarter of 2017 increased to $28.5 million, compared to $20.3 million for the third quarter of 2016.
- Selling, general and administrative expenses for the third quarter of 2017 increased to $38.1 million, compared to $32.5 million for the third quarter of 2016.
- Total other income (expense), net for the third quarter of 2017 increased to $3.4 million, compared to $(18.5) million for the third quarter of 2016.
- Cash and investments decreased to $422.3 million at September 30, 2017, compared to $479.6 million at December 31, 2016.

See “Results of Operations” below for a discussion of the detailed components and analysis of the amounts above. Although we reported net income of $115.7 million for the nine months ended September 30, 2017, we may not be able to maintain or increase profitability on a quarterly or annual basis and we are unable to accurately predict the extent of long-range future profits or losses. We expect to continue to spend significant additional amounts to fund the continued development and commercialization of cabozantinib. In addition, we intend to expand our product pipeline through the measured resumption of drug discovery and the evaluation of in-licensing and acquisition opportunities that align with our oncology drug expertise, which efforts could involve substantial costs. As a result, we are unable to predict the extent of any future profits or losses because we expect to continue to incur substantial operating expenses and, consequently, we will need to generate substantial revenues to maintain or increase profitability.

Challenges and Risks

We anticipate that we will continue to face a number of challenges and risks to our business that may impact our ability to execute on our business objectives. In particular, we anticipate that for the foreseeable future our ability to generate meaningful revenue 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 be approved. The commercial potential of CABOMETYX for the treatment of 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 generate meaningful product revenue from CABOMETYX is also affected by a number of other factors, including 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, efforts by payors to contain and slow increases in healthcare costs in the U.S. and worldwide. It is also potentially threatened by increasing interest among policymakers in the U.S. with respect to controlling pharmaceutical drug pricing practices. Our ability to fulfill the fullest commercial potential of cabozantinib also ultimately depends on our ability to expand the compound’s use by generating data in clinical development that will support regulatory approval of cabozantinib in additional indications. Our immediate focus in this regard is the potential regulatory approval of our sNDA for cabozantinib as a treatment for patients with previously untreated advanced RCC based upon data from CABOSUN. Obtaining this approval represents a significant challenge because CABOSUN was not originally designed as a registration enabling trial. However, given the positive nature of CABOSUN results, combined with the confirming analysis of such results by the IRRC, we submitted an sNDA to the FDA on August 15, 2017, which, as we announced on October 16, 2017, was deemed by the FDA as sufficiently complete to permit a substantive review. The FDA granted the file Priority Review and assigned a PDUFA action date of February 15, 2018.

Achievement of our business objectives will also depend on our ability to adapt our development and commercialization strategy to navigate the increasing prevalence of immunotherapy, which is both a competitive threat and a potential opportunity due to interest in the use of combination therapy to treat cancer.

In addition to the challenges we encounter while working toward the achievement of our development and commercial objectives, we also face significant challenges in our efforts to expand our pipeline through the measured resumption of internal drug discovery activities and the evaluation of in-licensing and acquisition opportunities. Internal discovery efforts require substantial technical, financial and human resources and may fail to yield product candidates for clinical development. Furthermore, we continue to operate in an environment with significant market competition for relevant product candidates, and, even if we are able to identify an attractive and available product candidate, we may not be able to in-license or acquire it on acceptable terms that would enable our continued growth as an organization.

Some of these challenges and risks are specific to our business, and others are common to companies in the pharmaceutical industry with development and commercial operations. For a complete discussion of challenges and risks we face, see “Risk Factors” in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Fiscal Year Convention

We have adopted a 52- or 53-week fiscal year policy that generally ends on the Friday closest to December 31st. Fiscal year 2017 will end on December 29, 2017 and fiscal year 2016 ended on December 30, 2016. For convenience, references in this report as of and for the fiscal periods ended September 29, 2017 and September 30, 2016, and as of and for the fiscal years ended December 29, 2017 and December 30, 2016, are indicated as being as of and for the

periods ended September 30, 2017 and September 30, 2016, and the years ended December 31, 2017 and December 31, 2016, respectively.

Table of Contents

Results of Operations

Revenues

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Product revenues:				
Gross product revenues	$111,148	$46,720	$289,365	$92,383
Discounts and allowances	(14,732)	(3,978)	(36,068)	(8,924)
Net product revenues	96,416	42,742	253,297	83,459
Collaboration revenues:				
Contract revenues [1]	45,000	15,000	47,500	20,000
License revenues [2]	7,572	3,780	21,335	8,570
Development cost reimbursements	2,316	—	5,623	—
Royalty and product supply revenues, net	1,206	672	4,650	1,844
Total collaboration revenues	56,094	19,452	79,108	30,414
Total revenues	$152,510	$62,194	$332,405	$113,873
Dollar change	$90,316		$218,532	
Percentage change	145 %		192 %	

(1) Includes milestone payments.

(2) Includes amortization of upfront payments.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
CABOMETYX	$90,362	$31,238	$233,582	$48,812
COMETRIQ	6,054	11,504	19,715	34,647
Net product revenues	$96,416	$42,742	$253,297	$83,459
Dollar change	$53,674		$169,838	
Percentage change	126 %		203 %	

For the three and nine months ended September 30, 2017, net product revenues increased 126% and 203%, respectively, as compared to the comparable periods in 2016. For the three and nine months ended September 30, 2017, the 189% and 379% increase in net product revenues for CABOMETYX as compared to the comparable period in 2016, was primarily due to a 174% and 353% increase, respectively, in the number of CABOMETYX units sold as well as an increase in the average selling price of the product. CABOMETYX was approved by the FDA on April 25, 2016 as a treatment for patients with advanced RCC who have received prior anti-angiogenic therapy. The increase in CABOMETYX sales volume was due to an increase in market share. For the three and nine months ended September 30, 2017, the 47% and 43% decrease in net product revenues for COMETRIQ as compared to the comparable periods in 2016, was primarily due to a 77% and 65% decrease, respectively, in the number of COMETRIQ units sold; the decrease in units sold was partially offset by an increase in the average selling price of the product. The decrease in COMETRIQ sales volume was primarily driven by the adoption of CABOMETYX by our customers.

Contract revenues for the three and nine months ended September 30, 2017 reflects recognition of two milestones totaling $45.0 million resulting from Ipsen’s receipt of the validation from the EMA for the application for variation to the CABOMETYX marketing authorization for the addition of a new indication in first-line treatment of advanced RCC in adults. Payment of the first milestone of $20.0 million is due in the fourth quarter of 2017 and payment of the second milestone of $25.0 million is due in the first quarter of 2018. Contract revenues for the nine months ended

September 30, 2017 also reflects recognition of a $2.5 million milestone earned from BMS related to the ROR program. Contract revenues for the three and nine months ended September 30, 2016 reflect recognition of $15.0 million from a milestone payment earned in

Table of Contents

September 2016 from Daiichi Sankyo related to its worldwide license of our compounds that modulate mineralocorticoid receptor, or MR, including CS-3150 (an isomer of XL550). Contract revenues for the nine months ended September 30, 2016 also reflects recognition of a $5.0 million from a milestone payment earned from Merck related to its worldwide license of our phosphoinositide-3 kinase-delta program.

License revenues consists of the recognition of the upfront payments and non-substantive milestone received in connection with our February 2016 collaboration agreement with Ipsen, or the Ipsen Collaboration Agreement, and the upfront payment received in connection with our January 2017 collaboration agreement with Takeda, or the Takeda Collaboration Agreement. For the three and nine months ended September 30, 2017, we recognized $4.7 million and $13.8 million, respectively, of such revenue in connection with the Ipsen Collaboration Agreement, as compared to $3.8 million and $8.6 million, respectively, during the comparable periods in 2016. For the three and nine months ended September 30, 2017, we recognized $2.8 million and $7.5 million, respectively, of such revenue in connection with the Takeda Collaboration Agreement. No such revenue was recognized for Takeda during the comparable periods in 2016. The increase in such revenues is due to the timing of the execution of those agreements.

Development cost reimbursements for the three and nine months ended September 30, 2017 consisted of reimbursements pursuant to our collaboration and license agreements, including $1.1 million and $2.3 million, respectively, under the Ipsen Collaboration Agreement and $1.2 million and $3.3 million, respectively, under the Takeda Collaboration Agreement. There were no such development cost reimbursements during the comparable periods in 2016.

Royalty and product supply revenues, net, primarily consisted of royalties on ex-U.S. net sales of COTELLIC under our collaboration agreement with Genentech for cobimetinib.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Diplomat Specialty Pharmacy	$20,460	$19,392	$62,909	$46,770
Ipsen	50,680	3,873	60,704	2,000 8,663
Caremark L.L.C.	20,272	5,591	52,526	8,728
Affiliates of McKesson Corporation	14,575	3,683	38,699	5,764
Accredo Health, Incorporated	13,445	5,880	36,504	8,340
Daiichi Sankyo	—	15,000	—	15,000
Others, individually less than 10% of total revenues for all periods presented	33,078	8,775	81,063	20,608
Total revenues	$152,510	$62,194	$332,405	$113,873

We recognize product revenue net of discounts and allowances that are further described in “Note 1. Organization and Summary of Significant Accounting Policies” to 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 27, 2017. The activities and ending reserve balances for each significant category of discount and allowance were as follows (in thousands):

	Chargebacks and discounts for prompt payment	Other customer credits and co-pay assistance	Rebates	Returns	Total
Balance at December 31, 2016	$ 1,802	$ 794	$2,627	$ 351	$5,574
Provision related to sales made in:					
Current period	22,823	5,135	8,389	—	36,347
Prior periods	(864)	—	584	—	(280)
Payments and customer credits issued	(22,221)	(4,501)	(7,533)	(351)	(34,606)

Balance at September 30, 2017	$ 1,540	$ 1,428	$4,067	$ —	$7,035

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. Balances as of December 31, 2016 have been reclassified to reflect that presentation.

Table of Contents

The increase in the reserve balance at September 30, 2017 was the result of an increase in product sales volume and a shift in payer mix to government programs, which was offset by payments, the issuance of customer credits and the prior period adjustments for chargebacks and certain rebates. We expect our discounts and allowances as a percentage of gross product revenue to increase during the remainder of 2017 as our business evolves and the number of patients participating in government programs increases, the discounts or rebates to government payers increase, and the engagement in commercial contracting which may result in additional discounts or rebates.

Cost of Goods Sold

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Cost of goods sold	$4,658	$2,455	$10,875	$4,700
Gross margin	95 %	94 %	96 %	94 %

Cost of goods sold is related to our product revenues and consists primarily of a 3% royalty payable to GlaxoSmithKline on net sales of any product incorporating cabozantinib, indirect labor costs, the cost of manufacturing, 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. The sale of products containing previously expensed materials resulted in a 1% and 6% reduction in the Cost of goods sold during the three and nine months ended September 30, 2017, respectively, as compared to a 6% and 5% reduction during the comparable periods in 2016. As of September 30, 2017 and December 31, 2016, our inventory includes approximately $0.5 million and $1.2 million, respectively, of materials that were previously expensed, are not capitalized, and will not be charged to Costs of goods sold in future periods. Write-downs related to excess and expiring inventory were $1.1 million for the three and nine months ended September 30, 2017 as compared to $0.4 million for the comparable periods in 2016.

The increase in Cost of goods sold was primarily related to the growth in sales of CABOMETYX due to an increase in market share.

Gross margin is net product revenues less cost of goods sold, divided by net product revenues. The increase in gross margin for the three and nine months ended September 30, 2017, as compared to the comparable periods in 2016, was related to the change in product mix as CABOMETYX sales volumes have increased while COMETRIQ volumes have decreased, and CABOMETYX tablets having a lower manufacturing cost than COMETRIQ capsules which have additional packaging requirements and are made in smaller batches due to limited demand.

Research and Development Expenses

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Research and development expenses	$28,543	$20,256	$79,967	$72,166
Dollar change	$8,287		$7,801	
Percentage change	41 %		11 %	

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

The increase in research and development expenses for the three months ended September 30, 2017, as compared to the comparable period in 2016, was primarily related to increases in personnel expenses, clinical trial costs and consulting and outside services. The increase in personnel expenses was $2.5 million for the three months ended September 30, 2017, as compared to the comparable period in 2016, and was primarily a result of an increase in

headcount associated with the re-launch of our internal discovery program and the build-out of our medical affairs organization. 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 $2.5 million for the three months ended September 30, 2017, as compared to

Table of Contents

the comparable period in 2016. The increase in clinical trial costs was predominantly due to start-up costs associated with CheckMate 9ER and the phase 1b trial of cabozantinib and atezolizumab in locally advanced or metastatic solid tumors; those increases were partially offset by decreases in costs related to METEOR, our completed phase 3 pivotal trial comparing CABOMETYX to everolimus in patients with advanced RCC. The increase in consulting and outside services was $1.1 million for the three months ended September 30, 2017, as compared to the comparable period in 2016, and was primarily in support of our medical affairs organization. The increase in research and development expenses also reflects a $1.0 million filing fee for the submission of our sNDA to the FDA in August 2017 for cabozantinib as a treatment for patients with previously untreated advanced RCC.

The increase in research and development expenses for the nine months ended September 30, 2017, as compared to the comparable period in 2016, was primarily related to an increase in personnel expenses and consulting and outside services that were partially offset by a decrease in stock-based compensation. The increase in personnel expenses of $6.7 million for the nine months ended September 30, 2017, as compared to the comparable period in 2016, was primarily a result of an increase in headcount associated with the re-launch of our internal discovery program and the build-out of our medical affairs organization. The increase in consulting and outside services was $1.2 million for the three months ended September 30, 2017, as compared to the comparable period in 2016, and was primarily in support of our medical affairs organization. The increase in research and development expenses also reflects a $1.0 million filing fee for the submission of our sNDA to the FDA. These increases were partially offset by a decrease in stock-based compensation of $3.2 million for the nine months ended September 30, 2017, as compared to the comparable period in 2016, primarily due to the 2016 recognition of stock-based compensation expense pertaining to the performance-based stock-options tied to the acceptance and anticipated approval of our CABOMETYX New Drug Application, or NDA, submission to the FDA and a 2016 bonus to our employees in the form of fully-vested restricted stock units.

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 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. Drug discovery expenses relate primarily to personnel expenses, consulting and outside services, and laboratory supplies. The “Other” category includes stock-based compensation and the allocation of general corporate costs to research and development. The expenditures for research and development expenses by category were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Development:				
Clinical trial costs	$9,754	$7,279	$27,966	$27,504
Personnel expenses	7,437	5,661	21,649	16,168
Consulting and outside services	2,464	1,938	6,370	6,453
Other development costs	3,771	2,228	10,318	8,273
Total development	23,426	17,106	66,303	58,398
Drug discovery	1,743	213	3,986	723
Other	3,374	2,937	9,678	13,045
Total	$28,543	$20,256	$79,967	$72,166

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, the results of and data from clinical trials, the potential indications for our drug candidates, the clinical and commercial potential for our drug candidates, and competitive

dynamics. We also make our research and development decisions in the context of our overall business strategy, 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

Table of Contents

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 approximately 50 ongoing or planned clinical trials across multiple indications. The most notable studies of this program are CELESTIAL, our company-sponsored phase 3 trial of cabozantinib in advanced HCC, our phase 3 study in collaboration with BMS, evaluating cabozantinib in combination with nivolumab or nivolumab and ipilimumab as compared to sunitinib in previously untreated patients with advanced RCC, and our phase 2 study, in collaboration with BMS, evaluating cabozantinib and nivolumab or nivolumab and ipilimumab in advanced HCC, as well as our phase 1b study, in collaboration with Roche, evaluating cabozantinib in combination with atezolizumab in patients with advanced malignancies. 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. As a result, we expect our research and development expenses to increase as we continue to develop cabozantinib and our 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 how many of those indications we will ultimately pursue regulatory approval for. In this regard, our decisions to pursue regulatory approval of cabozantinib for additional indications depend on several variables outside of our control, including the strength of the data generated in our prior, ongoing and potential future clinical trials. Furthermore, the scope and number of clinical trials required to obtain regulatory approval for each pursued indication is subject to the input of the applicable regulatory authorities, and we have not yet sought such input for all potential indications that we may elect to pursue, and 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 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 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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Selling, general and administrative expenses	$38,129	$32,463	$113,116	$103,143
Dollar change	$5,666		$9,973	
Percentage change	17 %		10 %	

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

The increase in selling, general and administrative expenses for the three and nine months ended September 30, 2017, as compared to the comparable periods in 2016, was primarily related to increases in personnel expenses, consulting

and outside services, and for the nine months ended September 30, 2017, legal and accounting costs; those increases were partially offset by a decrease in marketing costs. Personnel expenses increased by $2.0 million and $11.8 million for the three and nine months ended September 30, 2017, respectively, as compared to the comparable periods in 2016, primarily due to an increase in general and administrative headcount to support our commercial and research and development organizations, incentive compensation and the accrual for bonuses. Consulting and outside services increased by $4.3

Table of Contents

million and $6.0 million for the three and nine months ended September 30, 2017, respectively, as compared to the comparable periods in 2016, primarily due to increases in consulting for marketing activities. Legal and accounting expenses increased by $3.8 million for the nine months ended September 30, 2017 as compared to the comparable period in 2016, primarily due to increases in costs related to our dispute with Genentech. Marketing costs decreased by $3.3 million and $14.6 million for the three and nine months ended September 30, 2017, respectively, as compared to the comparable periods in 2016, primarily due to a decrease in losses recognized under our collaboration agreement with Genentech driven by Genentech's change in cost allocation approach in December 2016.

Other Income (Expense), Net

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Interest income and other, net	$3,408	$3,059	$6,098	$4,010
Interest expense	—	(7,834)	(8,679)	(28,575)
Loss on extinguishment of debt	—	(13,773)	(6,239)	(13,773)
Total other income (expense), net	$3,408	$(18,548)	$(8,820)	$(38,338)
Dollar change	$21,956		$29,518	
Percentage change	(118)%		(77)%	

Interest expense decreased by $7.8 million and $19.9 million for the three and nine months ended September 30, 2017, respectively, as compared to the comparable periods in 2016, primarily due to conversions and the redemption of the 4.25% convertible senior subordinated notes due 2019, or the 2019 Notes, during the third and fourth quarters of 2016, the repayment of the Silicon Valley Bank term loan in March 2017 and the repayment of the Secured Convertible Notes due 2018, or the Deerfield Notes, in June 2017.

During the nine months ended September 30, 2017, we recognized a $6.2 million loss on extinguishment of debt resulting primarily from the prepayment penalty associated with the early the repayment of the Deerfield Notes.

During the three and nine months ended September 30, 2016, we recognized a $13.8 million loss on extinguishment of debt associated with the conversion of $285.3 million in aggregate principal amount of the 2019 Notes for 53,704,911 shares of our Common Stock. See "Note 6 - Debt" in our "Notes to Condensed Consolidated Financial Statements" for more information on the repayment of our debt during 2017.

The increase in interest income and other, net for the three and nine months ended September 30, 2017, as compared to the comparable periods in 2016, was primarily related to increases in interest income. Interest income increased by $0.4 million and $1.8 million for the three and nine months ended September 30, 2017, respectively, as compared to the comparable periods in 2016, due to both an increase in our investment balances and an increase in the yield earned on those investments. Interest income and other, net also included the recognition of a $2.3 million and $3.0 million gain during the three and nine months ended September 30, 2017, respectively, related to the sale of our 9% interest in Akarna Therapeutics, Ltd. to Allergan Holdco UK Limited in August 2016. We acquired our interest in Akarna in 2015, in exchange for intellectual property rights related to the Exelixis discovered compound XL335.

Income Tax Expense

Income tax expense was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Income tax expense	$ 3,206	$ —	$ 3,921	$ —

Income tax expense for the three and nine months ended September 30, 2017 primarily relates to state taxes in jurisdictions outside of California, 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 any federal taxable income.

Table of Contents

Liquidity and Capital Resources

We have incurred net losses in every fiscal year since our inception, with the exception of the 2011 fiscal year, and as of September 30, 2017, we had an accumulated deficit of $1.9 billion. Although we reported net income of $115.7 million for the nine months ended September 30, 2017, we may not be able to maintain or increase profitability on a quarterly or annual basis and we are unable to accurately predict the extent of long-range future profits or losses. We expect to continue to spend significant additional amounts to fund the continued development and commercialization of cabozantinib. In addition, we intend to expand our product pipeline through the measured resumption of drug discovery and the evaluation of in-licensing and acquisition opportunities that align with our oncology drug expertise, which efforts could involve substantial costs. As a result, we are unable to predict the extent of any future profits or losses because we expect to continue to incur substantial operating expenses and, consequently, we will need to generate substantial revenues to maintain or increase profitability.

Since the launch of our first commercial product in January 2013, through September 30, 2017, we have generated an aggregate of $463.0 million in net product revenues, including $253.3 million for the nine months ended September 30, 2017. Other than sales of CABOMETYX and COMETRIQ, we have derived substantially all of our revenues since inception from collaborative arrangements, including upfront and milestone payments and research funding we earn from any products developed from the collaborative research. 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. (which may be impacted by our ability to obtain FDA approval for cabozantinib for additional indications); achievement of clinical, regulatory and commercial milestones and the amount of royalties, if any, from sales of CABOMETYX and COMETRIQ under the Ipsen Collaboration Agreement; 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 commercialization activities for cabozantinib and any pipeline expansion efforts.

As of September 30, 2017, we had $422.3 million in cash and investments, which included $417.6 million available for operations and $4.7 million of long-term restricted investments. We anticipate that our current cash and cash equivalents, and 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 business, and as a result we may not have the cash resources to fund our current and future operating plans. This in turn could require us to raise additional funds, which we may be unable to do, which could have a material adverse effect on our business. We may also choose to raise additional funds through the issuance of equity or debt to meet our business objectives.

Sources and Uses of Cash

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

	Nine Months Ended September 30,	
	2017	2016
Net cash provided by operating activities:		
Net income (loss)	$115,738	$(105,345)
Adjustments to reconcile net income (loss) to net cash provided by operating activities	9,017	45,945
Changes in operating assets and liabilities	(12,497)	184,695
Net cash provided by operating activities	112,258	125,295
Net cash provided by (used in) investing activities	54,628	(155,638)
Net cash used in financing activities	(169,215)	(72)
Net decrease in cash and cash equivalents	(2,329)	(30,415)
Cash and cash equivalents at beginning of period	151,686	141,634
Cash and cash equivalents at end of period	$149,357	$111,219

30

Table of Contents

Operating Activities

Cash flows provided by operating activities represent the cash receipts and disbursements related to all of our activities other than investing and financing activities. Cash provided by operating activities is derived by adjusting our net income (loss) for: non-cash operating items such as depreciation and amortization, non-cash interest expense 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. Our operating activities provided cash of $112.3 million for the nine months ended September 30, 2017, as compared to $125.3 million for the same period in 2016. The decrease in cash provided by operating activities was primarily due to the upfront nonrefundable payment of $200.0 million received from Ipsen in the nine months ended September 30, 2016 in consideration for the exclusive license and other rights contained in our collaboration and license agreement with Ipsen along with increasing operating expenses. That decrease was partially offset by a $169.8 million increase in net product revenues and the upfront nonrefundable payment of $50.0 million received from Takeda in the nine months ended September 30, 2017 in consideration for the exclusive license and other rights contained in the Takeda Collaboration Agreement.

Investing Activities

Our investing activities provided cash of $54.6 million for the nine months ended September 30, 2017, as compared to $155.6 million of cash used during the same period in 2016.

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 $277.0 million and the sale of investments of $37.3 million, less cash used for investment purchases of $259.2 million.

Cash used by investing activities for the nine months ended September 30, 2016 was primarily due to investment purchases of $262.7 million, less cash from the maturity of unrestricted and restricted investments of $103.3 million.

Financing Activities

Cash used in financing activities was $169.2 million for the nine months ended September 30, 2017, as compared to $0.1 million during the same period in 2016.

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.

Cash used in financing activities for the nine months ended September 30, 2016 was primarily a result of payments on conversion of convertible notes and employees' tax withholding paid to taxing authorities from shares withheld on stock awards which was almost completely offset by the issuance of common stock under our equity incentive plans.

Contractual Obligations

As of September 30, 2017, we have contractual obligations in the form of capital and operating leases, purchase obligations and other long-term liabilities.

On June 28, 2017, we repaid all amounts outstanding under the Deerfield Notes. On March 29, 2017, we repaid all amounts outstanding under our term loan with Silicon Valley Bank. See "Note 6 - Debt" in the accompanying Notes to the Condensed Consolidated Financial Statements for more information on the Deerfield Notes and our loan and security agreement with Silicon Valley Bank.

On May 2, 2017, we entered into a Lease Agreement, or the Lease, with Ascentris 105, LLC, or Ascentris, for an aggregate of 110,783 square feet of space in office and research facilities located at 1851, 1801 and 1751 Harbor Bay Parkway, Alameda, California. We are obligated to make lease payments totaling $24.1 million over the Lease term. The Lease further provides that we are obligated to pay to Ascentris certain costs, including taxes and operating expenses. See "Note 12. Commitments" in the accompanying Notes to the Condensed Consolidated Financial Statements for a description of the Lease.

There were no other material changes outside of the ordinary course of business in our contractual obligations from those as of December 31, 2016.

Table of Contents

Off-Balance Sheet Arrangements

As of September 30, 2017, we did not have any material off-balance-sheet arrangements, as defined by applicable SEC regulations.

Critical Accounting Estimates

The preparation of our Condensed Consolidated Financial Statements conforms to accounting principles generally accepted in the U.S. which requires management to make judgments, estimates and assumptions that affect the reported amounts of assets, liabilities, revenue 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 deductions from revenues (such as rebates, chargebacks, sales returns and sales allowances), the period of performance, identification of deliverables and evaluation of milestones with respect to our collaborations, the amounts of revenues and expenses under our profit and loss sharing agreement, recoverability of inventory, certain accrued liabilities including accrued clinical trial liability, and 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 share based compensation reflect the more significant estimates and assumptions used in the preparation of our Condensed Consolidated Financial Statements.

There have been no significant changes in our critical accounting policies and estimates during the nine months ended September 30, 2017, 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, 2016 filed with the SEC on February 27, 2017.

Recent Accounting Pronouncements

For a description of the expected impact of recent accounting pronouncements, see “Note 1 - Organization and Summary of Significant Accounting Policies” in the “Notes to Condensed Consolidated Financial Statements” included in this Quarterly Report on Form 10-Q and “Note 1 - Organization and Summary of Significant Accounting Policies” in the “Notes to Consolidated Financial Statements” included in our Annual Report on Form 10-K filed with the SEC on February 27, 2017.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our market risks at September 30, 2017 have not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2016, filed with the SEC on February 27, 2017.

Our exposure to market risk for changes in interest rates relates to our investment portfolio, and for prior periods, our debt. As of September 30, 2017, 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 and liabilities of $(1.5) million as compared to a net positive change in the fair value of $0.3 million as of December 31, 2016.

In addition, we have exposure to fluctuations in certain foreign currencies in countries in which we conduct clinical trials. As of September 30, 2017, and December 31, 2016, approximately $1.7 million and $2.2 million, respectively, of our accrued clinical trial liability was owed in foreign currencies. An adverse change of one percentage point in the foreign currency exchange rates would not have resulted in a material impact as of either of the dates presented. We recorded losses of $0.2 million relating to foreign exchange fluctuations for both the nine months ended September 30, 2017 and 2016.

Table of Contents

Item 4. Controls and Procedures.

Evaluation of disclosure controls and procedures. Based on the evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) of the Securities Exchange Act of 1934, as amended, or the Exchange Act) required by Rules 13a-15(b) or 15d-15(b) of the Exchange Act, our Chief Executive Officer and Chief Financial Officer have concluded that as of the end of the period covered by this report, our disclosure controls and procedures were effective at the reasonable assurance level.

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

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

Table of Contents

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

On June 3, 2016, we filed a Demand for Arbitration before JAMS in San Francisco, California asserting claims against Genentech (a member of the Roche Group) related to its clinical development, pricing and commercialization of COTELLIC, and cost and revenue allocations arising from COTELLIC's commercialization in the U.S. Our arbitration demand asserted that Genentech breached the parties' December 2006 collaboration agreement for the development and commercialization of COTELLIC, by, amongst other breaches, failing to meet its diligence and good faith obligations.

On July 13, 2016, Genentech asserted a counterclaim for breach of contract seeking monetary damages and interest related to the cost allocations under the collaboration agreement. On December 29, 2016, however, Genentech withdrew its counterclaim against us and stated that it would unilaterally change its approach to the allocation of promotional expenses arising from commercialization of the COTELLIC plus Zelboraf® combination therapy, both retrospectively and prospectively. The revised allocation approach substantially reduced our exposure to costs associated with promotion of the COTELLIC plus Zelboraf combination in the U.S.

On June 8, 2017, the parties settled the arbitration, which was dismissed with prejudice. The settlement was memorialized in a settlement agreement dated July 19, 2017, that included a mutual release of all claims arising out of or related in any way to the causes of actions and/or claims that were asserted or could have been asserted based on the facts alleged in the arbitration. The settlement does not provide for payments in settlement of the asserted claims; as part of the settlement, on July 19, 2017, the parties entered into an amendment to the Genentech Collaboration Agreement. Pursuant to the terms of the amendment, we continue to be entitled to a share of U.S. profits and losses received in connection with the commercialization of COTELLIC in accordance with the profit share tiers as originally set forth in the collaboration agreement, which share continues to decrease as sales of COTELLIC increase. However, effective as of July 1, 2017, the revenue for each sale of COTELLIC applied to the profit and loss statement for the collaboration agreement, or the Collaboration P&L, is being calculated using the average of the quarterly net selling prices of COTELLIC and any additional branded Genentech product(s) prescribed with COTELLIC in such sale. While we also continue to share U.S. commercialization costs for COTELLIC, the amendment expressly sets forth that the amount of commercialization costs Genentech is entitled to allocate to the Collaboration P&L is to be reduced based on the number of Genentech products in any given combination including COTELLIC. In addition, the amendment also sets forth the parties' confirmation and agreement that we have exercised our co-promotion option and that, as such, we have the option to co-promote current and future Genentech combinations that include COTELLIC in the U.S.

We may from time to time become a party to other legal proceedings arising in the ordinary course of business.

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 occurs, 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 30, 2016 filed with the Securities and Exchange Commission on February 27, 2017.

Risks Related to Our Business and Industry

Our future prospects are critically dependent upon the commercial success of CABOMETYX for advanced RCC and the further clinical development and commercial success of cabozantinib in additional indications.

Our mission is to maximize the clinical and commercial potential of cabozantinib and cobimetinib and position Exelixis for future growth through the resumption of our discovery efforts and expansion of our development pipeline. We anticipate that for the foreseeable future our ability to generate meaningful revenue 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. The commercial potential of

Table of Contents

CABOMETYX for the treatment of 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, we may need to reduce our operating expenses or raise additional funds to execute our business plan, which would have a material adverse effect on our business and financial condition, results of operations and growth prospects. Furthermore, as a consequence of the Ipsen Collaboration Agreement, we rely heavily upon Ipsen's regulatory, commercial, medical affairs, and other expertise and resources for commercialization of CABOMETYX in territories outside of the U.S. and Japan. If Ipsen is unable to, or does not invest the resources necessary to successfully commercialize CABOMETYX for the treatment of advanced RCC in the European Union and other international territories where it may be approved, this could reduce the amount of revenue we are due to receive under Ipsen Collaboration Agreement, thus resulting in harm to our business and operations.

We also believe that there are commercial opportunities for cabozantinib in therapeutic indications beyond advanced RCC, and we are dedicating substantial proprietary resources to developing cabozantinib into a potentially broad and significant oncology franchise. Even following the approval of CABOMETYX for the treatment of advanced RCC in the U.S. and European Union, our success remains contingent upon, among other things, successful clinical development, regulatory approval and market acceptance of cabozantinib in additional indications, such as previously untreated advanced RCC, advanced HCC, non-small cell lung cancer, and other forms of cancer. We cannot be certain that that the clinical trials we and our collaboration partners are currently conducting, or may conduct in the future, will demonstrate adequate safety and efficacy in clinical testing to receive regulatory approval. Should we prove unsuccessful in advancing the further clinical development and commercialization of cabozantinib beyond MTC or advanced RCC, we may be unable to execute our business plan and our revenues and financial condition would be materially adversely affected.

We are heavily dependent on our partner, Genentech (a member of the Roche group), for the successful development, regulatory approval and commercialization of cobimetinib.*

The terms of our collaboration agreement 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, 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 immuno-oncology agents, a promising and 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.

The commercial success of cabozantinib, as CABOMETYX tablets for advanced RCC and as COMETRIQ capsules for MTC, and if approved for additional indications, will depend upon the degree of market acceptance among physicians, patients, health care payers, and the medical community.

Our ability to successfully commercialize cabozantinib, as CABOMETYX tablets for advanced RCC and COMETRIQ capsules for MTC is, and if approved for additional indications, will be, highly dependent upon the extent to which cabozantinib gains market acceptance among physicians, patients, health care payers such as Medicare, Medicaid and commercial plans and the medical community. If cabozantinib does not achieve an adequate level of acceptance, we may not generate significant future product revenues. The degree of market acceptance of CABOMETYX and COMETRIQ will depend upon a number of factors, including:

- the effectiveness, or perceived effectiveness, of cabozantinib in comparison to competing products;
- the safety of cabozantinib, including the existence of serious side effects of cabozantinib and their severity in comparison to those of any competing products;
- cabozantinib's relative convenience and ease of administration;

- unexpected results connected with analysis of data from future or ongoing clinical trials;
- the timing of cabozantinib label expansions for additional indications, if any, relative to competitive treatments;

Table of Contents

- the price of cabozantinib relative to competitive therapies and any new government initiatives affecting pharmaceutical pricing;
- the strength of CABOMETYX sales efforts, marketing, medical affairs and distribution support;
- the sufficiency of commercial and government insurance coverage and reimbursement; and
- our ability to enforce our intellectual property rights with respect to cabozantinib.

If we are unable to maintain or scale adequate sales, marketing, market access and distribution capabilities 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, medical affairs and product distribution capabilities requires significant resources. If we cannot maintain effective sales, marketing, market access, medical affairs and product distribution capabilities, we may be unable to maximize the commercial potential of cabozantinib in its approved indications. Also, to the extent that the commercial opportunities for cabozantinib 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 cabozantinib 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.

We currently rely on third-party providers to handle storage and distribution for our commercial supply of both CABOMETYX and COMETRIQ in the U.S. While we have expanded our U.S. distribution and pharmacy channels in connection with the approval of CABOMETYX by the FDA for the treatment of patients with advanced RCC in the U.S., we still rely on a relatively limited distribution network to dispense COMETRIQ in fulfillment of prescriptions in the U.S. Furthermore, we rely on our collaboration partners for the commercialization and distribution of CABOMETYX and COMETRIQ in territories outside of the U.S., as well as for access and distribution activities for the approved products under the Named Patient Use program or a similar program with the effect of introducing earlier patient access to COMETRIQ and CABOMETYX.

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 cabozantinib 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 cabozantinib on acceptable terms, our commercialization efforts and those of our collaboration partners may be delayed or otherwise adversely affected, which could have 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, 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, educational programs, pricing policies, and relationships with healthcare providers or other entities. The AKS prohibits, among other things, 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 and providing anything at less than its fair market value. The AKS has been broadly interpreted to apply to manufacturer arrangements with prescribers, purchasers and formulary managers, among others;
-

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 food, drug, device, or cosmetic that is adulterated or misbranded;

Table of Contents

- federal civil and criminal false claims laws 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 their implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- 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);
- 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 that require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on our marketed drugs, as well as certain state and municipal government price reporting laws that require us to provide justifications where drug prices exceed a certain price increase threshold (and participation in these programs and compliance with the applicable 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);
- federal and state financial transparency laws, which generally require certain types of expenditures in the U.S. to be tracked and reported (and compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships with healthcare providers and healthcare entities, which could potentially have a negative effect on our business and/or increase enforcement scrutiny of our activities);
- proposals by state legislatures and regulators to impose caps on the amount that pharmaceutical manufacturers may compensate healthcare providers for certain services (which could potentially restrict, or increase enforcement scrutiny with respect to, certain of our activities); and
- federal and state healthcare fraud and abuse laws, FDA rules and regulations, as well as false claims laws, including the civil False Claims Act, which 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 "whistleblowers," may potentially then share in amounts paid by the entity to the government in fines or settlement. The filing of qui tam actions has caused a number of pharmaceutical, medical device and other healthcare companies to have to defend civil False Claims Act actions. When an entity is determined to have violated the civil False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

The legislative and regulatory landscape for privacy and data protection 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,

Table of Contents

govern the collection, use and disclosure of personal information. 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), which will be replaced on May 28, 2018 by the more restrictive General Data Protection Regulation (Regulation (EU) 2016/679) and the Swiss Federal Act on Data Protection, regulate the processing of personal data within the European Union and between countries in the European Union and countries outside of the European Union, including the U.S. Failure to provide adequate privacy protections and maintain compliance with the new EU-U.S. Privacy Shield framework, which will replace the previous safe harbor mechanisms, could jeopardize business transactions across borders and result in significant penalties, These laws could create liability for us or increase our cost of doing business.

If we are unable to obtain both adequate 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 cabozantinib. There has been negative publicity regarding, and increasing legislative and enforcement interest in the U.S. with respect to, drug pricing and the use of specialty pharmacies, which may result in physicians being less willing to participate in our patient access programs and thereby limit our ability to increase patient access and adoption of cabozantinib. Specifically, there have been several recent U.S. Congressional inquiries and proposed bills 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, and reform government program reimbursement methodologies for drugs. If future legislation were to impose direct governmental price controls and access restrictions, it could have a significant adverse impact on our business and financial results.

In addition, in some foreign countries, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control under the respective national health system. In these countries, price negotiations with governmental authorities or payers can take six to twelve months or longer after marketing authorization is granted for a product, which has the potential to substantially delay broad availability of the product in some of those countries. To obtain reimbursement and/or pricing approval in some countries, we and 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 to support health technology appraisal. The conduct of such a study could be expensive and result in delays in the commercialization of CABOMETYX. Third-party payers are challenging the prices charged for medicinal products and services, and many third-party payers limit reimbursement for newly-approved health care products. In particular, third-party payers may limit the indications for which they will reimburse patients who use CABOMETYX or COMETRIQ. Cost-control initiatives could decrease the price we and our collaboration partner, Ipsen, might establish for CABOMETYX, which would result in lower license revenues to us.

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 Affordable Care Act, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the

Table of Contents

Affordable Care Act. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of any certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. The Trump administration has also announced that it will discontinue the payment of cost-sharing reduction (CSR) payments to insurance companies until Congress approves the appropriation of funds for the CSR payments. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the Affordable Care Act. A bipartisan bill to appropriate funds for CSR payments has been introduced in the Senate, but the future of that bill is uncertain. Further, each chamber of Congress has put forth multiple bills this year designed to repeal or repeal and replace portions of the Affordable Care Act. Although none of these measures has been enacted by Congress to date, Congress may consider other legislation to repeal and replace elements of the Affordable Care Act. Moreover, certain politicians, including the President, have announced plans to regulate the prices of pharmaceutical products. Congress has also signaled an intent to address pharmaceutical pricing, with Senate hearings to examine the cost of prescription drugs held on June 13 and October 17, 2017. Federal legislators have proposed legislation that would require pharmaceutical manufacturers to report price increases and provide a public justification for increases that exceed given benchmarks and authorize the U.S. Department of Health and Human Services to negotiate the price of Part D prescription drugs. Other proposals would allow drug importation from Canada and potentially other countries. 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. We cannot predict what form such regulatory actions may take and how they could affect us.

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. These entities could refuse or limit coverage for CABOMETYX and COMETRIQ, such as by using tiered reimbursement, 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 prospects for 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. 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.

In addition, the Trump Administration has indicated interest in taking measures pertaining to drug pricing, including potential proposals relating to Medicare price negotiations, importation of drugs from other countries and facilitating value-based arrangements between manufacturers and payers. At this time, it is unclear whether any of these proposals will be pursued and how they would impact our products or our future product candidates.

Table of Contents

State and local governments continue to consider prescription drug pricing transparency proposals. In October 2017, California Governor Jerry Brown signed legislation requiring pharmaceutical manufacturers to report certain price increases. We will review the specific provisions of this new law to assess how it will impact public perception or how it might otherwise affect us. Additionally, Ohio voters will consider a ballot initiative on November 7, 2017, which would require state agencies to pay no more for prescription drugs than the price paid by the U.S. Department of Veterans Affairs. We cannot predict the outcome of this ballot initiative, the market's perception or the potential impact on us.

Our competitors may develop products and technologies that impair the value of cabozantinib, cobimetinib and any future product candidates.

The pharmaceutical, biopharmaceutical and biotechnology industries are highly diversified and are characterized by rapid technological change. In particular, the area of novel oncology therapies is a rapidly evolving and competitive field. Specifically, the indication of advanced RCC is highly competitive and several novel therapies and combinations of therapies are in advanced stages of clinical development in this indication, and may compete with or displace cabozantinib. 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. Some of our competitors have entered into collaborations with leading companies within our target markets, including some of our existing collaborators. Some of our competitors are further along in the development of their products than we are. 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. 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. Our products may become less marketable if we are unable to successfully adapt our development strategy to address the likelihood that this new approach to treating cancer with immuno-oncology agents will become prevalent in indications for which our products are approved, most notably advanced RCC, and in additional indications where we may seek regulatory approval. Furthermore, the complexities of such a strategy has and may continue to require collaboration with some of our competitors.

The markets for which we intend to pursue regulatory approval of cabozantinib and for which Roche and Genentech intend to pursue regulatory approval for cobimetinib are highly competitive. Further, our competitors may be more effective at using their technologies to develop commercial products. 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. 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 of which we are not aware at an earlier stage of development that may compete with cabozantinib, cobimetinib, and our other product candidates.

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

Under the FDCA, the FDA can approve an Abbreviated New Drug Application, or ANDA, for a generic version of a branded drug without the applicant undertaking the human clinical testing necessary to obtain approval to market a new drug. The FDA can also approve a 505(b)(2) NDA that relies on the agency's findings of safety and/or effectiveness for a previously approved drug. The filing of an ANDA or 505(b)(2) NDA with respect to cabozantinib could have an adverse impact on our stock price. Moreover, if any such ANDAs or 505(b)(2) NDAs were to be approved and the patents covering cabozantinib were not upheld in litigation, or if a generic competitor is found not to infringe these 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, after the introduction of a generic competitor, a significant percentage of the sales of any branded product are typically lost to the generic product.

Clinical testing of 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 a product candidate, even if it is approved for other indications, is ineffective or has an unacceptable safety profile that may significantly decrease the likelihood of regulatory approval in a new indication. For example, COMET-1 and COMET-2, our two phase 3 pivotal trials of cabozantinib in metastatic castration-resistant prostate cancer, or mCRPC, failed to meet their respective primary endpoints of

Table of Contents

demonstrating a statistically significant increase in OS for patients treated with cabozantinib as compared to prednisone and to demonstrate improvement in pain response for patients treated with cabozantinib as compared to mitoxantrone/prednisone. Based on the outcome of the COMET trials, we deprioritized the clinical development of cabozantinib in mCRPC.

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 our 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 our product candidates, including:

- lack of efficacy or harmful side effects;
- negative or inconclusive clinical trial results may require us to conduct further testing or to abandon projects that we had expected to be promising;
- our competitors may discover or commercialize other compounds or therapies that show significantly improved safety or efficacy compared to our 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;
- patient registration or enrollment in our clinical testing may be lower than we anticipate, resulting in the delay or cancellation of clinical testing;
- failure by our collaborators to supply us on a timely basis with the product required for a combination trial;
- failure of our third-party contract research organization or investigators to satisfy their contractual obligations, including deviating from trial protocol; and
- regulators or institutional review boards may withhold authorization to commence or conduct clinical trials of a 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 our clinical testing of our 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.

We may not be able to rapidly or effectively continue the further development of our 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.

Completion of clinical trials may take several years or more, but the length of time generally varies substantially according to the type, complexity, novelty and intended use of the product candidate. The duration and the cost of clinical trials may vary significantly over the life of a project as a result of factors relating to the clinical trial, including, among others:

- 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.

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.

Table of Contents

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy and uncertain, and may not result in regulatory approvals for our product candidates, which could adversely affect our business.

The activities associated with the research, development and commercialization of our products and 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 filing 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 our 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 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.

We are committed to the discovery, development and promotion of new medicines with the potential to improve care and outcomes for people with cancer. In this regard, we have resumed 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 fail to yield product candidates for clinical development for a number of reasons, including where the research methodology used may not be successful in identifying potential product candidates, or where potential product candidates may, on further study, be shown to have inadequate efficacy, harmful side effects, suboptimal pharmaceutical profile or other characteristics suggesting that they are unlikely to be effective 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 competitive area, and many other companies are pursuing the same or similar product candidates to those that we may consider attractive. Established companies, in particular, 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 a relevant product candidate 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

Table of Contents

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.

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.

Risks Related to Our Capital Requirements and Financial Results

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, 2017, we had $422.3 million in cash and investments, which included $417.6 million available for operations and $4.7 million of long-term restricted investments. Our business operations grew substantially during 2016 and experienced further development during the nine months ended September 30, 2017. In order to maintain business growth and maximize the clinical and commercial opportunities for cabozantinib and cobimetinib, 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, 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, medical affairs and distribution capabilities for CABOMETYX in advanced RCC and COMETRIQ in the approved MTC indications;
- the achievement of stated regulatory and commercial milestones under the Ipsen Collaboration Agreement;
- 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 untreated advanced RCC, and in other indications, both in the U.S. and abroad;
- our ability to timely prepare and submit an sNDA for cabozantinib as a treatment for patients with advanced HCC;
- 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 European Union;
- 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, continued research and development 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. 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

Table of Contents

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.

We have a history of net losses and may incur net losses in the future, and may be unable to maintain profitability.*

We have incurred net losses in every fiscal year since our inception, with the exception of the 2011 fiscal year, and as of September 30, 2017, we had an accumulated deficit of $1.9 billion. Although we reported net income of $115.7 million for the nine months ended September 30, 2017, we may not be able to maintain or increase profitability on a quarterly or annual basis and we are unable to accurately predict the extent of long-range future profits or losses. We expect to continue to spend significant additional amounts to fund the continued development and commercialization of cabozantinib. In addition, we intend to expand our product pipeline through the measured resumption of drug discovery and the evaluation of in-licensing and acquisition opportunities that align with our oncology drug expertise, which efforts could involve substantial costs. As a result, we are unable to predict the extent of any future profits or losses because we expect to continue to incur substantial operating expenses and, consequently, we will need to generate substantial revenues to maintain or increase profitability.

Since the launch of our first commercial product in January 2013, through September 30, 2017, we have generated an aggregate of $463.0 million in net product revenues, including $253.3 million for the nine months ended September 30, 2017. Other than sales of CABOMETYX and COMETRIQ, we have derived substantially all of our revenues since inception from collaborative arrangements, including upfront and milestone payments and research funding we earn from any products developed from the collaborative research. 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 and the amount of royalties, if any, from sales of CABOMETYX and COMETRIQ under the Ipsen Collaboration Agreement; 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 commercialization activities for cabozantinib and any pipeline expansion efforts.

We are exposed to risks related to foreign currency exchange rates.

Most of our foreign expenses incurred are associated with establishing and conducting clinical trials for cabozantinib. The amount of these expenses will be impacted by fluctuations in the currencies of those countries in which we conduct clinical trials. Our agreements with the foreign sites that conduct such clinical trials generally provide that payments for the services provided will be calculated in the currency of that country, and converted into U.S. dollars using various exchange rates based upon when services are rendered or the timing of invoices. When the U.S. dollar weakens against foreign currencies, the U.S. dollar value of the foreign-currency denominated expense increases, and when the U.S. dollar strengthens against these currencies, the U.S. dollar value of the foreign-currency denominated expense decreases. Consequently, changes in exchange rates may affect our financial position and results of operations.

Global credit and financial market conditions could negatively impact the value of our current portfolio of cash equivalents, short-term investments or long-term investments and our ability to meet our financing objectives.

Our cash and cash equivalents are maintained in highly liquid investments with remaining maturities of 90 days or less at the time of purchase. Our short-term and long-term investments consist primarily of readily marketable debt securities with remaining maturities of more than 90 days at the time of purchase. While as of the date of this report we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents, short-term investments or long-term investments since September 30, 2017, no assurance can be given that a deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or investments or our ability to meet our financing objectives.

Our financial results are impacted by management’s selection of accounting methods and certain assumptions and estimates.*

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

Table of Contents

circumstances, yet may result in our reporting materially different results than would have been reported under a different alternative.

Certain accounting policies are critical to the presentation of our financial condition and results of operations. 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. Significant estimates that may be made by us include assumptions used in the determination of revenue recognition, discounts and allowances from gross revenue, inventory and stock-based compensation. Although we base our estimates and judgments on historical experience, our interpretation of existing accounting literature and on various other assumptions that we believe to be reasonable under the circumstances, if our assumptions prove to be materially incorrect, actual results may differ materially from these estimates.

In addition, future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our financial position or results of operations. New pronouncements 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, prospects for profitability or financial position. For example, in May 2014, the Financial Accounting Standards Board issued an Accounting Standards Update entitled Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers (Topic 606), or ASU 2014-09, which will replace existing revenue recognition guidance in U.S. generally accepted accounting pronouncements when it becomes effective for us in the first quarter of fiscal year 2018. ASU 2014-09 will not have a material impact on the recognition of revenue from product sales. ASU 2014-09 will impact the timing of recognition of revenue for our Ipsen and Takeda collaboration arrangements. We expect to reclassify deferred revenue to accumulated deficit (a concept known as “lost revenue”) for amounts associated with these collaboration arrangements upon recording our transition adjustment in the first quarter of 2018, primarily due to the timing of recognition of revenue related to intellectual property licenses that we have transferred for development and commercialization of our products. Additionally, for all of our collaboration arrangements, the timing of recognition of certain of our development and regulatory milestones could change as a result of the variable consideration guidance included in ASU 2014-09. In any event, we will continue to evaluate the impact of the new standard on all of our revenues, including those mentioned above, and our preliminary assessments may change in the future based on our continuing evaluation. The application of existing or future financial accounting standards, particularly those relating to the way we account for revenues and costs, could have a significant impact on our reported results.

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 (known as MSD outside of the U.S. and Canada), 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 existing collaborators for the development and commercialization of compounds under the collaborations subjects us to, and our dependence on future collaborators for development and commercialization of additional compounds will subject 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 cobimetinib, 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, 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;

45

Table of Contents

- 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;
- 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 revenue 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 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, 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 for additional indications beyond the advanced RCC and MTC.

We lack the 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 who, on our behalf, manufacture clinical and commercial supplies of CABOMETYX and COMETRIQ, and will continue to do so for the foreseeable future. To establish and manage this supply chain requires a significant financial commitment, the creation of numerous third-party contractual relationships and continued oversight of these third parties. Although we maintain significant resources to directly oversee the activities and relationships with companies in our supply chain effectively, we do not have direct control over their operations. Our third-party 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 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, and 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. Additionally, as part of the Ipsen Collaboration Agreement, we are responsible for the manufacturing and supply of finished, labeled cabozantinib products. Failure to meet our supply obligations under the

Table of Contents

collaboration could impair Ipsen's ability to successfully commercialize cabozantinib and generate revenues to which we are entitled under the collaboration.

Risks Related to Our Intellectual Property

Data breaches and cyber-attacks could compromise our intellectual property or other sensitive information and cause significant damage 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. We believe that companies have been increasingly subject to a wide variety of security incidents, cyber-attacks and other attempts to gain unauthorized access. 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 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, customers and others. Cyber-attacks could cause us to incur significant remediation costs, result in product development delays, disrupt key business operations and divert attention of management and key information technology resources. Our network security and data recovery measures and those of our vendors may not be adequate to protect against such security breaches and disruptions. These incidents could also subject us to liability, expose us to significant expense and cause significant harm to our reputation and business.

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

Our success will depend in part upon our ability to obtain patents and maintain adequate protection of the intellectual property related to our technologies and products. The patent positions of biopharmaceutical companies, including our patent position, are generally uncertain and involve complex legal and factual questions. We will be able to protect our intellectual property rights from unauthorized use by third parties only to the extent that our technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. We will continue to apply for patents covering our technologies and products as, where and when we deem 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. As a result, 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 may be substantial and the outcome can be uncertain. An adverse outcome may allow third parties to use our intellectual property without a license and negatively impact our business.

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

Table of Contents

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. Compulsory licensing of life-saving drugs is also becoming increasingly popular in developing countries either through direct legislation or international initiatives. Such compulsory licenses could be extended to include our products or product candidates, which could limit our potential revenue opportunities. 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 obtain or could require substantial time and expense. Third parties may accuse us of employing their proprietary technology without authorization. In addition, third parties may obtain patents that relate to our technologies and claim that use of such technologies infringes on their patents. 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 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 third parties. We may not be able to obtain these licenses at a reasonable cost, 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 these employees, independent contractors or we 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

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, 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

Table of Contents

and retaining qualified individuals is difficult. In addition, the physical expansion of our operations 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.

Our collaborations with outside scientists 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.

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 headquarters are located in the San Francisco Bay Area, California and, therefore our facilities are vulnerable to damage from earthquakes. We do not carry earthquake insurance. 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.

We plan to move our headquarters and may face disruption and turnover of employees.*

In 2018, we plan to move our corporate headquarters from South San Francisco, California to Alameda, California. As a result, we expect to incur additional expenses, including those related to tenant improvements to and furniture for the new corporate headquarters, as well as moving and exit costs, and may encounter disruption of operations related to the move, all of which could have an adverse effect on our financial condition and results of operations. In addition, relocation of our corporate headquarters may make it more difficult to retain certain of our employees, and any resulting need to recruit and train new employees could be disruptive to our 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, 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 radioactive and biological materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

49

Table of Contents

Our research and development processes involve the controlled use of hazardous materials, including chemicals and radioactive 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, these 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. These claims might be made directly by consumers, health care providers, pharmaceutical companies or others selling or testing our products. We have obtained limited product liability insurance coverage for our clinical trials and commercial activities for cabozantinib in the amount of $20.0 million per occurrence and $20.0 million in the aggregate. However, our insurance may not reimburse us or may not be sufficient to reimburse us for expenses or losses we may suffer. Moreover, if insurance coverage becomes more expensive, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. On occasion, juries have awarded large judgments in class action lawsuits for claims based on drugs that had unanticipated side effects. In addition, the pharmaceutical, biopharmaceutical and biotechnology industries, in general, have been subject to significant medical malpractice litigation. A successful product liability claim or series of claims brought against us could harm our reputation and business and would decrease our cash reserves.

Risks Related to Our Common Stock

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

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

- the commercial success of both CABOMETYX and COMETRIQ and the revenues we generate from those approved products;
- customer ordering patterns for CABOMETYX and COMETRIQ, which may vary significantly from period to period;
- 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;
- costs associated with maintaining our sales, marketing, medical affairs and distribution capabilities for CABOMETYX, COMETRIQ and COTELLIC;
- our ability to obtain regulatory approval for cabozantinib as a treatment for patients with previously untreated advanced RCC;
- our ability to timely prepare and submit an sNDA for cabozantinib as a treatment for patients with advanced HCC;
- the achievement of stated regulatory and commercial milestones, under our collaboration agreements;

50

Table of Contents

- 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 corporate 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;
- 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 may be extremely 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 results or delays in our or our collaborators' clinical trials;
- the announcement of FDA approval or non-approval, or delays in the FDA review process, of cabozantinib or our collaborators' product candidates or those of our competitors or actions taken by regulatory agencies with respect to our, our collaborators' or our competitors' clinical trials;
- 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 with respect to cabozantinib or our clinical trials for cabozantinib;
- the announcement of new products by our competitors;
- 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;

Table of Contents

- 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;
- FDA or international regulatory actions;
- third-party coverage and reimbursement policies;
- disposition of any of our technologies or compounds; and
- general market, economic and political conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

These factors, as well as general economic, political and market conditions, may materially adversely affect the market price of our common stock. In addition, the stock markets in general, and the markets for biotechnology and pharmaceutical stocks in particular, have historically experienced significant volatility that has often been unrelated or disproportionate to the operating performance of particular companies. For example, negative publicity regarding drug pricing and price increases by pharmaceutical companies has negatively impacted, and may continue to negatively impact, the markets for biotechnology and pharmaceutical stocks. Likewise, as a result of the United Kingdom's pending withdrawal from the European Union 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 potential repeal and/or replacement of all or portions of the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, 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, upon a purchase under our employee stock purchase plan and upon exercise of certain outstanding warrants. 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;

Table of Contents

- 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.

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

Under the Internal Revenue Code, or 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. We concluded, as of December 31, 2016, 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, or NOLs. Furthermore, our ability to utilize our NOLs, other than the NOLs expected to be utilized to offset income in 2017, is conditioned upon our attaining profitability and generating U.S. federal taxable income. We have incurred significant cumulative operating losses since our inception; thus, we do not know whether or when we will generate the U.S. federal taxable income necessary to utilize our remaining NOLs. A full valuation allowance has been provided for the entire amount of our remaining NOLs.

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

On September 11, 2017, we issued an aggregate of 877,451 shares of common stock pursuant to the cashless exercises of warrants issued to an accredited investor transferee that were originally issued to Deerfield Partners, L.P. and Deerfield International Master Fund, L.P. in January 2014 in connection with a financing arrangement. The warrants were exercisable for an aggregate of 1,000,000 shares of common stock and had an exercise price of $3.445 per share. The number of shares issued upon exercise was net of 122,549 shares withheld to effect the cashless exercise of such warrants in accordance with their terms.

All of the shares of common stock identified above were issued pursuant to the exemption from the registration requirements of the Securities Act of 1933, as amended, or the Securities Act, afforded by Section 3(a)(9) of the Securities Act. We received no cash proceeds from such issuances of common stock.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit/ Appendix Reference	Filing Date	
3.1	Amended and Restated Certificate of Incorporation of Exelixis, Inc.	10-K	000-30235	3.1	3/10/2010	

Table of Contents

Exhibit Number	Exhibit Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit/ Appendix Reference	Filing Date	
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 Ownership and Merger Merging X-Ceptor Therapeutics, Inc. with and into Exelixis, Inc.	8-K	000-30235	3.1	10/15/2014	
3.5	Certificate of Change of Registered Agent and/or Registered Office of 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*	Third Amendment dated July 19, 2017, to Collaboration Agreement between Exelixis, Inc. and Genentech dated December 22, 2006	10-Q	000-30235	10.5	8/2/2017	
10.2**	Second Amendment dated September 14, 2017, to Collaboration and License Agreement by and between Exelixis, Inc. and Ipsen Pharma SAS					X
10.3	Exelixis, Inc. Non-Employee Director Equity Compensation Policy					X
10.4	Exelixis, Inc. Change in Control and Severance Benefit Plan, as amended and restated.					X
12.1	Statement Re Computation of Earnings to Fixed Charges					X
31.1	Certification required by Rule 13a-14(a) or Rule 15d-14(a).					X
31.2	Certification required by Rule 13a-14(a) or Rule 15d-14(a).					X
32.1‡	Certification by the Chief Executive Officer and the Chief Financial Officer of Exelixis, Inc., as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).					X
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document					X
101.PRE						X

XBRL Taxonomy Extension Presentation
Linkbase Document

Table of Contents

* Confidential treatment granted for certain portions of this exhibit.

** 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.

Table of Contents

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, 2017 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)