

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**FORM 10-Q**

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**(Mark One)**

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended July 1, 2016

or

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934** For the transition period from \_\_\_\_\_ to \_\_\_\_\_

**Commission File Number:** 000-30235

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**EXELIXIS, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**

(State or other jurisdiction of incorporation or organization)

**04-3257395**

(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  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  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of July 28, 2016, there were 230,325,741 shares of the registrant's common stock outstanding.

**EXELIXIS, INC.**  
**QUARTERLY REPORT ON FORM 10-Q**  
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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

EXELIXIS, INC.  
CONDENSED CONSOLIDATED BALANCE SHEETS  
(in thousands, except share and per share data)

	June 30, 2016 (unaudited)	December 31, 2015*
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 129,827	\$ 141,634
Short-term investments	198,292	25,426
Trade and other receivables	17,799	5,183
Inventory	2,808	2,616
Prepaid expenses and other current assets	4,657	3,806
Total current assets	353,383	178,665
Long-term investments	51,727	83,600
Long-term restricted cash and investments	4,150	2,650
Property and equipment, net	1,982	1,434
Goodwill	63,684	63,684
Other long-term assets	2,210	2,309
Total assets	\$ 477,136	\$ 332,342
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable	\$ 5,435	\$ 6,401
Accrued collaboration liability	16,993	10,938
Accrued clinical trial liabilities	15,681	18,071
Accrued compensation and benefits	10,307	3,629
Current portion of term loan payable	80,000	—
Current portion of convertible notes	27,500	—
Current portion of deferred revenue	14,631	—
Other accrued liabilities	22,248	13,212
Total current liabilities	192,795	52,251
Long-term portion of convertible notes	288,555	301,435
Long-term portion of term loan payable	—	80,000
Long-term portion of deferred revenue	180,838	—
Other long-term liabilities	1,082	2,960
Total liabilities	663,270	436,646
Commitments		
Stockholders' deficit:		
Preferred stock	—	—
Common stock, \$0.001 par value; 400,000,000 shares authorized; issued and outstanding: 230,241,106 and 227,960,943 shares at June 30, 2016 and December 31, 2015, respectively	230	228
Additional paid-in capital	1,848,910	1,832,741
Accumulated other comprehensive income (loss)	129	(232)
Accumulated deficit	(2,035,403)	(1,937,041)
Total stockholders' deficit	(186,134)	(104,304)
Total liabilities and stockholders' deficit	\$ 477,136	\$ 332,342

\* The condensed consolidated balance sheet as of December 31, 2015 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
<b>Revenues:</b>				
Net product revenues	\$ 31,618	\$ 7,992	\$ 40,717	\$ 17,380
Royalty, license and contract revenues	4,634	—	10,962	—
Total revenues	<u>36,252</u>	<u>7,992</u>	<u>51,679</u>	<u>17,380</u>
<b>Operating expenses:</b>				
Cost of goods sold	1,560	686	2,245	1,452
Research and development	22,984	24,506	51,910	46,788
Selling, general and administrative	35,823	12,789	70,680	22,320
Restructuring charge	1,021	1,291	1,115	860
Total operating expenses	<u>61,388</u>	<u>39,272</u>	<u>125,950</u>	<u>71,420</u>
Loss from operations	<u>(25,136)</u>	<u>(31,280)</u>	<u>(74,271)</u>	<u>(54,040)</u>
<b>Other income (expense), net:</b>				
Interest income and other, net	749	(123)	951	(130)
Interest expense	(12,628)	(11,959)	(25,042)	(24,362)
Total other income (expense), net	<u>(11,879)</u>	<u>(12,082)</u>	<u>(24,091)</u>	<u>(24,492)</u>
Net loss	<u>\$ (37,015)</u>	<u>\$ (43,362)</u>	<u>\$ (98,362)</u>	<u>\$ (78,532)</u>
Net loss per share, basic and diluted	<u>\$ (0.16)</u>	<u>\$ (0.22)</u>	<u>\$ (0.43)</u>	<u>\$ (0.40)</u>
Shares used in computing basic and diluted net loss per share	229,310	196,201	228,860	196,052

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Net loss	\$ (37,015)	\$ (43,362)	\$ (98,362)	\$ (78,532)
Other comprehensive income (loss) (1)	171	(113)	361	(53)
Comprehensive loss	<u>\$ (36,844)</u>	<u>\$ (43,475)</u>	<u>\$ (98,001)</u>	<u>\$ (78,585)</u>

(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 no reclassification adjustments to net 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.

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

	Six Months Ended June 30,	
	2016	2015
<b>Cash flows from operating activities:</b>		
Net loss	\$ (98,362)	\$ (78,532)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	456	684
Stock-based compensation expense	14,743	3,394
Accretion of debt discount and debt issuance costs	10,712	14,891
Accrual of interest paid in kind	3,908	—
Gain on sale of equity investment	—	(95)
Change in the fair value of warrants	—	549
Other	(1,138)	1,093
Changes in assets and liabilities:		
Trade and other receivables	(12,361)	746
Inventory	(192)	(227)
Prepaid expenses and other current assets	(851)	751
Other long term assets	99	202
Accounts payable, accrued compensation and benefits, and other accrued liabilities	14,289	(6,563)
Accrued collaboration liability	6,055	6,968
Clinical trial liabilities	(2,390)	(8,973)
Restructuring liability	(927)	(3,321)
Deferred revenue	195,469	(2,583)
Other long-term liabilities	(493)	(903)
Net cash provided by (used in) operating activities	<u>129,017</u>	<u>(71,919)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(1,083)	(94)
Proceeds from sale of property and equipment	112	1,295
Proceeds from equity investment	—	95
Proceeds from maturities of restricted cash and investments	2,650	12,247
Purchase of restricted cash and investments	(4,150)	(4,184)
Proceeds from sale of investments	17	—
Proceeds from maturities of investments	58,340	94,438
Purchases of investments	(199,396)	(46,217)
Net cash (used in) provided by investing activities	<u>(143,510)</u>	<u>57,580</u>
<b>Cash flows from financing activities:</b>		
Proceeds from exercise of stock options	2,207	—
Proceeds from employee stock purchase plan	479	274
Principal payments on debt	—	(4,381)
Net cash provided by (used in) financing activities	<u>2,686</u>	<u>(4,107)</u>
Net decrease in cash and cash equivalents	(11,807)	(18,446)
Cash and cash equivalents at beginning of period	141,634	80,395
Cash and cash equivalents at end of period	<u>\$ 129,827</u>	<u>\$ 61,949</u>

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

**EXELIXIS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(unaudited)**

**NOTE 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Organization**

Exelixis, Inc. (“Exelixis,” “we,” “our” or “us”) is a biopharmaceutical company committed to the discovery, development and commercialization of new medicines that will improve care and outcomes for people with cancer. Since its founding in 1994, three products discovered at Exelixis have progressed through clinical development, received regulatory approval, and entered the commercial marketplace. This portfolio includes two products derived from cabozantinib, an inhibitor of multiple tyrosine kinases including MET, AXL and VEGF receptors. They are CABOMETYX™ tablets for the treatment of advanced kidney cancer in the United States and COMETRIQ® capsules for the treatment of certain forms of thyroid cancer in both the United States and European Union. The third product is COTELLIC®, a product derived from cobimetinib, a selective inhibitor of MEK, marketed under a collaboration with Roche and Genentech (a member of the Roche Group) that has been approved in combination with ZELBORAF® (vemurafenib) to treat advanced melanoma in several major territories, including the United States and European Union.

**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 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 United States 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 adopted a 52- or 53-week fiscal year that generally ends on the Friday closest to December 31<sup>st</sup>. Fiscal year 2016 will end on December 30, 2016, and fiscal year 2015, ended on January 1, 2016. For convenience, references in this report as of and for the fiscal periods ended September 30, 2016, July 1, 2016 and July 3, 2015, and as of and for the fiscal years ended December 30, 2016 and January 1, 2016, are indicated as being as of and for the periods ended September 30, 2016, June 30, 2016, June 30, 2015, and the years ended December 31, 2016, and December 31, 2015, respectively.

Operating results for the six months ended June 30, 2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016 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, 2015, included in our Annual Report on Form 10-K filed with the SEC on February 29, 2016.

**Segment Information**

We operate as a single reportable segment.

**Use of Estimates**

The preparation of our consolidated financial statements is in conformity with accounting principles generally accepted in the United States 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 for deductions from revenues (such as rebates, chargebacks, sales returns and sales allowances) and the period of performance, identification of deliverables and evaluation of milestones with respect to our collaborations, recoverability of inventory, certain accrued liabilities including clinical trial and collaboration liability accruals, and share-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.

### **Limited Sources of Revenues and the Need to Raise Additional Capital**

We have incurred net losses since inception through June 30, 2016, with the exception of the 2011 fiscal year. We anticipate annual net losses for the foreseeable future. For the six months ended June 30, 2016, we incurred a net loss of \$98.4 million and as of June 30, 2016, we had an accumulated deficit of \$2.0 billion. These losses have had, and will continue to have, an adverse effect on our stockholders' deficit and working capital. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses or whether or when we will become profitable, if at all. Excluding fiscal 2011, our research and development expenditures and selling, general and administrative expenses have exceeded our revenues for each fiscal year, and we expect to spend significant additional amounts to fund the continued development and commercialization of cabozantinib. As a result, we expect to continue to incur substantial operating expenses and, consequently, we will need to generate significant additional revenues to achieve future profitability.

Since the launch of our first commercial product in January 2013, through June 30, 2016, we have generated an aggregate of \$115.0 million in net product revenues. Other than sales of CABOMETYX and COMETRIQ, we have derived substantially all of our revenues since inception from collaborative research and development agreements, which depend on royalties, license fees, the achievement of milestones, and research funding we earn from any products developed from the collaborative research.

The amount of our net losses will depend, in part, on: the level of sales of CABOMETYX in the U.S. for the treatment of advanced renal cell carcinoma ("RCC"); our sales of COMETRIQ; achievement of clinical, regulatory and commercial milestones and the amount of royalties, if any, from sales of cabozantinib under our collaboration with Ipsen Pharma SAS ("Ipsen"); our share of the net profits and losses for the commercialization of COTELLIC in the U.S. under our collaboration with Genentech (a member of the Roche group); 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, primarily with respect to expanded commercialization activities for cabozantinib.

As of June 30, 2016, we had \$384.0 million in cash and investments, which included \$298.2 million available for operations, \$81.6 million of compensating balance investments that we are required to maintain on deposit with Silicon Valley Bank, and \$4.2 million of long-term restricted investments. We anticipate that our current cash and cash equivalents, and short-term investments available for operations, and product revenues, will enable us to maintain our operations for a period of at least 12 months following the filing date of this report. Our capital requirements will depend on many factors, and we may need to use available capital resources and raise additional capital significantly earlier than we currently anticipate.

### **Revenue Recognition**

We recognize revenue from product sales and from license fees, milestones, contingent payments and royalties earned on research, collaboration and license arrangements.

See "Note 1 - Organization and Summary of Significant Accounting Policies" to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2015 for a description of our revenue recognition policies for product sales discounts and allowances, license and contract revenues under our collaboration agreement with Genentech and our Patient Assistance Program.

### **Net Product Revenues**

We recognize revenue when it is both realized or realizable and earned, meaning persuasive evidence of an arrangement exists, delivery has occurred, title has transferred, the price is fixed or determinable, there are no remaining customer acceptance requirements, and collectability of the resulting receivable is reasonably assured. For product sales in the United States, this generally occurs upon delivery of the product to a specialty pharmacy or distributor. For product sales in Europe, this generally occurs when our European distribution partner, Swedish Orphan Biovitrum ("Sobi"), has accepted the product.

In the United States, we sell our products, CABOMETYX and COMETRIQ, to specialty pharmacies and distributors that benefit from customer incentives and have a right of return. Prior to 2015, COMETRIQ had limited sales history and we could not reliably estimate expected future returns, discounts and rebates of the product at the time the product was sold to a single specialty pharmacy, therefore we recognized revenue when the specialty pharmacy provided the product to a patient based on the fulfillment of a prescription, which is frequently referred to as the "sell-through" revenue recognition model. In January 2015, we established that we had sufficient historical experience and data to reasonably estimate expected future

returns of COMETRIQ and the discounts and rebates due to payors at the time of shipment to the specialty pharmacy. Accordingly, beginning in January 2015 we began to recognize revenue upon delivery to the specialty pharmacy. This approach is frequently referred to as the “sell-in” revenue recognition model. In connection with the change in the timing of recognition of U.S. COMETRIQ sales, we recorded a one-time adjustment to recognize revenue that had previously been deferred under the “sell-through” revenue recognition model, resulting in the additional recognition of gross product revenues of \$2.6 million for the six months ended June 30, 2015; there were no such additional amounts recorded during the comparable period in 2016.

In determining discounts and allowances for the initial launch and sale of CABOMETYX, in addition to using payer data received from the specialty pharmacies and distributors that sell CABOMETYX and historical data for COMETRIQ, we also utilized claims data from third party sources for competitor products for the treatment of advanced RCC. Based in part on the availability of this third party data, we made the determination that we had sufficient experience and data to reasonably estimate expected future returns and the discounts and allowances due to payers at the time of shipment to the specialty pharmacy or distributor, and therefore record revenue for the product using the “sell-in” revenue recognition model. Net product revenues during the three and six months ended June 30, 2016 was impacted by the build of channel inventory related to the initial launch period for CABOMETYX.

We also utilize the “sell-in” revenue recognition model for sales to Sobi for all periods presented. Once Sobi has accepted the product, the product is generally no longer subject to return; therefore, we record revenue at the time Sobi has accepted the product. As described further in “Note 2 - Research and Collaboration Agreements”, under the terms of our collaboration and license agreement with Ipsen for the commercialization and further development of cabozantinib, we provided Sobi with a notice of termination of our distribution and commercial agreement for COMETRIQ which will become effective during the fourth quarter of 2016. Pursuant to our commercialization agreement with Sobi, we expect to repurchase the remaining product on hand from Sobi at the termination of that agreement.

As of June 30, 2016, we recorded reserves for expected future returns totaling \$0.7 million; there were no such reserves recorded as of December 31, 2015 or June 30, 2015.

### ***Royalty, License and Contract Revenues***

We enter into corporate collaboration and license agreements under which we may obtain upfront license fees, research funding, and contingent, milestone and royalty payments. Our deliverables under these arrangements may include intellectual property rights, distribution rights, delivery of manufactured product, participation on joint steering committees and/or research and development services. In order to account for the multiple-element arrangements, we identify the deliverables included within the arrangement and evaluate whether the delivered elements under these arrangements have value to our collaboration partner on a stand-alone basis and represent separate units of accounting. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver future goods or services, a right or license to use an asset, or another performance obligation. If we determine that multiple deliverables exist, the consideration is allocated to one or more units of accounting based upon the best estimate of the selling price of each deliverable. The selling price used for each deliverable will be based on vendor-specific objective evidence, if available, third-party evidence if vendor-specific objective evidence is not available, or estimated selling price if neither vendor-specific or third-party evidence is available. A delivered item or items that do not qualify as a separate unit of accounting within the arrangement shall be combined with the other applicable undelivered items within the arrangement. The allocation of arrangement consideration and the recognition of revenue then shall be determined for those combined deliverables as a single unit of accounting. For a combined unit of accounting, non-refundable upfront fees are recognized in a manner consistent with the final deliverable, which has generally been ratably over the period of continued involvement. Amounts received in advance of performance are recorded as deferred revenue. Upfront fees are classified as license revenues in our consolidated statements of operations.

We consider sales-based contingent payments to be royalty revenue which is generally recognized at the date the contingency is achieved. Royalties are recorded based on sales amounts reported to us for the preceding quarter.

For certain contingent payments under collaboration and license arrangements, we recognize revenue using the milestone method. Under the milestone method a payment that is contingent upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is an event: (i) that can be achieved based in whole or in part on either our performance or on the occurrence of a specific outcome resulting from our performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to us. The determination that a milestone is substantive requires estimation and judgment and is made at the inception of the arrangement. Milestones are considered substantive when the consideration earned from the achievement of the milestone is: (i) commensurate with either our performance to achieve



the milestone or the enhancement of value of the item delivered as a result of a specific outcome resulting from our performance to achieve the milestone, (ii) relates solely to past performance and (iii) reasonable relative to all deliverables and payment terms in the arrangement. In making the determination as to whether a milestone is substantive or not, we consider all facts and circumstances relevant to the arrangement, including factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether any portion of the milestone consideration is related to future performance or deliverables.

### **Recently Adopted Accounting Pronouncements**

In April 2015, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update No. 2015-05, *Customer’s Accounting for Fees Paid in a Cloud Computing Arrangement*, (“ASU 2015-05”). ASU 2015-05 provides guidance to customers about whether a cloud computing arrangement includes a software license. If a cloud computing arrangement includes a software license, then the customer should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the customer should account for the arrangement as a service contract. ASU 2015-05 was effective for all interim and annual reporting periods beginning after December 15, 2015 and therefore we adopted ASU 2015-05 in the three months ended March 31, 2016 on a prospective basis. The adoption of ASU 2015-05 did not have a material impact on our Condensed Consolidated Statements of Operations during the period of adoption and is not expected to have a material effect on our Consolidated Financial Statements in future periods.

### **Recently Issued Accounting Pronouncements**

In March 2016, the FASB issued Accounting Standards Update No. 2016-09, *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 the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for all interim and annual reporting periods beginning after December 15, 2016. Early adoption is permitted. We are currently evaluating the impact that the adoption of ASU 2016-09 will have on our consolidated financial statements and related disclosures.

## **NOTE 2: RESEARCH AND COLLABORATION AGREEMENTS**

### ***Ipsen Collaboration***

On February 29, 2016, we entered into a collaboration and license agreement (the “Agreement”) with Ipsen for the commercialization and further development of cabozantinib. Pursuant to the terms of the Agreement, Ipsen will have exclusive commercialization rights for current and potential future cabozantinib indications outside of the United States, Canada and Japan. We have agreed to collaborate on the development of cabozantinib for current and potential future indications.

In consideration for the exclusive license and other rights contained in the Agreement, Ipsen paid us an upfront nonrefundable payment of \$200.0 million in March 2016. We will be eligible to receive development and regulatory milestones, totaling up to \$252.5 million, including a \$60.0 million milestone payment upon approval of cabozantinib by the European Medicines Agency (“EMA”) in second-line RCC, milestone payments of \$10.0 million and \$40.0 million upon the filing and the approval of cabozantinib in second-line hepatocellular carcinoma, and additional milestones for other future indications. We will also be eligible to receive two \$10.0 million milestone payments upon the launch of the product in the first two of the following countries: Germany, France, Italy, Spain and the United Kingdom. The Agreement also provides that we will be eligible to receive contingent payments of up to \$525.0 million associated with the achievement of specified sales levels. We will also receive royalties on net sales of cabozantinib outside of the United States, Canada and Japan. We will receive a 2% royalty on the initial \$50.0 million of net sales, and a 12% royalty on the next \$100.0 million of net sales. After the initial \$150.0 million of sales, we will receive a tiered royalty of 22% to 26% on annual net sales; these tiers will reset each calendar year. We are primarily responsible for funding cabozantinib related development costs for existing trials; global development costs for potential future trials will be shared between the parties, with Ipsen to reimburse us for 35% of such costs. Pursuant to the terms of the Agreement, we will remain responsible for the manufacture and supply of cabozantinib for all development and commercialization activities under the Agreement. As part of the Agreement, we entered into a supply agreement which provides that through the end of the second quarter of 2018, we will supply finished, labeled product to Ipsen for distribution in the territories outside of the United States, Canada and Japan, and from the end of the second quarter of 2018 forward, we will supply primary packaged bulk tablets to Ipsen. No manufacturing rights were granted to Ipsen.

The agreement contains multiple elements, and the deliverables under the Agreement consist of intellectual property licenses, delivery of cabozantinib to Ipsen for all development and commercial activities, research and development services, and participation on the joint steering and development committees (as defined in the Agreement) with Ipsen. These

deliverables are non-contingent in nature. The Company determined that these deliverables do not have stand-alone value, because each one of them has value only if the Company meets its obligation to provide Ipsen with cabozantinib, which the Company deems to be the predominant deliverable under the Agreement. The Company also determined that the level of effort required of the Company to meet its obligations under the Agreement is not expected to vary significantly over the life of the Agreement. Accordingly, the Company 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 is being recognized ratably over the effective term of the agreement, which is early 2030, the current estimated patent expiration of cabozantinib in the European Union. We have also determined that the \$60.0 million milestone payment we are eligible to receive upon the approval of cabozantinib by the EMA in second-line RCC is 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 the agreement; upon achieving the milestone, the \$60.0 million to which we are contractually entitled will be deferred and recognized ratably over the remaining term of the Agreement. We have 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. Subsequent to February 29, 2016, we transferred the intellectual property rights to Ipsen, and participated in steering committee meetings which activities included regulatory filing activities, and planning for the production, delivery and distribution of manufactured product and therefore have begun recognition of the upfront payment under the Agreement. During the three and six months ended June 30, 2016, we have recognized \$3.6 million and \$4.8 million, respectively, in license revenue under the Agreement. As of June 30, 2016, short-term and long-term deferred revenue relating to the Agreement was \$14.4 million and \$180.8 million, respectively.

In connection with the establishment of the Agreement with Ipsen, we provided Sobi with a notice of termination of our distribution and commercialization agreement for COMETRIQ which will become effective during the fourth quarter of 2016, as Ipsen will become responsible for the continued distribution and commercialization of COMETRIQ for the approved medullary thyroid cancer indication in territories supported by Sobi. Pursuant to our commercialization agreement with Sobi we are required to pay a termination fee. As of June 30, 2016, we had a \$2.7 million accrual for the estimated termination fee to be paid to Sobi, the related expense, which was recorded during the three months ended March 31, 2016, is included in Selling, general and administrative expenses in the accompanying Condensed Consolidated Statements of Operations. Additionally, pursuant to our commercialization agreement with Sobi, we expect to repurchase unsold product from Sobi and have recorded a returns reserve of \$0.5 million as of June 30, 2016, the related charge for which is included in Net product revenues in the accompanying Condensed Consolidated Statements of Operations.

### ***Genentech Collaboration***

In December 2006, we out-licensed the development and commercialization of cobimetinib to Genentech (a member of the Roche group) pursuant to a worldwide collaboration agreement. We discovered cobimetinib internally and advanced the compound to investigational new drug (“IND”) status.

Genentech paid upfront and milestone payments of \$25.0 million in December 2006 and \$15.0 million in January 2007 upon signing of the collaboration agreement and with the submission of the IND application for cobimetinib. Under the terms of the agreement, we were responsible for developing cobimetinib through the determination of the maximum-tolerated dose in a phase 1 clinical trial, and Genentech had the option to co-develop cobimetinib, which Genentech could exercise after receipt of certain phase 1 data from us. In March 2008, Genentech exercised its option to co-develop cobimetinib. In March 2009, we granted to Genentech an exclusive worldwide revenue-bearing license to cobimetinib, at which point Genentech became responsible for completing the phase 1 clinical trial and subsequent clinical development.

The U.S. Food and Drug Administration (“FDA”) approved cobimetinib in the United States under the brand name COTELLIC on November 10, 2015. It is indicated in combination with vemurafenib as a treatment for patients with BRAF V600E or V600K mutation-positive advanced melanoma. COTELLIC in combination with vemurafenib has also been approved in multiple other territories including the European Union and Canada.

Under the terms of our collaboration agreement with Genentech for cobimetinib, we are entitled to a share of U.S. profits and losses for cobimetinib. The 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. We are entitled to low double-digit royalties on ex-U.S. net sales. In November 2013, we exercised an option under the collaboration agreement to co-promote in the United States. Following the approval of COTELLIC in the United States in November 2015, we began fielding 25% of the sales force promoting COTELLIC in combination with vemurafenib as a treatment for patients with BRAF V600E or V600K mutation-positive advanced melanoma.

We recorded net losses of \$4.6 million and \$11.9 million under the collaboration agreement during the three and six months ended June 30, 2016, respectively as compared to \$4.0 million and \$7.0 million for the comparable periods in 2015; those costs are included in Selling, general and administrative expenses on the accompanying Condensed Consolidated Statements of Operations. A portion of the liability for those costs, identified as Accrued collaboration liability on the accompanying Condensed Consolidated Balance Sheets, includes commercialization expenses that Genentech has allocated to the collaboration but are in dispute. 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 United States.

Our arbitration demand asserts that Genentech has breached the parties' contract for, amongst other breaches, failing to meet its diligence and good faith obligations. The demand seeks various forms of declaratory, monetary, and equitable relief, including without limitation that the cost and revenue allocations for COTELLIC be shared equitably consistent with the collaboration agreement's terms, along with attorneys' fees and costs of the arbitration. Genentech has asserted a counterclaim for breach of contract, which seeks monetary damages and interest related to the cost allocations under the collaboration agreement. While the ultimate outcome of the arbitration is difficult to predict, a resolution of the matter adverse to us could result in, among other things, significant payments and higher than expected commercialization costs, which may have a material adverse effect on our results of operations, cash flows or financial condition.

We also recognized license revenues of \$1.0 million and \$1.2 million for royalties on ex-U.S. net sales of COTELLIC during the three and six months ended June 30, 2016, respectively, based on sales amounts reported by Genentech for the preceding quarter. We recognized no such royalties during the comparable periods in 2015.

#### ***Other Collaborations***

During the six months ended June 30, 2016, we recognized \$5.0 million in contract revenues from a contingent payment received from Merck related to its worldwide license of our phosphoinositide-3 kinase-delta program. There was no such contract revenue during the three months ended June 30, 2016 or the comparable periods in 2015.

See "Note 2 - Research and Collaboration Agreements" to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2015 for a description of our existing collaboration agreements.

#### **NOTE 3: RESTRUCTURINGS**

Between March 2010 and May 2013, we implemented five restructurings (which we refer to collectively as the "2010 Restructurings") to manage costs and as a consequence of our decision in 2010 to focus our proprietary resources and development efforts on the development and commercialization of cabozantinib. In September 2014, as a consequence of the failure of COMET-1, one of our two phase 3 pivotal trials of cabozantinib in metastatic castration-resistant prostate cancer, we initiated a restructuring (which we refer to as the "2014 Restructuring") to enable us to focus our financial resources on the phase 3 pivotal trials of cabozantinib in advanced RCC and advanced hepatocellular carcinoma. See "Note 3 - Restructurings" to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2015 for additional information about the restructurings.

For the six months ended June 30, 2016 and 2015, we recorded a restructuring charge of \$1.1 million and \$0.9 million, respectively, for the restructurings. Both periods included the effect of the passage of time on our discounted cash flow computations ("accretion expense") for the exit, in prior periods, of certain of our South San Francisco buildings. During the three and six months ended June 30, 2016, the restructuring charge also included \$1.0 million in additional charges related to a decrease in anticipated proceeds under one of our existing subleases due to a tenant's default on the sublease. During the six months ended June 30, 2015, the restructuring charge also included \$1.8 million in additional charges due to the partial termination of one of our building leases, the impact of a new sublease executed in June 2015, changes in assumptions regarding anticipated sublease activities and additional facility-related charges related to the decommissioning and exit of certain buildings; the 2015 restructuring charge was partially offset by \$0.9 million in recoveries recorded in connection with the sale of excess equipment and other assets.

The total outstanding restructuring liability is included in the current and long-term portion of restructuring on the accompanying Condensed Consolidated Balance Sheets. The changes of these liabilities during the six months ended June 30, 2016, which related primarily to facilities, are summarized in the following table (in thousands):

	2010 Restructurings	2014 Restructuring	Total
Restructuring liability as of December 31, 2015	\$ 4,087	\$ 503	\$ 4,590
Restructuring charge	1,106	9	1,115
Proceeds from sale of assets	—	34	34
Cash payments, net	(1,694)	(347)	(2,041)
Other items	—	(34)	(34)
Restructuring liability as of June 30, 2016	\$ 3,499	\$ 165	\$ 3,664

We expect to pay accrued facility charges of \$3.7 million, net of cash received from our subtenants, through the end of the lease terms of the buildings, all of which end in May 2017. We expect to incur additional restructuring charges of approximately \$0.1 million relating to the effect of accretion expense through to the end of the lease terms of the buildings.

#### NOTE 4: 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 June 30, 2016 and December 31, 2015 (in thousands):

	June 30, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents	\$ 129,827	\$ —	\$ —	\$ 129,827
Short-term investments	198,148	150	(6)	198,292
Long-term investments	51,636	96	(5)	51,727
Long-term restricted cash and investments	4,150	—	—	4,150
Total cash and investments	\$ 383,761	\$ 246	\$ (11)	\$ 383,996

	December 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents	\$ 141,634	\$ —	\$ —	\$ 141,634
Short-term investments	25,484	5	(63)	25,426
Long-term investments	83,665	2	(67)	83,600
Long-term restricted cash and investments	2,650	—	—	2,650
Total cash and investments	\$ 253,433	\$ 7	\$ (130)	\$ 253,310

Under our loan and security agreement with Silicon Valley Bank, we are 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 balances were \$81.6 million as of both June 30, 2016 and December 31, 2015 and are reflected in our Condensed Consolidated Balance Sheets in short-term investments as of June 30, 2016 and long-term investments as of December 31, 2015; the change in classification from long-term to short-term was the result of a corresponding change in the classification for our term loan payable to Silicon Valley Bank which matures in May 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, 2015, for more information regarding the collateral balance requirements under our Silicon Valley Bank loan and security agreement.

As part of a purchasing card program with a bank we initiated during 2007, we are required to provide collateral in the form of a non-interest bearing certificate of deposit. Long-term restricted cash and investments includes a \$1.5 million certificate of deposit acquired during the three months ended June 30, 2016 in order to expand the program which we expect to pledge as collateral under the program shortly after June 30, 2016.

The following tables summarize our cash equivalents and investments by security type as of June 30, 2016 and December 31, 2015. The amounts presented exclude cash, but include investments classified as cash equivalents (in thousands):

	June 30, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	\$ 27,517	\$ —	\$ —	\$ 27,517
Commercial paper	163,062	—	—	163,062
Corporate bonds	120,389	150	(11)	120,528
U.S. Treasury and government sponsored enterprises	63,587	96	—	63,683
<b>Total investments</b>	<b>\$ 374,555</b>	<b>\$ 246</b>	<b>\$ (11)</b>	<b>\$ 374,790</b>

	December 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	\$ 72,000	\$ —	\$ —	\$ 72,000
Commercial paper	78,155	—	—	78,155
Corporate bonds	72,205	4	(118)	72,091
U.S. Treasury and government sponsored enterprises	28,434	1	(12)	28,423
Marketable equity security	16	2	—	18
<b>Total investments</b>	<b>\$ 250,810</b>	<b>\$ 7</b>	<b>\$ (130)</b>	<b>\$ 250,687</b>

All of our investments are subject to a quarterly impairment review. During the six months ended June 30, 2016 and 2015, we did not record any other-than-temporary impairment charges on our available-for-sale securities. As of June 30, 2016, there were six investments in an unrealized loss position with gross unrealized losses of \$11,000 and an aggregate fair value of \$13.1 million. The investments in an unrealized loss position are comprised of corporate bonds. 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 June 30, 2016 (in thousands):

	Mature within One Year	After One Year through Two Years	Fair Value
Money market funds	\$ 27,517	\$ —	\$ 27,517
Commercial paper	163,062	—	163,062
Corporate bonds	72,806	47,722	120,528
U.S. Treasury and government sponsored enterprises	59,678	4,005	63,683
<b>Total investments</b>	<b>\$ 323,063</b>	<b>\$ 51,727</b>	<b>\$ 374,790</b>

Cash is excluded from the table above.

**NOTE 5. INVENTORY**

Inventory consists of the following (in thousands):

	June 30, 2016	December 31, 2015
Raw materials	\$ 973	\$ 1,037
Work in process	2,277	2,251
Finished goods	714	583
Total	3,964	3,871
Less: non-current portion included in Other assets	(1,156)	(1,255)
Inventory	\$ 2,808	\$ 2,616

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 CABOMETRYX and COMETRIQ and, therefore, were expensed as research and development costs when those costs were incurred, rather than capitalized as inventory. Write-downs related to expiring inventory are charged to cost of goods sold. Such write-downs were nominal for the six months ended June 30, 2016 as compared to \$0.2 million for the comparable period in 2015. The non-current portion of inventory recorded as other assets consists of raw materials and a portion of the active pharmaceutical ingredient which is included in work in process. There were no other write-downs for obsolete or excess inventory.

**NOTE 6. DEBT**

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

	June 30, 2016	December 31, 2015
Convertible Senior Subordinated Notes due 2019	\$ 209,214	\$ 198,708
Secured Convertible Notes due 2018	106,841	102,727
Term loan payable	80,000	80,000
Total debt	396,055	381,435
Less: current portion	(107,500)	—
Long-term debt	\$ 288,555	\$ 381,435

See “Note 7 - Debt” to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2015, for additional information on the terms of our debt, including a description of the conversion features of the of 4.25% Convertible Senior Subordinated Notes due 2019 (the “2019 Notes”) and our Secured Convertible Notes due 2018 (the “Deerfield Notes”).

**Convertible Senior Subordinated Notes due 2019**

In August 2012, we issued and sold \$287.5 million aggregate principal amount of the 2019 Notes. As of both June 30, 2016 and December 31, 2015, \$287.5 million of aggregate principal amount of the 2019 Notes remains outstanding. The 2019 Notes bear interest at a rate of 4.25% per annum, payable semi-annually in arrears on February 15 and August 15 of each year.

The following is a summary of the liability component of the 2019 Notes (in thousands):

	June 30, 2016	December 31, 2015
Net carrying amount of the liability component	\$ 209,214	\$ 198,708
Unamortized discount of the liability component	78,286	88,792
Face amount of the 2019 Notes	\$ 287,500	\$ 287,500

The 2019 Notes are convertible at the note-holder's option during the quarter ending September 30, 2016 as one of the conversion criteria has been met. Specifically, the price of our common stock exceeded \$6.91 for 20 of the last 30 consecutive trading days during the quarter ended June 30, 2016. The continuance of such conversion rights subsequent to September 30, 2016 is subject to the occurrence of certain circumstances. The 2019 Notes are convertible at a conversion rate of 188.2353 shares of common stock per \$1,000 principal amount of the 2019 Notes, subject to adjustment in connection with certain events. Upon conversion, we have the option to pay or deliver, as the case may be, cash, shares of our common stock or a combination of cash and shares of our common stock, at our election. Because we have the intent and ability to deliver shares of our common stock upon conversion, the 2019 Notes remain classified as long-term debt. Subject to the occurrence of certain circumstances, on or after August 15, 2016, we may redeem for cash all or a portion of the 2019 Notes. The redemption price will equal 100% of the principal amount of the 2019 Notes to be redeemed plus accrued and unpaid interest, if any, to, but excluding, the redemption date.

The following is a summary of the interest expense for the 2019 Notes (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Stated coupon interest	\$ 3,054	\$ 3,055	\$ 6,109	\$ 6,110
Amortization of debt discount and debt issuance costs	5,315	4,833	10,506	9,554
<b>Total interest expense</b>	<b>\$ 8,369</b>	<b>\$ 7,888</b>	<b>\$ 16,615</b>	<b>\$ 15,664</b>

The balance of unamortized fees and costs was \$2.2 million and \$2.6 million as of June 30, 2016 and December 31, 2015, respectively, which is recorded as a reduction of the carrying amount of the 2019 Notes on the accompanying Condensed Consolidated Balance Sheets. The debt discount and debt issuance costs will be amortized as interest expense through August 2019.

### Secured Convertible Notes due 2018

As of June 30, 2016 and December 31, 2015, the outstanding principal balance on the Deerfield Notes was \$107.7 million and \$103.8 million, respectively, which, subject to certain limitations, is payable in cash or in stock at our discretion. Beginning on July 2, 2015, the outstanding principal amount of the Deerfield Notes bears 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. Through July 1, 2015, the outstanding principal amount of the Deerfield Notes bore interest in the annual amount of \$6.0 million, payable quarterly in arrears.

The following is a summary of the interest expense for the Deerfield Notes (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Stated coupon interest paid in cash	\$ 1,972	\$ 1,496	\$ 3,908	\$ 2,975
Amortization of debt discount, debt issuance costs and accrual of interest paid in kind	2,085	2,373	4,114	5,320
<b>Total interest expense</b>	<b>\$ 4,057</b>	<b>\$ 3,869</b>	<b>\$ 8,022</b>	<b>\$ 8,295</b>

The balance of unamortized fees and costs was \$0.6 million and \$0.7 million as of June 30, 2016 and December 31, 2015, respectively, which is recorded as a reduction of the carrying amount of the Deerfield Notes on the accompanying Condensed Consolidated Balance Sheets. Effective March 4, 2015, upon notification of our election to extend the maturity date to July 1, 2018, we began to amortize the remaining unamortized discount, fees and costs through July 1, 2018 using the effective interest method and an effective interest rate of 15.3%.

We were required to make an additional mandatory prepayment on the Deerfield Notes in January 2015 and 2016 equal to 15% of certain revenues from collaborative arrangements, which we refer to as Development/Commercialization Revenue, received during the prior fiscal year, subject to a maximum prepayment amount of \$27.5 million. We made no such mandatory prepayments due to the fact that we received no such revenues during the fiscal year ended December 31, 2014 and Deerfield's election not to receive the mandatory prepayment in January 2016 related to development/commercialization revenue received during the year ended December 31, 2015. As a result of the extension of the maturity date of the Deerfield Notes to July 1, 2018, our obligation to make annual mandatory prepayments equal to 15% of Development/Commercialization Revenue received by us during the prior fiscal year will continue to apply in January 2017 and January 2018. However, we will only be obligated to make any such annual mandatory prepayment if the note holders provide notice to us of their election to receive the prepayment. Pursuant to this requirement, we may be required make a mandatory prepayment of \$27.5 million in

January 2017 as a result of the upfront payment of \$200.0 million received in March 2016 in consideration for the exclusive license and other rights contained in the collaboration and license agreement with Ipsen. That portion of the Deerfield Notes is included in current liabilities. The definition of “Development/Commercialization Revenue” expressly excludes any sale or distribution of drug or pharmaceutical products in the ordinary course of our business, and any proceeds from any Intellectual Property Sale, but would include our share of the net profits from the commercialization of cobimetinib in the U.S. and the receipt of royalties from cobimetinib sales outside the U.S., if any.

**NOTE 7. FAIR VALUE MEASUREMENTS**

The following table sets forth the fair value of our financial assets and liabilities that were measured and recorded on a recurring basis as of June 30, 2016 and December 31, 2015. We did not have any financial liabilities that were measured and recorded on a recurring basis or Level 3 investments as of June 30, 2016. The amounts presented exclude cash, but include investments classified as cash equivalents (in thousands):

	June 30, 2016		
	Level 1	Level 2	Total
Money market funds	\$ 27,517	\$ —	\$ 27,517
Commercial paper	—	163,062	163,062
Corporate bonds	—	120,529	120,529
U.S. Treasury and government sponsored enterprises	—	63,683	63,683
<b>Total financial assets</b>	<b>\$ 27,517</b>	<b>\$ 347,274</b>	<b>\$ 374,791</b>

	December 31, 2015		
	Level 1	Level 2	Total
Money market funds	\$ 72,000	\$ —	\$ 72,000
Commercial paper	—	78,155	78,155
Corporate bonds	—	72,091	72,091
U.S. Treasury and government sponsored enterprises	—	28,423	28,423
Marketable equity securities	18	—	18
<b>Total financial assets</b>	<b>\$ 72,018</b>	<b>\$ 178,669</b>	<b>\$ 250,687</b>

The estimated fair value of our financial instruments that are carried at amortized cost is as follows (in thousands):

	June 30, 2016		December 31, 2015	
	Carrying Amount	Fair Value	Carrying Amount	Fair Value
2019 Notes	\$ 209,214	\$ 427,283	\$ 198,708	\$ 336,260
Deerfield Notes	\$ 106,841	\$ 111,226	\$ 102,727	\$ 101,096
Term loan payable	\$ 80,000	\$ 79,717	\$ 80,000	\$ 79,815

The carrying amounts of cash, trade and other receivables, accounts payable, accrued clinical trial liabilities, accrued compensation and benefits, accrued collaboration liability, and other accrued liabilities approximate their fair values and are excluded from the tables above.

The following methods and assumptions were used to estimate the fair value of each class of financial instrument:

- 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 is a Level 2 input.
- The 2019 Notes are valued using a third-party pricing model that is based in part on average trading prices, which is a Level 2 input.
- We estimate the fair value of our other debt instruments, where possible, using the net present value of the payments. For the term loan, we use an interest rate that is consistent with money-market rates that would have been earned on our non-interest-bearing compensating balances as our discount rate, which is a Level 2 input. For the Deerfield Notes,



we used a discount rate of 15%, which we estimate as our current borrowing rate for similar debt as of June 30, 2016, which is a Level 3 input.

**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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Research and development expense	\$ 1,165	\$ 746	\$ 6,729	\$ 1,373
Selling, general and administrative expense	2,393	988	8,014	2,021
Total employee stock-based compensation expense	\$ 3,558	\$ 1,734	\$ 14,743	\$ 3,394

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Stock options	\$ 3.17	\$ 2.41	\$ 2.67	\$ 1.28
ESPP	\$ 1.60	\$ 1.11	\$ 1.79	\$ 0.85

The fair value of employee stock option awards and ESPP purchases was estimated using the following assumptions:

	Stock Options			
	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Risk-free interest rate	0.90%	1.27%	1.10%	1.20%
Dividend yield	—%	—%	—%	—%
Volatility	67%	106%	76%	89%
Expected life	4.4 years	4.5 years	4.4 years	4.5 years

  

	Employee Stock Purchase Plan			
	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Risk-free interest rate	0.39%	0.07%	0.42%	0.10%
Dividend yield	—%	—%	—%	—%
Volatility	65%	104%	69%	99%
Expected life	6 months	6 months	6 months	6 months

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

A summary of all stock option activity for the six months ended June 30, 2016 is presented below (dollars in thousands, except per share amounts):

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Options outstanding at December 31, 2015	27,425,854	\$ 4.22		
Granted	2,727,350	\$ 4.63		
Exercised	(1,321,802)	\$ 1.89		
Forfeited	(197,038)	\$ 4.32		
Expired	(80,516)	\$ 10.89		
Options outstanding at June 30, 2016	28,553,848	\$ 4.35	4.68 years	\$ 112,155
Exercisable at June 30, 2016	20,872,344	\$ 4.02	4.13 years	\$ 89,643

As of June 30, 2016, a total of 2,790,649 shares were available for grant under our stock option plans.

As of June 30, 2016, we had \$17.7 million of unrecognized compensation expense related to employee stock options that is expected to be recognized over a weighted-average period of 3.02 years.

On March 7, 2016, as a result of the FDA acceptance of our New Drug Application “NDA” submission and on April 28, 2016, as a result of the FDA’s approval of our NDA submission, the Compensation Committee of the Board of Directors of Exelixis convened to determine we had met certain performance objectives related to performance-based stock options granted to employees in 2014 and 2015. As a result of these determinations, 5,870,303 performance-based stock options vested during the six months ended June 30, 2016 and we recorded an additional \$4.1 million in stock-based compensation expense during the period related to those options. During 2015, we recorded \$3.3 million in employee stock-based compensation expense related to those options.

A summary of all restricted stock unit (“RSU”) activity for the six months ended June 30, 2016 is presented below (dollars in thousands, except per share amounts):

	Shares	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Awards outstanding at December 31, 2015	1,002,188	\$ 5.16		
Awarded	2,126,191	\$ 4.32		
Vested and released	(1,215,756)	\$ 4.22		
Forfeited	(10,059)	\$ 5.64		
Awards outstanding at June 30, 2016	1,902,564	\$ 4.82	1.71 years	\$ 15,544

As of June 30, 2016, we had \$3.7 million of unrecognized compensation expense related to employee RSUs that is expected to be recognized over a weighted-average period of 2.88 years.

During the six months ended June 30, 2016, we made a bonus payment to our employees in the form of 1,072,833 shares of fully-vested restricted stock units which have a grant date fair value of \$4.5 million.

**NOTE 9. NET LOSS PER SHARE**

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
<b>Numerator:</b>				
Net loss	\$ (37,015)	\$ (43,362)	\$ (98,362)	\$ (78,532)
<b>Denominator:</b>				
Shares used in computing basic and diluted net loss per share	229,310	196,201	228,860	196,052
Net loss per share, basic and diluted	\$ (0.16)	\$ (0.22)	\$ (0.43)	\$ (0.40)

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

	June 30	
	2016	2015
Convertible Senior Subordinated Notes due 2019	54,118	54,118
Secured Convertible Notes due 2018	33,890	33,890
Outstanding stock options, unvested RSUs and ESPP contributions	30,637	29,049
Warrants	1,000	1,000
Total potentially dilutive shares	119,645	118,057

The warrants are participating securities and the warrant holders do not have a contractual obligation to share in our losses.

**NOTE 10. 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, taxable commercial paper, corporate bonds with high credit quality, U.S. Treasury and government sponsored enterprises, and municipal bonds. 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 companies. We have incurred no bad debt expense since inception. As of June 30, 2016, 43%, 17% and 10% of our trade receivables are with Diplomat Specialty Pharmacy, Caremark L.L.C. and affiliates of McKesson Corporation, respectively. All of these customers pay promptly and within their respective payment terms.

All of our long-lived assets are located in the United States.

We have operations primarily in the United States, while some of our collaboration partners have headquarters outside of the United States and some of our clinical trials for cabozantinib are also conducted outside of the United States. The following table shows the percentage of revenues earned in the United States and European Union.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Percentage of revenues earned in the United States	89%	88%	89%	87%
Percentage of revenues earned in the European Union	11%	12%	11%	13%

The following table sets forth the percentage of revenues recognized by customer that represent 10% or more of total revenues:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Product sales:				
Diplomat Specialty Pharmacy	52%	88%	53%	87%
Sobi	1%	12%	2%	13%
Collaboration agreements:				
Merck	—%	—%	10%	—%
Ipsen	10%	—%	9%	—%

## 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," "may be," "initiate," "believe," "could," "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, 2015, filed with the Securities and Exchange Commission, or SEC, on February 29, 2016. 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

Exelixis, Inc. is a biopharmaceutical company committed to the discovery, development and commercialization of new medicines that will improve care and outcomes for people with cancer. Since its founding in 1994, three products discovered at Exelixis have progressed through clinical development, received regulatory approval, and entered the commercial marketplace. This portfolio includes two products derived from cabozantinib, an inhibitor of multiple tyrosine kinases including MET, AXL and VEGF receptors. They are CABOMETYX™ tablets for the treatment of advanced kidney cancer in the United States and COMETRIQ® capsules for the treatment of certain forms of thyroid cancer in both the United States and European Union. The third product is COTELLIC®, a product derived from cobimetinib, a selective inhibitor of MEK, marketed under a collaboration with Roche and Genentech (a member of the Roche Group) that has been approved in combination with ZELBORAF® (vemurafenib) to treat advanced melanoma in several major territories, including the United States and European Union.

The approval of CABOMETYX on April 25, 2016 as a treatment for patients with advanced renal cell carcinoma, or RCC, who have received prior anti-angiogenic therapy was a significant advance for us because of the substantial commercial opportunity that the advanced RCC market represents in the United States. Based upon cabozantinib's potential in this sizable market, we were able to attract top talent and build commercial and medical affairs organizations of considerable size and strength in advance of its approval for this indication. Upon approval from the United States Food and Drug Administration, or FDA, our sales team immediately commenced calling on the appropriate clinicians to promote the availability of CABOMETYX consistent with its FDA-approved labeling, our marketing and access service teams put into motion well-laid plans for enabling compliant communications and the prompt availability of CABOMETYX for all appropriate patients, and our expanded medical information group began to respond to questions arising from physicians and patients. The execution of these efforts enabled the first prescriptions for CABOMETYX to be filled within three days of approval. As our now fully integrated and robust organization builds on collective expertise and experience, it will support the further clinical development and commercial growth of cabozantinib, as well as other anti-cancer therapies that we may develop and market over time.

With the early strength of the launch, the realization of our goal to drive the business to become cash flow positive is increasingly achievable, through growth of our revenue streams both from product revenues, as well as anticipated partnership royalty and contract revenue and vigilant expense management. This would provide us with the opportunity at the appropriate time to reinvest in our drug discovery efforts and evaluate in-licensing opportunities to identify new molecules for our pipeline.

The approval of CABOMETYX was based on results of our phase 3 pivotal trial METEOR (Metastatic RCC Phase 3 Study Evaluating Cabozantinib vs. Everolimus), which met its primary endpoint of improving progression-free survival, or PFS. The median PFS was 7.4 months for the cabozantinib arm versus 3.8 months for the everolimus arm, and the hazard ratio [HR] was 0.58 (95% confidence interval [CI] 0.45-0.74,  $p < 0.0001$ ), corresponding to a 42% reduction in the rate of disease progression or death for cabozantinib compared to everolimus. CABOMETYX also significantly improved the objective response rate, or ORR, and demonstrated a statistically significant and clinically meaningful increase in overall survival, or OS. Compared with everolimus, CABOMETYX was associated with a 34% reduction in the rate of death and median OS was 21.4 months for patients receiving CABOMETYX versus 16.5 months for those receiving everolimus (HR=0.66, 95% CI 0.53-0.83,  $P=0.0003$ ). CABOMETYX, which was granted Fast Track and Breakthrough Therapy designations by the FDA, is the first therapy to demonstrate in a phase 3 trial for patients with advanced RCC, robust and clinically meaningful improvements in all three key efficacy parameters - OS, PFS and ORR. A review of adverse events, or AEs, demonstrated that the frequency of AEs of any grade regardless of causality was approximately balanced between study arms, and the rate of treatment discontinuation due to adverse events was 10% for each of the cabozantinib and everolimus arms.

We believe that cabozantinib's prospects for improving the lives of patients living with cancer reaches beyond the United States. Thus, on February 29, 2016, we entered into a collaboration and license agreement with Ipsen Pharma SAS, or Ipsen, focused on the further development of cabozantinib and the exclusive commercialization of current and potential future cabozantinib indications outside of the United States, Canada and Japan, if and when additional regulatory approvals are secured in those territories. A key reason we chose Ipsen as a partner was because the company is established and engaged in the global distribution of oncology medicines. Following the July 22, 2016 positive opinion issued by the European Committee for Medicinal Products for Human Use, or CHMP, on our Marketing Authorization Application, or MAA, for cabozantinib as a treatment for adult patients with advanced RCC following prior VEGF-targeted therapy, we and our partner, Ipsen, are one step closer to potential approval in the European Union, and are poised to capitalize on the sizable European commercial opportunity. At the same time, we are engaged in an effort to determine the most effective means to obtain cabozantinib's approval and launch in Japan and Canada, either by partnering in those territories or potentially launching the product ourselves.

Beyond the FDA-approved indications of cabozantinib for second-line RCC and progressive, metastatic medullary thyroid carcinoma, or MTC, we are engaged in a broad development program composed of over 45 ongoing or planned clinical trials in additional tumor types, many of which are conducted through our Cooperative Research and Development Agreement, or CRADA, with the National Cancer Institute's Cancer Therapy Evaluation Program, or NCI-CTEP, or our investigator sponsored trial program. The most notable studies at this time are our company-sponsored phase 3 trial of cabozantinib in advanced hepatocellular carcinoma, or HCC, called CELESTIAL (Cabozantinib Phase 3 Controlled Study In Hepatocellular Carcinoma) and CABOSUN, a randomized phase 2 trial comparing cabozantinib to sunitinib in the first-line treatment of intermediate- or poor-risk RCC patients. We anticipate top-line results from CELESTIAL in 2017. The CABOSUN trial is being conducted by The Alliance for Clinical Trials in Oncology, or The Alliance, through our CRADA with NCI-CTEP. In May 2016, The Alliance informed us that CABOSUN met its primary endpoint demonstrating a statistically significant and clinically meaningful improvement of PFS compared with sunitinib. Results from the CABOSUN trial are being discussed with regulators and if reviewed favorably, these data could significantly expand cabozantinib's potential to treat patients with advanced RCC in the front-line setting. We also expect results

in 2016 from a phase 1b trial of cabozantinib plus nivolumab alone, or in combination with ipilimumab, in patients with genitourinary tumors, including bladder cancer and RCC, which is being conducted under our collaboration with NCI-CTEP.

In addition to these advances connected with cabozantinib, significant progress continues to be made with respect to the clinical development, regulatory status and commercial potential of certain of our other partnered compounds. In the aggregate, these partnered compounds could be of significant value to us if their development programs progress successfully. For example, cobimetinib, a compound we out-licensed in 2006 to Genentech was approved by the FDA on November 10, 2015, under the brand name COTELLIC, in combination with vemurafenib, as a treatment for patients with BRAF V600E or V600K mutation-positive advanced melanoma. It was launched in the United States soon thereafter and in the United States we contribute 25% of the sales force to the commercialization effort. COTELLIC in combination with vemurafenib has also been approved and launched by Genentech in multiple other territories, including the European Union, Canada, Australia and Brazil. Cobimetinib is also being evaluated in a broad development program comprising several clinical trials investigating cobimetinib in combination with a variety of agents in multiple tumor types. Owing to disagreements over clinical development, pricing and commercialization of COTELLIC, and cost and revenue allocations arising from COTELLIC's commercialization in the United States, on June 3, 2016, we filed a demand for arbitration against Genentech. For additional information on our arbitration with Genentech please see, "- Part II - Other Information - *Legal Proceedings*."

## **Collaborations**

We have established collaborations with Ipsen for cabozantinib, Genentech (a member of the Roche group) for cobimetinib, and other collaborations with leading pharmaceutical companies including Bristol-Myers Squibb Company, or Bristol-Myers Squibb, Sanofi, Merck (known as MSD outside of the United States and Canada) and Daiichi Sankyo Company Limited, or Daiichi Sankyo, for compounds and programs in our portfolio. Excluding our collaboration agreement with Ipsen for cabozantinib and our co-promotion agreement with Genentech, we have fully out-licensed compounds or programs to a partner for further development and commercialization under these collaborations and have no further development cost obligations under our collaborations. Under each of our collaborations, we are entitled to receive milestones and royalties or, in the case of cobimetinib, a share of profits (or losses) from commercialization.

### ***Cabozantinib Collaboration***

On February 29, 2016, we entered into a collaboration and license agreement, or the Agreement, with Ipsen for the commercialization and further development of cabozantinib. Pursuant to the terms of the Agreement, Ipsen will have exclusive commercialization rights for current and potential future cabozantinib indications outside of the United States, Canada and Japan. We have agreed to collaborate on the development of cabozantinib for current and potential future indications.

In consideration for the exclusive license and other rights contained in the Agreement, Ipsen paid us an upfront nonrefundable payment of \$200.0 million in March 2016. We will be eligible to receive development and regulatory milestones, totaling up to \$252.5 million, including a \$60.0 million milestone payment upon approval of cabozantinib by the European Medicines Agency, or EMA, in second-line RCC, milestone payments of \$10.0 million and \$40.0 million upon the filing and the approval of cabozantinib in second-line HCC, and additional milestones for other future indications. We will also be eligible to receive two \$10.0 million milestone payments upon the launch of the product in the first two of the following countries: Germany, France, Italy, Spain and the United Kingdom. The Agreement also provides that we will be eligible to receive contingent payments of up to \$525.0 million associated with the achievement of specified sales levels. We will also receive royalties on net sales of cabozantinib outside of the United States, Canada and Japan. We will receive a 2% royalty on the initial \$50.0 million of net sales, and a 12% royalty on the next \$100.0 million of net sales. After the initial \$150.0 million of sales, we will receive a tiered royalty of 22% to 26% on annual net sales; these tiers will reset each calendar year. We are primarily responsible for funding cabozantinib related development costs for existing trials; global development costs for potential future trials will be shared between the parties, with Ipsen to reimburse us for 35% of such costs. Pursuant to the terms of the Agreement, we will remain responsible for the manufacture and supply of cabozantinib for all development and commercialization activities under the Agreement. As part of the Agreement, we entered into a supply agreement which provides that through the end of the second quarter of 2018, we will supply finished, labeled product to Ipsen for distribution in the territories outside of the United States, Canada and Japan, and from the end of the second quarter of 2018 forward, we will supply primary packaged bulk tablets to Ipsen. No manufacturing rights were granted to Ipsen.

### ***Cobimetinib Collaboration***

Cobimetinib in combination with vemurafenib has been approved in multiple territories, including the United States, European Union and Canada as a treatment for patients with advanced melanoma harboring a BRAF V600E or V600K mutation, and is marketed as COTELLIC. Results from coBRIM, the phase 3 pivotal trial conducted by Genentech evaluating cobimetinib in combination with vemurafenib in previously untreated patients with unresectable locally advanced or metastatic melanoma harboring a BRAF V600E or V600K mutation served as the basis for such regulatory approvals.

In addition to the coBRIM trial, additional clinical trials are ongoing studying the combination of cobimetinib with a variety of agents in multiple tumor types. These include:

- COTEZO, a phase 3 pivotal trial evaluating the combination of cobimetinib and atezolizumab, an anti-PD-L1 antibody, or atezolizumab alone versus regorafenib, in unresectable locally advanced or metastatic colorectal cancer, or CRC. COTEZO is expected to enroll 360 patients who have received at least two prior chemotherapies in the metastatic disease setting, and the primary endpoint of the trial is OS. The decision to start COTEZO was informed by results from the ongoing phase 1b trial of the combination in advanced solid tumors;
- The combination of cobimetinib and vemurafenib in additional melanoma patient populations and settings;
- A phase 2 trial of cobimetinib in combination with paclitaxel in triple negative breast cancer; and
- Phase 1 studies of cobimetinib in combination with atezolizumab in melanoma and non-small cell lung cancer, or NSCLC, in combination with GDC-0994 in advanced metastatic solid tumors, and in combination with venetoclax in relapsed or refractory acute myeloid leukemia.

A complete listing of all ongoing trials can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

Under the terms of our collaboration agreement with Genentech for cobimetinib, we are entitled to a share of U.S. profits and losses for cobimetinib. The profit 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. We are entitled to low double-digit royalties on ex-U.S. net sales. In November 2013, we exercised an option under the collaboration agreement to co-promote in the United States. Following the approval of COTELLIC in the United States in November 2015, we began fielding 25% of the sales force promoting COTELLIC in combination with vemurafenib as a treatment for patients with BRAF V600E or V600K mutation-positive advanced melanoma.

We believe that cobimetinib has the potential to provide us with an additional meaningful source of revenue. Our objective, therefore, is and has been to work with Genentech on the execution of the U.S. COTELLIC commercial plan in order to maximize the product's revenue potential. However, to date, we believe Genentech's pricing of and cost and revenue allocations for COTELLIC, as determined exclusively by Genentech, have been contrary to the applicable terms of the collaboration agreement. We raised this concern with Genentech, along with other material concerns regarding Genentech's performance under the collaboration agreement, but were unable to come to resolution on any of these issues. Accordingly, on June 3, 2016, following a 30 day dispute resolution period, we filed a demand for arbitration 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 United States.

### ***Other Collaborations***

With respect to our partnered compounds, other than cabozantinib and cobimetinib, we are eligible to receive potential contingent payments totaling approximately \$3.1 billion in the aggregate on a non-risk adjusted basis, of which 8% are related to clinical development milestones, 39% are related to regulatory milestones and 53% are related to commercial milestones, all to be achieved by the various licensees, which may not be paid, if at all, until certain conditions are met.

### **Business Highlights for the Three Months Ended June 30, 2016 and Recent Events**

#### ***European CHMP Adopts Positive Opinion for cabozantinib for the Treatment of Advanced RCC***

On July 22, 2016, CHMP adopted a positive opinion of our MAA for cabozantinib for the treatment of adult patients with advanced RCC following prior VEGF-targeted therapy. The CHMP's positive opinion will now be reviewed by the European Commission, or EC, which has the authority to approve medicines for the European Union. Along with our collaboration partner Ipsen, we anticipate a decision from the EC before the end of this year.

#### ***Positive Top-Line Results from CABOSUN Randomized Phase 2 Trial***

On May 23, 2016, we announced that CABOSUN, a randomized phase 2 trial of cabozantinib in patients with previously untreated advanced RCC being conducted by The Alliance for Clinical Trials in Oncology as part of our collaboration with NCI-CTEP, met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in PFS compared with sunitinib in patients with advanced intermediate- or poor-risk RCC. Results from the CABOSUN trial are being discussed with regulators and if reviewed favorably, these data could significantly expand cabozantinib's potential to treat patients with advanced RCC in the front-line setting. Presentation of the results is planned for an upcoming medical meeting.

#### ***Cabozantinib, Cobimetinib and XL888 Data Presentations at the 2016 Annual Meeting of the American Society of Clinical Oncology, or 2016 ASCO Annual Meeting***

Exelixis-discovered compounds were the subject of 18 presentations at the 2016 ASCO Annual Meeting, including an oral presentation of the OS results from our phase 3 pivotal trial METEOR study advanced RCC, as well as a poster presentation from the same trial on outcomes based on prior therapy and a poster focusing on outcomes in patients with bone metastases. Additional presentations highlighted results from early and mid-stage trials of cabozantinib in other disease settings, including, CRC, endometrial cancer and metastatic urothelial carcinomas. Cobimetinib data included updates on combination trials of the compound in metastatic melanoma, triple-negative breast cancer, and CRC.

#### ***FDA Approval and launch of CABOMETYX Tablets for Patients with Previously Treated Advanced RCC***

On April 25, 2016, the FDA approved CABOMETYX tablets for the treatment of patients with advanced RCC who have received prior anti-angiogenic therapy. The approval of CABOMETYX is based on results of METEOR, which met its primary endpoint of improving PFS. CABOMETYX also significantly improved the ORR, and demonstrated a statistically significant and clinically meaningful increase in OS. We are now focused on continuing to execute on the launch of CABOMETYX as a treatment for patients with advanced RCC who have received prior anti-angiogenic therapy. The first prescriptions for CABOMETYX were filled within three days of approval.

#### ***Additional Regulatory Approvals for COTELLIC***

In April and May 2016, Australia's Therapeutic Goods Administration and Brazil's ANVISA, respectively, approved COTELLIC in combination with vemurafenib for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600 mutation.



### **Initiation of COTEZO Phase 3 Pivotal Trial in Advanced CRC**

In June 2016, our partner Genentech (a member of the Roche Group) announced the initiation of COTEZO, a phase 3 pivotal trial of the combination of cobimetinib and atezolizumab, an anti-PD-L1 antibody, in unresectable locally advanced or metastatic CRC. COTEZO is expected to enroll 360 patients who have received at least two prior chemotherapies in the metastatic disease setting, and the primary endpoint of the trial is OS. The decision to start COTEZO was informed by results from the ongoing phase 1b trial of the combination in advanced solid tumors.

### **Certain Factors Important to Understanding Our Financial Condition and Results of Operations**

Successful development and commercialization of drugs is inherently difficult and uncertain. Products often fail during the research and development process and, if and when they are approved by regulatory authorities, they must then compete in highly competitive therapeutic areas, such as cancer treatment. Our financial performance is driven by many factors, including those described below, and is subject to the risks set forth in “Item 1A - Risk Factors” below.

#### ***Limited Sources of Revenues and the Need to Raise Additional Capital***

We have incurred net losses since inception through June 30, 2016, with the exception of the 2011 fiscal year. We anticipate annual net losses for the foreseeable future. For the six months ended June 30, 2016, we incurred a net loss of \$98.4 million and as of June 30, 2016, we had an accumulated deficit of \$2.0 billion. These losses have had, and will continue to have, an adverse effect on our stockholders’ deficit and working capital. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses or whether or when we will become profitable, if at all. Excluding fiscal 2011, our research and development expenditures and selling, general and administrative expenses have exceeded our revenues for each fiscal year, and we expect to spend significant additional amounts to fund the continued development and commercialization of cabozantinib. As a result, we expect to continue to incur substantial operating expenses and, consequently, we will need to generate significant additional revenues to achieve future profitability.

Since the launch of our first commercial product in January 2013, through June 30, 2016, we have generated an aggregate of \$115.0 million in net product revenues. Other than sales of CABOMETRYX and COMETRIQ, we have derived substantially all of our revenues since inception from collaborative research and development agreements, which depend on royalties, license fees, the achievement of milestones, and research funding we earn from any products developed from the collaborative research.

The amount of our net losses will depend, in part, on: the level of sales of CABOMETRYX in the U.S. for the treatment of advanced RCC; our sales of COMETRIQ; achievement of clinical, regulatory and commercial milestones and the amount of royalties, if any, from sales of cabozantinib under our collaboration with Ipsen; our share of the net profits and losses for the commercialization of COTELLIC in the U.S. under our collaboration with Genentech (a member of the Roche group); 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, primarily with respect to expanded commercialization activities for cabozantinib.

As of June 30, 2016, we had \$384.0 million in cash and investments, which included \$298.2 million available for operations, \$81.6 million of compensating balance investments that we are required to maintain on deposit with Silicon Valley Bank, and \$4.2 million of long-term restricted investments. We anticipate that our current cash and cash equivalents, and short-term investments available for operations, and product revenues, will enable us to maintain our operations for a period of at least 12 months following the filing date of this report. Our capital requirements will depend on many factors, and we may need to use available capital resources and raise additional capital significantly earlier than we currently anticipate. For a description of the factors upon which our capital requirements depend, please see “- Liquidity and Capital Resources - Capital Requirements.”

#### ***Clinical Development and Commercialization of Cabozantinib***

Our primary development and commercialization program is focused on cabozantinib, an inhibitor of multiple receptor tyrosine kinases, currently approved under the brand name CABOMETRYX for the treatment of advanced RCC in the United States and under the brand name COMETRIQ in the United States and the European Union for the treatment of the approved MTC indications. However, cabozantinib may fail to show adequate safety or efficacy as an anti-cancer drug in clinical testing in other types of cancer. For example, our two phase 3 clinical trials (COMET-1 and COMET-2) of cabozantinib in metastatic castration-resistant prostate cancer, or mCRPC, failed to meet their primary endpoints. Based on the outcomes of the COMET trials, we terminated the clinical development of cabozantinib in mCRPC, and other studies in mCRPC sponsored by us, including a randomized phase 2 study of cabozantinib in combination with abiraterone, have been halted. Furthermore, predicting the timing of the initiation or completion of clinical trials is difficult, and our trials may be delayed due to many factors, including factors outside of our control. The future development path of cabozantinib depends upon the results of each

stage of clinical development. We continue to incur significant expenses for the development of cabozantinib as it advances in clinical development.

The commercial success of cabozantinib depends upon the degree of market acceptance of both CABOMETYX and COMETRIQ among physicians, patients, health care payers such as Medicare and Medicaid, and the medical community. It also depends upon how cabozantinib fares in competition with other products. For a description of the competition CABOMETYX and COMETRIQ face in the market for products treating advanced RCC and the approved MTC indications, respectively, and may face in the future should cabozantinib be approved for other indications, please see “Part II, Item 1A. Risk Factors - Risks Related to Cabozantinib and Cobimetinib - Our competitors may develop products and technologies that impair the value of cabozantinib and cobimetinib - Competition for cabozantinib.”

In connection with the FDA’s approval of cabozantinib for the treatment of patients with advanced RCC who have received prior anti-angiogenic therapy, we increased our sales, marketing and distribution capabilities. Establishing and maintaining sales, marketing and distribution capabilities are expensive and time-consuming. Such expenses may be disproportional compared to the revenues we may be able to generate and may have an adverse impact on our results of operations.

### ***Convertible Senior Subordinated Notes***

In August 2012, we issued and sold \$287.5 million aggregate principal amount of the 4.25% Convertible Senior Subordinated Notes due 2019, or the 2019 Notes, for net proceeds of \$277.7 million. The 2019 Notes mature on August 15, 2019, unless earlier converted, redeemed or repurchased, and bear interest at a rate of 4.25% per annum, payable semi-annually in arrears on February 15 and August 15 of each year. Subject to the occurrence of certain circumstances, on or after August 15, 2016, we may redeem for cash all or a portion of the 2019 Notes. The redemption price will equal 100% of the principal amount of the 2019 Notes to be redeemed plus accrued and unpaid interest, if any, to, but excluding, the redemption date. On or after May 15, 2019, until the close of business on the second trading day immediately preceding August 15, 2019, holders may surrender their 2019 Notes for conversion. Upon the occurrence of certain circumstances, holders may convert their 2019 Notes prior to the close of business on the business day immediately preceding May 15, 2019. The 2019 Notes are convertible at the note-holder’s option during the quarter ending September 30, 2016 as to one of the conversion criteria has been met. Specifically, the price of our common stock exceeded \$6.91 for 20 of the last 30 consecutive trading days during the quarter ended June 30, 2016. The continuance of such conversion rights subsequent to September 30, 2016 is subject to the occurrence of certain circumstances. The 2019 Notes are convertible at a conversion rate of 188.2353 shares of common stock per \$1,000 principal amount of the 2019 Notes, subject to adjustment in connection with certain events. Upon conversion, we have the option to pay or deliver, as the case may be, cash, shares of our common stock or a combination of cash and shares of our common stock, at our election. Because we have the intent and ability to deliver shares of our common stock upon conversion, the 2019 Notes remain classified as long-term debt. If a Fundamental Change, as defined in the indenture governing the 2019 Notes, occurs, holders of the 2019 Notes may require us to purchase for cash all or any portion of their 2019 Notes at a purchase price equal to 100% of the principal amount of the Notes to be purchased plus accrued and unpaid interest, if any, to, but excluding, the Fundamental Change purchase date. In addition, if certain specified bankruptcy and insolvency-related events of default occur, the principal of, and accrued and unpaid interest on, all of the then outstanding notes will automatically become due and payable. If an event of default other than certain specified bankruptcy and insolvency-related events of default occurs and is continuing, the Trustee by notice to us or the holders of at least 25% in principal amount of the outstanding 2019 Notes by notice to us and the Trustee, may declare the principal of, and accrued and unpaid interest on, all of the then outstanding 2019 Notes to be due and payable.

### ***Deerfield Facility***

In June 2010, we entered into a note purchase agreement with Deerfield Private Design Fund, L.P. and Deerfield Private Design International, L.P., or the Original Deerfield Purchasers, pursuant to which, on July 1, 2010, we sold to the Original Deerfield Purchasers an aggregate of \$124.0 million principal amount of our Secured Convertible Notes due July 1, 2015, which we refer to as the Original Deerfield Notes, for an aggregate purchase price of \$80.0 million, less closing fees and expenses of approximately \$2.0 million. On January 22, 2014, the note purchase agreement was amended to provide us with an option to extend the maturity date of our indebtedness under the note purchase agreement to July 1, 2018. On July 1, 2015, we made a \$4.0 million principal payment and then extended the maturity date of the Original Deerfield Notes from July 1, 2015 to July 1, 2018. In connection with the extension, affiliates of the Original Deerfield Purchasers, which we refer to as the New Deerfield Purchasers, acquired the \$100.0 million principal amount of the Original Deerfield Notes and we issued restated notes, which we refer to as the Restated Deerfield Notes with each of the New Deerfield Purchasers, representing the \$100.0 million principal amount. We refer to the Original Deerfield Purchasers and the New Deerfield Purchasers collectively as Deerfield, and to the Original Deerfield Notes and Restated Deerfield Notes, collectively as the Deerfield Notes.

As of June 30, 2016 and December 31, 2015, the outstanding principal balance on the Deerfield Notes was \$107.7 million and \$103.8 million, respectively, which, subject to certain limitations, is payable in cash or in stock at our discretion. Beginning on July 2, 2015, the outstanding principal amount of the Deerfield Notes bears 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. Through July 1, 2015, the outstanding principal amount of the Deerfield Notes bore interest in the annual amount of \$6.0 million, payable quarterly in arrears.

On August 6, 2012, the parties amended the note purchase agreement to permit the issuance of the 2019 Notes and modify certain optional prepayment rights. The amendment became effective upon the issuance of the 2019 Notes and the payment to the Original Deerfield Purchasers of a \$1.5 million consent fee. On August 1, 2013, the parties further amended the note purchase agreement to clarify certain of our other rights under the note purchase agreement. On January 22, 2014, the note purchase agreement was amended to provide us with an option to extend the maturity date of our indebtedness under the note purchase agreement to July 1, 2018, which extension was completed on July 1, 2015. On July 10, 2014, the parties further amended the note purchase agreement to clarify certain provisions of the note purchase agreement.

The following is a summary of the interest expense for the Deerfield Notes (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Stated coupon interest	\$ 1,972	\$ 1,496	\$ 3,908	\$ 2,975
Amortization of debt discount, debt issuance costs and accrual of interest paid in kind	2,085	2,373	4,114	5,320
Total interest expense	\$ 4,057	\$ 3,869	\$ 8,022	\$ 8,295

The balance of unamortized fees and costs was \$0.6 million and \$0.7 million as of June 30, 2016 and December 31, 2015, respectively, which is recorded as a reduction of the carrying amount of the 2019 Notes on the accompanying Condensed Consolidated Balance Sheets. Effective March 4, 2015, upon notification of our election to require the New Deerfield Purchasers to acquire the Deerfield Notes and extend the maturity date to July 1, 2018, we began to amortize the remaining unamortized discount, fees and costs through July 1, 2018 using the effective interest method and an effective interest rate of 15.3%.

In each of January 2014 and 2013, we made mandatory prepayments of \$10.0 million on the Deerfield Notes. We were required to make an additional mandatory prepayment on the Deerfield Notes in January 2015 and 2016 equal to 15% of certain revenues from collaborative arrangements, which we refer to as Development/Commercialization Revenue, received during the prior fiscal year, subject to a maximum prepayment amount of \$27.5 million. We made no such mandatory prepayments due to the fact that we received no such revenues during the fiscal year ended December 31, 2014 and Deerfield's election not to receive the mandatory prepayment in January 2016 related to development/commercialization revenue received during the year ended December 31, 2015. As a result of the extension of the maturity date of the Deerfield Notes to July 1, 2018, our obligation to make annual mandatory prepayments equal to 15% of Development/Commercialization Revenue received by us during the prior fiscal year will continue to apply in January 2017 and January 2018. However, we will only be obligated to make any such annual mandatory prepayment if the note holders provide notice to us of their election to receive the prepayment. Pursuant to this requirement, we may be required make a mandatory prepayment of \$27.5 million in January 2017 as a result of the \$200.0 million upfront nonrefundable payment received in March 2016 in consideration for the exclusive license and other rights contained in the collaboration and license agreement with Ipsen. That portion of the Deerfield Notes is included in current liabilities. The definition of "Development/Commercialization Revenue" expressly excludes any sale or distribution of drug or pharmaceutical products in the ordinary course of our business, and any proceeds from any Intellectual Property Sale, but would include our share of the net profits from the commercialization of cobimetinib in the U.S. and the receipt of royalties from cobimetinib sales outside the U.S., if any.

Under the note purchase agreement, we may at our sole discretion, prepay all of the principal amount of the Deerfield Notes at a prepayment price equal to 105% of the outstanding principal amount of the Deerfield Notes, plus all accrued and unpaid interest through the date of such prepayment, plus, if prior to July 1, 2017, all interest that would have accrued on the principal amount of the Deerfield Notes between the date of such prepayment and July 1, 2017, if the outstanding principal amount of the Deerfield Notes as of such prepayment date had remained outstanding through July 1, 2017, plus all other accrued and unpaid obligations, collectively referred to as the Prepayment Price.

In lieu of making any portion of the Prepayment Price or mandatory prepayment in cash, subject to certain limitations (including a cap on the number of shares issuable under the note purchase agreement), we have the right to convert all or a portion of the principal amount of the Deerfield Notes into, or satisfy all or any portion of the Prepayment Price amounts or mandatory prepayment amounts with shares of our common stock. Additionally, in lieu of making any payment of accrued and

unpaid interest in respect of the Deerfield Notes in cash, subject to certain limitations, we may elect to satisfy any such payment with shares of our common stock. The number of shares of our common stock issuable upon conversion or in settlement of principal and interest obligations will be based upon the discounted trading price of our common stock over a specified trading period. Upon certain changes of control of Exelixis, a sale or transfer of assets in one transaction or a series of related transactions for a purchase price of more than (i) \$400 million or (ii) 50% of our market capitalization, Deerfield may require us to prepay the Deerfield Notes at the Prepayment Price. Upon an event of default, as defined in the Deerfield Notes, Deerfield may declare all or a portion of the Prepayment Price to be immediately due and payable.

We are required to notify the applicable Deerfield entities of certain sales, assignments, grants of exclusive licenses or other transfers of our intellectual property pursuant to which we transfer all or substantially all of our legal or economic interests, defined as an Intellectual Property Sale, and the Deerfield entities may elect to require us to prepay the principal amount of the Deerfield Notes in an amount equal to (i) 100% of the cash proceeds of any Intellectual Property Sale relating to cabozantinib and (ii) 50% of the cash proceeds of any other Intellectual Property Sale.

In connection with the January 2014 amendment to the note purchase agreement, on January 22, 2014, we issued to the New Deerfield Purchasers two-year warrants, which we refer to as the 2014 Warrants, to purchase an aggregate of 1,000,000 shares of our common stock at an exercise price of \$9.70 per share. Subsequent to 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 and the term was extended by two years to January 22, 2018. In August 2015 the New Deerfield Purchasers assigned the 2014 Warrants to OTA LLC. The 2014 Warrants contain certain limitations that prevent the holder from acquiring shares upon exercise that would result in the number of shares beneficially owned by the holder to exceed 9.98% of the total number of shares of our common stock then issued and outstanding. In addition, upon certain changes in control of Exelixis, to the extent the 2014 Warrants are not assumed by the acquiring entity, or upon certain defaults under the 2014 Warrants, the holder has the right to net exercise the 2014 Warrants for shares of common stock, or be paid an amount in cash in certain circumstances where the current holders of our common stock would also receive cash, equal to the Black-Scholes Merton value of the 2014 Warrants.

In connection with the issuance of the 2014 Warrants, we entered into a registration rights agreement with Deerfield, pursuant to which we filed a registration statement with the SEC covering the resale of the shares of common stock issuable upon exercise of the 2014 Warrants.

In connection with the note purchase agreement, we also entered into a security agreement in favor of Deerfield which provides that our obligations under the Deerfield Notes will be secured by substantially all of our assets except intellectual property. On August 1, 2013, the security agreement was amended to limit the extent to which voting equity interests in any of our foreign subsidiaries shall be secured assets.

The note purchase agreement as amended and the security agreement include customary representations and warranties and covenants made by us, including restrictions on the incurrence of additional indebtedness.

#### ***Loan Agreement with Silicon Valley Bank***

On May 22, 2002, we entered into a loan and security agreement with Silicon Valley Bank for an equipment line of credit. On June 2, 2010, we amended the loan and security agreement to provide for a new seven-year term loan in the amount of \$80.0 million. As of both June 30, 2016 and December 31, 2015, the outstanding principal balance due under the term loan was \$80.0 million. All other amounts due under the agreement were repaid prior to December 31, 2015. The principal amount outstanding under the term loan accrues interest at 1.0% per annum, which interest is due and payable monthly. We are required to repay the term loan in one balloon principal payment, representing 100% of the principal balance and accrued and unpaid interest, on May 31, 2017, and therefore have classified the term loan as a current liability as of June 30, 2016. We have the option to prepay all, but not less than all, of the amounts advanced under the term loan, provided that we pay all unpaid accrued interest thereon that is due through the date of such prepayment and the interest on the entire principal balance of the term loan that would otherwise have been paid after such prepayment date until the maturity date of the term loan. In accordance with the terms of the loan and security agreement, we are required to maintain an amount equal to at least 100%, but not to exceed 107%, of the outstanding principal balance of the term loan and all equipment lines of credit under the loan and security agreement, if any, on deposit in one or more investment accounts with Silicon Valley Bank or one of its affiliates as support for our obligations under the loan and security agreement (although we are entitled to retain income earned or the amounts maintained in such accounts). Any amounts outstanding under the term loan during the continuance of an event of default under the loan and security agreement will, at the election of Silicon Valley Bank, bear interest at a per annum rate equal to 6.0%. If one or more events of default under the loan and security agreement occurs and continues beyond any applicable cure period, Silicon Valley Bank may declare all or part of the obligations under the loan and security agreement to be immediately due and payable and stop advancing money or extending credit to us under the loan and security agreement.

## Critical Accounting Estimates

The preparation of our consolidated financial statements is in conformity with accounting principles generally accepted in the United States 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 for deductions from revenues (such as rebates, chargebacks, sales returns and sales allowances) and the period of performance, identification of deliverables and evaluation of milestones with respect to our collaborations, recoverability of inventory, certain accrued liabilities including clinical trial and collaboration liability accruals, and share-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.

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 the financial statements. We believe our critical accounting policies relating to inventory, revenue recognition, clinical trial accruals, restructuring liability, share based compensation and warrant valuation reflect the more significant estimates and assumptions used in the preparation of our consolidated financial statements.

### **Revenue Recognition**

#### *Net Product Revenues including Discounts and Allowances*

In the United States, we sell our products, CABOMETYX and COMETRIQ, to specialty pharmacies and distributors that benefit from customer incentives and have a right of return. Historically we have relied on payer data received from the specialty pharmacy that sells COMETRIQ in the United States and historical utilization rates in determining our discounts and allowances. In determining discounts and allowances for the sale of CABOMETYX, in addition to using payer data received from the specialty pharmacies and distributors that sell CABOMETYX and historical data for COMETRIQ, we also utilized claims data from third party sources for competitor products for the treatment of advanced RCC. Based in part on the availability of this third party data, we made the determination that we had sufficient experience and data to reasonably estimate expected future returns and the discounts and allowances due to payers at the time of shipment to the specialty pharmacy or distributor, and therefore record revenue for the product using the “sell-in” revenue recognition model.

#### *Royalty, License and Contract Revenues*

We enter into corporate collaboration and license agreements under which we may obtain upfront license fees, research funding, and contingent, milestone and royalty payments. Our deliverables under these arrangements may include intellectual property rights, distribution rights, delivery of manufactured product, participation on joint steering committees and/or research and development services. In order to account for the multiple-element arrangements, we identify the deliverables included within the arrangement and evaluate whether the delivered elements under these arrangements have value to our collaboration partner on a stand-alone basis and represent separate units of accounting. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver future goods or services, a right or license to use an asset, or another performance obligation. If we determine that multiple deliverables exist, the consideration is allocated to one or more units of accounting based upon the best estimate of the selling price of each deliverable. The selling price used for each deliverable will be based on vendor-specific objective evidence, if available, third-party evidence if vendor-specific objective evidence is not available, or estimated selling price if neither vendor-specific or third-party evidence is available. A delivered item or items that do not qualify as a separate unit of accounting within the arrangement shall be combined with the other applicable undelivered items within the arrangement. The allocation of arrangement consideration and the recognition of revenue then shall be determined for those combined deliverables as a single unit of accounting. For a combined unit of accounting, non-refundable upfront fees are recognized in a manner consistent with the final deliverable, which has generally been ratably over the period of continued involvement. Amounts received in advance of performance are recorded as deferred revenue. Upfront fees are classified as license revenues in our consolidated statements of operations.

We consider sales-based contingent payments to be royalty revenue which is generally recognized at the date the contingency is achieved. Royalties are recorded based on sales amounts reported to us for the preceding quarter.

For certain contingent payments under collaboration and license arrangements, we recognize revenue using the milestone method. Under the milestone method a payment that is contingent upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is an event: (i) that can be achieved

based in whole or in part on either our performance or on the occurrence of a specific outcome resulting from our performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to us. The determination that a milestone is substantive requires estimation and judgment and is made at the inception of the arrangement. Milestones are considered substantive when the consideration earned from the achievement of the milestone is: (i) commensurate with either our performance to achieve the milestone or the enhancement of value of the item delivered as a result of a specific outcome resulting from our performance to achieve the milestone, (ii) relates solely to past performance and (iii) reasonable relative to all deliverables and payment terms in the arrangement. In making the determination as to whether a milestone is substantive or not, we consider all facts and circumstances relevant to the arrangement, including factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether any portion of the milestone consideration is related to future performance or deliverables.

There have been no other significant changes in our critical accounting policies and estimates during the six months ended June 30, 2016, 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, 2015.

#### **Recently Adopted Accounting Pronouncements**

In April 2015, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update No. 2015-05, *Customer’s Accounting for Fees Paid in a Cloud Computing Arrangement*, or ASU 2015-05. ASU 2015-05 provides guidance to customers about whether a cloud computing arrangement includes a software license. If a cloud computing arrangement includes a software license, then the customer should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the customer should account for the arrangement as a service contract. ASU 2015-05 was effective for all interim and annual reporting periods beginning after December 15, 2015 and therefore we adopted ASU 2015-05 in the three months ended March 31, 2016 on a prospective basis. The adoption of ASU 2015-05 did not have a material impact on our Condensed Consolidated Statements of Operations for the three months ended March 31, 2016 and is not expected to have a material effect on our Consolidated Financial Statements in future periods.

#### **Recently Issued Accounting Pronouncements**

In March 2016, the FASB issued Accounting Standards Update No. 2016-09, *Improvements to Employee Share-Based Payment Accounting*, or ASU 2016-09. ASU 2016-09 is aimed at the simplification of several aspects of the accounting for employee share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for all interim and annual reporting periods beginning after December 15, 2016. Early adoption is permitted. We are currently evaluating the impact that the adoption of ASU 2016-09 will have on our consolidated financial statements and related disclosures.

#### **Fiscal Year Convention**

We adopted a 52- or 53-week fiscal year that generally ends on the Friday closest to December 31<sup>st</sup>. Fiscal year 2016 will end on December 30, 2016, and fiscal year 2015, ended on January 1, 2016. For convenience, references in this report as of and for the fiscal periods ended September 30, 2016, July 1, 2016 and July 3, 2015, and as of and for the fiscal years ended December 30, 2016 and January 1, 2016, are indicated as being as of and for the periods ended September 30, 2016, June 30, 2016, June 30, 2015, and the years ended December 31, 2016, and December 31, 2015, respectively.

**Results of Operations**

**Revenues**

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Gross product revenues	\$ 35,049	\$ 8,431	\$ 45,663	\$ 18,564
Discounts and allowances	(3,431)	(439)	(4,946)	(1,184)
Net product revenues	31,618	7,992	40,717	17,380
Royalty and license revenues <sup>(1)</sup>	4,634	—	5,962	—
Contract revenues <sup>(2)</sup>	—	—	5,000	—
Total revenues	\$ 36,252	\$ 7,992	\$ 51,679	\$ 17,380
Dollar change	\$ 28,260		\$ 34,299	
Percentage change	354%		197%	

(1) Includes royalties and amortization of upfront payments.

(2) Includes contingent and milestone payments.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
COMETRIQ	\$ 14,044	\$ 7,992	\$ 23,143	\$ 17,380
CABOMETYX	17,574	—	17,574	—
Net product revenues	\$ 31,618	\$ 7,992	\$ 40,717	\$ 17,380
Dollar change	\$ 23,626		\$ 23,337	
Percentage change	296%		134%	

The increase in net product revenues for the three and six months ended June 30, 2016, as compared to the comparable periods in 2015, reflects the impact of the commercial launch of CABOMETYX in late April 2016. 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.

Net product revenues for both CABOMETYX and COMETRIQ are recorded using the “sell-in” method of revenue recognition. Net product revenues during the three and six months ended June 30, 2016 were impacted by the build of channel inventory related to the initial launch period for CABOMETYX. Net product revenues during the six months ended June 30, 2015 were impacted by a change to the “sell-in” method for COMETRIQ, which resulted in the one-time recognition of \$2.6 million of deferred revenue during the period.

Royalty and license revenues for the three and six months ended June 30, 2016 included recognition of \$3.6 million and \$4.8 million, respectively, of the \$200.0 million upfront nonrefundable payment received in March 2016 in consideration for the exclusive license and other rights contained in the collaboration and license agreement with Ipsen. During the three and six months ended June 30, 2016, we also recognized \$1.0 million and \$1.2 million, respectively, of royalties on ex-U.S. net sales of COTELLIC. There were no such royalty and license revenue during the comparable periods in 2015.

Contract revenues for the six months ended June 30, 2016 reflect a \$5.0 million milestone earned from Merck related to its worldwide license of our phosphoinositide-3 kinase-delta program. There was no such contract revenue during the three months ended June 30, 2016 or during the comparable periods in 2015.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Diplomat Specialty Pharmacy	\$ 18,916	\$ 7,035	\$ 27,380	\$ 15,110
Merck	—	—	5,000	—
Ipsen	3,592	—	4,790	—
Swedish Orphan Biovitrum	468	957	1,103	2,270
Others, individually less than 10% of total revenues for all periods presented	13,276	—	13,406	—
Total revenues	\$ 36,252	\$ 7,992	\$ 51,679	\$ 17,380
Dollar change	\$ 28,260		\$ 34,299	
Percentage change	354%		197%	

### Cost of Goods Sold

Cost of goods sold is related to our product revenues and consists primarily of a 3% royalty on net sales of any product incorporating cabozantinib payable to GlaxoSmithKline, indirect labor costs, the cost of manufacturing, write-downs related to expiring and excess inventory, and other third party logistics costs of our product. A portion of the manufacturing costs for inventory was incurred prior to regulatory approval of CABOMETYX and COMETRIQ and, therefore, were expensed as research and development costs when those costs were incurred, rather than capitalized as inventory.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Cost of goods sold	\$ 1,560	\$ 686	\$ 2,245	\$ 1,452
Gross margin	95%	91%	94%	92%

The increase in gross margins for the three and six months ended June 30, 2016 as compared to the comparable period in 2015, was primarily related to the launch of CABOMETYX which has lower manufacturing costs than COMETRIQ. The cost of goods sold and gross margin we have experienced in this early stage of the CABOMETYX product launch may not be representative of what we may experience going forward.

### Research and Development Expenses

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Research and development expenses	\$ 22,984	\$ 24,506	\$ 51,910	\$ 46,788
Dollar change	\$ (1,522)		\$ 5,122	
Percentage change	(6)%		11%	

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

The decrease in research and development expenses for the three months ended June 30, 2016 as compared to the comparable period in 2015, was primarily related to a decrease in clinical trial costs, which includes services performed by third-party contract research organizations and other vendors who support our clinical trials, and a decrease in the allocation of general corporate costs; those decreases were partially offset by increases in personnel expenses and consulting and outside services. The decrease in clinical trial costs was \$6.3 million, or 44%, for the three months ended June 30, 2016 as compared to the comparable period in 2015. The decrease in clinical trial costs was predominantly due to decreases in costs related to METEOR, our phase 3 pivotal trial in advanced RCC and a reduction of general program level costs. The allocation of general corporate costs decreased by \$1.6 million for the three months ended June 30, 2016 as compared to the comparable period in 2015, primarily due to the increase in allocations to sales as a result of headcount changes and the overall decrease in allocable administrative costs. Personnel expenses increased by \$3.8 million for the three months ended June 30, 2016 as compared to the comparable period in 2015 primarily due to the hiring of medical science liaisons as a result of the launch of



CABOMETYX and an increase in the accrual for corporate bonuses. Consulting and outside services increased by \$1.1 million for the three months ended June 30, 2016 as compared to the comparable period in 2015 primarily due to increases in activities related to medical affairs and drug safety.

The increase in research and development expenses for the six months ended June 30, 2016 as compared to the comparable period in 2015, was primarily related to stock-based compensation, personnel expenses, and consulting and outside services; those increases were partially offset by decreases in clinical trial costs and a decrease in the allocation of general corporate costs. Stock-based compensation increased by \$5.3 million for the six months ended June 30, 2016 as compared to the comparable period in 2015 primarily due to performance-based stock-options tied to the acceptance and approval of our New Drug Application, or NDA, filing with the FDA and a bonus to our employees in the form of fully-vested restricted stock units. Personnel expenses increased by \$4.9 million for the six months ended June 30, 2016 as compared to the comparable period in 2015 primarily due to the hiring of medical science liaisons as a result of the launch of CABOMETYX and an increase in the accrual for corporate bonuses. Consulting and outside services increased by \$2.2 million for the six months ended June 30, 2016 as compared to the comparable period in 2015 primarily due to increases in activities related to medical affairs and drug safety. The decrease in clinical trial costs was \$6.3 million, or 24%, for the six months ended June 30, 2016 as compared to the comparable period in 2015. The decrease in clinical trial costs was predominantly due to decreases in costs related METEOR, our phase 3 pivotal trial in advanced RCC and a reduction of general program level costs. The allocation of general corporate costs decreased by \$3.0 million for the six months ended June 30, 2016 as compared to the comparable period in 2015, primarily due to the increase in allocations to sales as a result of headcount changes and the overall decrease in allocable administrative costs.

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 nearly all of our future research and development expenses to relate to the clinical development of cabozantinib. We expect to continue to incur significant development costs for cabozantinib in future periods as we evaluate its potential in a broad development program comprising over 45 ongoing or planned clinical trials across multiple indications. The most notable study of this program is our company-sponsored phase 3 trial of cabozantinib in advanced HCC called CELESTIAL. In addition, postmarketing commitments in connection with the approval of COMETRIQ in progressive, metastatic MTC dictate that we conduct an additional study in that indication.

We anticipate that research and development expenses will increase during the second half of 2016 with an increase in costs associated with Medical Affairs to support the launch of CABOMETYX.

We do not have reliable estimates regarding the timing of our clinical trials. We estimate that typical phase 1 clinical trials last approximately one year, phase 2 clinical trials last approximately one to two years and phase 3 clinical trials last approximately two to four years. However, the length of time may vary substantially according to factors relating to the particular clinical trial, such as the type and intended use of the drug candidate, the clinical trial design and the ability to enroll suitable patients.

We do not have reliable estimates of total costs for a particular drug candidate, or for cabozantinib for a particular indication, to reach the market. Our potential therapeutic products are subject to a lengthy and uncertain regulatory process that may involve unanticipated additional clinical trials and 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. In addition, clinical trials of our potential product candidates may fail to demonstrate safety and efficacy, which could prevent or significantly delay regulatory approval.

### ***Selling, General and Administrative Expenses***

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Selling, general and administrative expenses	\$ 35,823	\$ 12,789	\$ 70,680	\$ 22,320
Dollar change	\$ 23,034		\$ 48,360	
Percentage change	180%		217%	

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

The increase in selling, general and administrative expenses for the three and six months ended June 30, 2016 was primarily related to personnel expenses, consulting and outside services, marketing, and to a lesser extent, stock-based compensation, and travel and entertainment costs. Personnel expenses increased by \$11.3 million and \$19.5 million for the three and six months ended June 30, 2016, respectively, as compared to the comparable periods in 2015 primarily due to the expansion of our U.S. sales force as a result of the launch of CABOMETYX as well as an increase in the accrual for corporate bonuses and incentive compensation. Consulting and outside services increased by \$4.3 million and \$9.6 million for the three and six months ended June 30, 2016, respectively, as compared to the comparable periods in 2015, which includes costs supporting the commercialization and launch of CABOMETYX, and also for the six months ended June 30, 2016, our accrual for a termination fee to be paid to Swedish Orphan Biovitrum, or Sobi. Marketing expenses increased by \$3.0 million and \$8.4 million for the three and six months ended June 30, 2016, respectively, as compared to the comparable periods in 2015 due to an increase in marketing activities for CABOMETYX; for the six months ended June 30, 2016, the increase in marketing expenses was also a result of an increase in COTELLIC commercialization expenses under the collaboration with Genentech (a member of the Roche Group). Stock-based compensation increased by \$1.4 million and \$6.0 million for the three and six months ended June 30, 2016, respectively, as compared to the comparable periods in 2015 primarily due to new-hire grants; for the six months ended June 30, 2016, the increase in stock-based compensation was also a result of performance-based stock-options tied to the acceptance and approval of our NDA filing with the FDA and a bonus to our employees in the form of fully-vested restricted stock units. Travel and entertainment costs increased by \$1.8 million and \$2.7 million for the three and six months ended June 30, 2016, respectively, as compared to the comparable periods in 2015, primarily due to the increase in activities of our U.S. sales force following the launch of CABOMETYX.

We anticipate selling, general and administrative expenses will increase for the remainder of 2016 due to increases in personnel costs and CABOMETYX marketing expenses.

**Total Other Income (Expense), Net**

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Interest income and other, net	\$ 749	\$ (123)	\$ 951	\$ (130)
Interest expense	(12,628)	(11,959)	(25,042)	(24,362)
Total other income (expense), net	\$ (11,879)	\$ (12,082)	\$ (24,091)	\$ (24,492)
Dollar change	\$ 203		\$ 401	
Percentage change	(2)%		(2)%	

Total other income (expense), net consists primarily of interest expense incurred on our debt, partially offset by interest income earned on our cash and investments and gains and losses on derivatives and foreign exchange fluctuations.

**Liquidity and Capital Resources**

**Sources and Uses of Cash**

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

	Six Months Ended June 30,	
	2016	2015
Net loss	\$ (98,362)	\$ (78,532)
Net cash provided by (used in) operating activities	129,017	(71,919)
Net cash (used in) provided by investing activities	(143,510)	57,580
Net cash provided by (used in) financing activities	2,686	(4,107)
Net decrease in cash and cash equivalents	(11,807)	(18,446)
Cash and cash equivalents at beginning of period	141,634	80,395
Cash and cash equivalents at end of period	\$ 129,827	\$ 61,949

Since the launch of our first commercial product in January 2013, through June 30, 2016, we have generated an aggregate of \$115.0 million in net product revenues. Other than sales of CABOMETYX and COMETRIQ, we have derived substantially all of our revenues since inception from collaborative research and development agreements, which depend on

royalties, license fees, the achievement of milestones, and research funding we earn from any products developed from the collaborative research. For a discussion of potential future capital requirements, please see “– Liquidity and Capital Resources – *Capital Requirements*.”

### *Operating Activities*

Our operating activities provided cash of \$129.0 million for the six months ended June 30, 2016, compared to cash used of \$71.9 million for the same period in 2015. Operating cash flows can differ from our consolidated net loss as a result of differences in the timing of cash receipts and non-cash charges.

Cash provided by operating activities for the six months ended June 30, 2016 was primarily a result of the \$200.0 million upfront payment Ipsen paid us in consideration for the exclusive license and other rights contained in the collaboration and license agreement we entered into on February 29, 2016 and cash receipts from net product revenues. Those proceeds were partially offset by operating expenses of \$126.0 million for the period, less non-cash expenses for stock-based compensation totaling \$14.7 million and the amortization of debt discount, debt issuance costs and accrual of interest paid in kind totaling \$14.6 million. Our operating expenses were largely attributable to the development and commercialization of cabozantinib. In addition, cash provided by operating activities also increased as a result of a \$14.3 million increase in accounts payable, accrued compensation, and other accrued liabilities and a \$6.1 million increase in our accrued collaboration liability, and was partially offset by a \$12.4 million increase of trade and other receivables and a \$2.4 million reduction in accrued clinical trial liabilities.

Cash used in operating activities for the six months ended June 30, 2015 related primarily to our \$71.4 million operating expenses for the period, less non-cash expenses for accretion of debt discount totaling \$14.9 million on the Deerfield Notes and the 2019 Notes and stock-based compensation totaling \$3.4 million. Our operating expenses were largely attributable to the development of cabozantinib. In addition, we made cash payments that resulted in a \$9.0 million reduction in accrued clinical trial liabilities. We also paid \$4.8 million for restructuring activities.

### *Investing Activities*

Our investing activities used cash of \$143.5 million for the six months ended June 30, 2016, compared to \$57.6 million of cash provided for the same period in 2015.

Cash used by investing activities for the six months ended June 30, 2016 was primarily due to investment purchases of \$203.5 million, less cash from the maturity of unrestricted and restricted investments of \$61.0 million.

Cash provided by investing activities for the six months ended June 30, 2015 was primarily due to the maturity of unrestricted and restricted investments of \$106.7 million, less investment purchases of \$50.4 million.

### *Financing Activities*

Cash provided by financing activities was \$2.7 million for the six months ended June 30, 2016, compared to \$4.1 million of cash used for the same period in 2015.

Cash provided by financing activities for the six months ended June 30, 2016 was a result of the issuance of common stock under our equity incentive plans.

Cash used for financing activities for the six months ended June 30, 2015 was primarily due to principal payments on our debt of \$4.4 million.

Proceeds from common stock and debt issuances are used for general working capital purposes, including for clinical trials, build-out of commercial infrastructure, research and development, capital expenditures and working capital. Over the next several years, we are required to make certain payments on notes and bank obligations. See “--Certain Factors Important to Understanding Our Financial Condition and Results of Operations,” for a description of those payment obligations.

### *Capital Requirements*

We have incurred net losses since inception through June 30, 2016, with the exception of the 2011 fiscal year. We anticipate annual net losses for the foreseeable future. For the six months ended June 30, 2016, we incurred a net loss of \$98.4 million and as of June 30, 2016, we had an accumulated deficit of \$2.0 billion. These losses have had, and will continue to have, an adverse effect on our stockholders’ deficit and working capital. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses or whether or when we will become profitable, if at all. Excluding fiscal 2011, our research and development expenditures and selling, general and administrative

expenses have exceeded our revenues for each fiscal year, and we expect to spend significant additional amounts to fund the continued development and commercialization of cabozantinib. As a result, we expect to continue to incur substantial operating expenses and, consequently, we will need to generate significant additional revenues to achieve future profitability.

Since the launch of our first commercial product in January 2013, through June 30, 2016, we have generated an aggregate of \$115.0 million in net product revenues. Other than sales of CABOMETYX and COMETRIQ, we have derived substantially all of our revenues since inception from collaborative research and development agreements, which depend on royalties, license fees, the achievement of milestones, and research funding we earn from any products developed from the collaborative research.

The amount of our net losses will depend, in part, on: the level of sales of CABOMETYX in the U.S. for the treatment of advanced RCC; our sales of COMETRIQ; achievement of clinical, regulatory and commercial milestones and the amount of royalties, if any, from sales of cabozantinib under our collaboration with Ipsen; our share of the net profits and losses for the commercialization of COTELLIC in the U.S. under our collaboration with Genentech (a member of the Roche group); 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, primarily with respect to expanded commercialization activities for cabozantinib.

As of June 30, 2016, we had \$384.0 million in cash and investments, which included \$298.2 million available for operations, \$81.6 million of compensating balance investments that we are required to maintain on deposit with Silicon Valley Bank, and \$4.2 million of long-term restricted investments. We anticipate that our current cash and cash equivalents, and short-term investments available for operations, and product revenues, will enable us to maintain our operations for a period of at least 12 months following the filing date of this report. Our capital requirements will depend on many factors, and we may need to use available capital resources and raise additional capital significantly earlier than we currently anticipate. Our capital requirements 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 our collaboration with Ipsen;
- the commercial success of COTELLIC and the calculation of 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 outcome of our arbitration demand 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 United States;
- the speed of a potential regulatory approval of cabozantinib for the treatment of advanced RCC in the European Union, following the CHMP's positive opinion, and in other indications both in the United States and abroad;
- the outcome of discussions with regulatory authorities regarding the development and submission strategy for cabozantinib as a treatment of previously untreated advanced RCC;
- future clinical trial results, notably the results from CELESTIAL, our phase 3 pivotal trial in patients with advanced HCC;
- repayment of the Deerfield Notes (see "Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations - Certain Factors Important to Understanding Our Financial Condition and Results of Operations - Deerfield Facility" for a description of these notes) which mature on July 1, 2018, subject to a requirement to make a mandatory prepayment in each of 2017 and 2018 equal to 15% of certain revenues from collaborative arrangements (other than intercompany arrangements) received during the prior fiscal year, subject to a maximum annual prepayment amount of \$27.5 million;
- our ability to repay the Deerfield Notes with our common stock, which we are only able to do under specified conditions;
- repayment of our \$287.5 million aggregate principal amount of the 4.25% Convertible Senior Subordinated Notes due 2019, or the 2019 Notes, (see "Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations - Certain Factors Important to Understanding Our Financial Condition and Results of Operations - Convertible Senior Subordinated Notes" for a description of these notes), which mature on August 15, 2019, unless earlier converted, redeemed or repurchased;
- repayment of our term loan from Silicon Valley Bank, which had an outstanding balance at June 30, 2016, of \$80.0 million and is due in May 2017;

- our ability to control costs;
- our ability to remain in compliance with, or amend or cause to be waived, financial covenants contained in agreements with third parties;
- the cost of clinical drug supply for our clinical trials;
- trends and developments in the pricing of oncologic therapeutics in the United States 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.

#### **Contractual Obligations**

We have contractual obligations in the form of debt, operating leases, purchase obligations and other long-term liabilities. There were no material changes outside of the ordinary course of business in our contractual obligations from those as of December 31, 2015.

#### **Off-Balance Sheet Arrangements**

As of June 30, 2016, we did not have any material off-balance-sheet arrangements, as defined by applicable SEC regulations.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

Our market risks at June 30, 2016 have not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the Securities and Exchange Commission on February 29, 2016.

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio and our long-term debt. As of June 30, 2016, and December 31, 2015, a decrease 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 \$7.0 million and \$8.7 million, respectively.

In addition, we have exposure to fluctuations in certain foreign currencies in countries in which we conduct clinical trials. As of June 30, 2016, and December 31, 2015, approximately \$3.5 million and \$3.2 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 for any periods presented. We recorded a \$0.1 million loss and a \$0.1 million gain relating to foreign exchange fluctuations for six months ended June 30, 2016 and 2015, respectively.

### **Item 4. Controls and Procedures.**

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

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

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

## 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 United States.

In December 2006, we entered into a worldwide collaboration for the development and commercialization of cobimetinib with Genentech. The terms of the collaboration agreement provide Genentech with authority over the global development and commercialization plans for cobimetinib and the execution of those plans. The collaboration agreement further provides that we are entitled to an initial equal share of U.S. profits and losses for cobimetinib, with our share decreasing as sales increase, as well as low double-digit royalties on ex-U.S. net sales of cobimetinib. To date, cobimetinib has been approved for use exclusively in combination with vemurafenib (ZELBORAF) and launched by Genentech in the United States and multiple other territories, including the European Union, Canada, Australia and Brazil as a treatment for patients with advanced melanoma harboring a BRAF V600E or V600K mutation. It is marketed as COTELLIC.

Our arbitration demand asserts that Genentech has breached the parties' contract for, amongst other breaches, failing to meet its diligence and good faith obligations. The demand seeks various forms of declaratory, monetary, and equitable relief, including without limitation that the cost and revenue allocations for COTELLIC be shared equitably consistent with the collaboration agreement's terms, along with attorneys' fees and costs of the arbitration. Genentech has asserted a counterclaim for breach of contract, which seeks monetary damages and interest related to the cost allocations under the collaboration agreement. While the ultimate outcome of the arbitration is difficult to predict, a resolution of the matter adverse to us could result in, among other things, significant payments and higher than expected commercialization costs, which may have a material adverse effect on our results of operations, cash flows or financial condition.

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 January 1, 2016 filed with the Securities and Exchange Commission on February 29, 2016.***

#### Risks Related to Cabozantinib and Cobimetinib

***In the short-term, our prospects are critically dependent upon the commercial success of CABOMETYX for advanced RCC in the United States and our ability to obtain regulatory approval for cabozantinib in the same indication in the European Union.\****

The success of our business is dependent upon the successful development and commercialization of cabozantinib. Of greatest short-term importance is the commercialization of CABOMETYX for advanced RCC in the United States following approval by the FDA on April 25, 2016. 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 available competitive treatments. The principal competition for CABOMETYX for the treatment of advanced RCC includes nivolumab, lenvatinib, axitinib and everolimus, which are already approved in this indication, as well as other agents currently approved for 1st-line RCC including sunitinib, sorafenib, pazopanib, temsirolimus, and bevacizumab.

With respect to regulatory and commercialization activities for cabozantinib in the European Union, on July 22, 2016, the EMA's CHMP adopted a positive opinion of our MAA for cabozantinib as a treatment for adult patients with advanced RCC following prior VEGF-targeted therapy. The CHMP's positive opinion will now be reviewed by the EC, which has the authority to approve medicines for the European Union. Failure to obtain regulatory approval for cabozantinib in advanced RCC in the European Union, or the imposition of significant restrictions or limitations on use in the terms of approval, may negatively affect our business, results of operations and financial condition. Furthermore, in February 2016, we entered into a

collaboration with Ipsen to enable us to capitalize on the potential opportunity of cabozantinib in advanced RCC and potentially other indications, if approved by the EMA and elsewhere internationally outside of the U.S., Canada, and Japan. As a result, we now rely heavily upon Ipsen's regulatory, commercial, medical affairs, and other expertise and resources. If Ipsen is unable to, or does not invest the resources necessary to, obtain regulatory approvals for cabozantinib in the European Union and elsewhere; or, if Ipsen is not able to, or does not invest the resources necessary to, successfully commercialize cabozantinib in those international territories where it is approved, this will minimize our potential revenue under the collaboration agreement, thus resulting in harm to our business and operations.

***Our longer-term prospects remain dependent on cabozantinib's further clinical development and commercial success in additional indications beyond advanced RCC.\****

We are dedicating substantially all of our proprietary resources to developing cabozantinib into a broad and significant oncology franchise. Even following the approval of CABOMETYX for the treatment of advanced RCC in the United States and assuming cabozantinib's approval in the European Union for the same indication, our longer-term success remains contingent upon, among other things, successful clinical development, regulatory approval and market acceptance of cabozantinib in additional indications, such as advanced HCC, first-line RCC, NSCLC, and other forms of cancer. In 2014, the failure of COMET-1 and COMET-2, our two phase 3 pivotal trials of cabozantinib in mCRPC, to meet their respective primary endpoints negatively impacted our ability to achieve our development and commercialization goals for cabozantinib in prostate cancer. The failure in mCRPC demonstrates that cabozantinib will not likely be successful in all future clinical trials. Should we prove unsuccessful in the further development of cabozantinib beyond MTC or advanced RCC, our longer-term prospects, revenues and financial condition would be materially adversely affected. With top-line results from CELESTIAL, our phase 3 pivotal trial comparing cabozantinib to placebo in patients with advanced HCC, expected in 2017, the successful development of cabozantinib in advanced HCC is important to our long-term success.

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

The terms of our collaboration agreement with Genentech provide them with exclusive authority over the global development and commercialization plans for cobimetinib and the execution of those plans. We have no effective influence over those plans and are heavily dependent on Genentech's decision making. The collaboration agreement provides that we are entitled to an initial equal share of U.S. profits and losses for cobimetinib, with our share decreasing as sales increase. We are also entitled to low double-digit royalties on ex-U.S. net sales of cobimetinib. In both cases, we are heavily dependent on Genentech's internal accounting procedures for determining how much, if any, profit we may derive from the collaboration. To date, we believe Genentech's pricing of, and cost and revenue allocations for, COTELLIC, as determined exclusively by Genentech, have been contrary to the applicable terms of the collaboration agreement. We raised this concern with Genentech, along with other material concerns regarding Genentech's performance under the collaboration agreement, but were unable to come to resolution on any of these issues. Accordingly, on June 3, 2016, following a 30 day dispute resolution period, we filed a demand for arbitration 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 United States. If we are unable to successfully resolve the dispute with Genentech, our business, operating results and financial condition could be adversely affected.

We are also heavily dependent upon Genentech's leadership and expertise to develop cobimetinib further. 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. Genentech has complete financial responsibility for cobimetinib's development program and regulatory strategy, 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. While Genentech recently initiated a phase 3 pivotal trial combining cobimetinib with its anti-PD-L1 antibody atezolizumab, we are dependent on Genentech for all future development of cobimetinib in combination with atezolizumab or any other immuno-oncology agents. Regardless of Genentech's efforts toward the further development of cobimetinib, such additional clinical investigation may not provide positive results supporting product label expansions or approval in additional indications.

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

Our ability to commercialize cabozantinib, as CABOMETYX tablets for the approved advanced RCC indication, COMETRIQ capsules for the approved MTC indications, or if approved in a tablet formulation 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 and Medicaid, and the medical community. If cabozantinib does not achieve an adequate level of acceptance, we may not generate significant future product revenues, and we may not become profitable. The degree of market acceptance of CABOMETYX, COMETRIQ and other cabozantinib products, if approved, will depend upon a number of factors, including:

- the effectiveness, or perceived effectiveness, of cabozantinib in comparison to competing products;
- the existence of any significant side effects of cabozantinib, as well as their severity in comparison to those of any competing products;
- cabozantinib's potential advantages or disadvantages in relation to alternative treatments;
- the timing of market entry relative to competitive treatments;
- indications for which cabozantinib is approved;
- the ability to offer cabozantinib for sale at competitive prices;
- relative convenience and ease of administration;
- the strength of sales, marketing, medical affairs and distribution support; and
- sufficient third-party coverage and reimbursement.

***If we are unable to maintain or scale adequate sales, marketing and distribution capabilities or enter into or maintain agreements with third parties to do so, we may be unable to commercialize cabozantinib successfully.\****

We have designed our commercial organization and strategic commercial approach to maintain flexibility in response to market opportunities. In connection with the FDA's approval of CABOMETYX for the treatment of patients with advanced RCC, we increased our sales, marketing, market access and distribution capabilities. Establishing and maintaining sales, marketing and distribution capabilities are expensive and time-consuming. Such expenses may be disproportionate compared to the revenues we may be able to generate and may have an adverse impact on our results of operations. We expect to be able to scale up our commercialization capabilities quickly if additional indications for cabozantinib are approved in the future, or to scale down, if necessary. Our ex-US distribution arrangements with Sobi are also right-sized for the European Union MTC opportunity and retain strategic flexibility. Overall, we believe the design of our commercial organization, and our strategic commercial approach, are efficient, taking advantage of outsourcing options where prudent to maximize the effectiveness of our commercial expenditures.

However, we believe the commercial opportunity for cabozantinib will grow over time, but we may not properly judge the requisite size, and experience of the commercialization team or the scale of distribution necessary to market and sell cabozantinib successfully. Maintaining sales, marketing, medical affairs, and distribution capabilities is expensive and time-consuming. Such expenses may be disproportionate compared to the revenues we may be able to generate on sales of cabozantinib and could have an adverse impact on our results of operations. If we are unable to maintain adequate sales, marketing, medical affairs, and distribution capabilities, independently or with others, we may not be able to generate product revenues and our business may be adversely affected.

We currently rely on a single third party logistics provider to handle shipping and warehousing for our commercial supply of both CABOMETYX and COMETRIQ. 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 United States, we still rely on a single specialty pharmacy to dispense COMETRIQ to patients in fulfillment of prescriptions in the United States. Outside the U.S., we currently rely on a third party, Sobi, to distribute and commercialize COMETRIQ for the approved MTC indications primarily in the European Union, but also in other countries through the named patient use, or NPU, program.

The terms of our commercialization agreement with Sobi provide us with the ability to terminate the agreement at will upon payment of certain pre-determined termination fees. In connection with the establishment of our collaboration with Ipsen, we provided Sobi with notice of termination and following a transition period expected to conclude in 2016, Ipsen will become responsible for the continued distribution and commercialization of COMETRIQ for the approved MTC indications in territories currently supported by Sobi and potentially other countries in the event that COMETRIQ is approved for commercial sale in such territories, as well as access and distribution activities for COMETRIQ under our NPU program.

Our current and anticipated future dependence upon the activities, and legal and regulatory compliance, of these or other third parties may adversely affect our future profit margins and our ability to supply cabozantinib to the marketplace on a timely and competitive basis. For example, if our third party logistics provider's warehouse suffers a fire or damage from another type of disaster, the commercial supply of CABOMETYX and COMETRIQ could be destroyed, resulting in a disruption in our commercialization efforts. These or other third parties may not be able to provide services in the time we

require 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, at a time that is costly or inconvenient for us. If we are unable to contract for logistics services or distribution of cabozantinib on acceptable terms, our commercialization efforts may be delayed or otherwise adversely affected.

***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. The laws that may affect our ability to operate include, without limitation:

- the federal Anti-Kickback Law, which constrains our business activities, including our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, 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;
- 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;
- 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;
- state and federal 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 (participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our products, increased infrastructure costs, and potentially limit our ability to offer certain marketplace discounts); and
- state and federal marketing expenditure tracking and reporting laws, which generally require certain types of expenditures in the United States to be tracked and reported (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, which could potentially have a negative effect on our business and/or increase enforcement scrutiny of our activities).

In addition, certain marketing practices, including off-label promotion, may also violate certain federal and state health regulatory fraud and abuse laws as well as false claims laws. 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, withdrawal of regulatory approval, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to sell our products or operate our business and also adversely affect our financial results.

Numerous federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use and disclosure of personal information. Other

countries also have, or are developing, laws governing the collection, use and transmission 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. 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 recently enacted laws in a majority of states requiring security breach notification. These laws could create liability for us or increase our cost of doing business. International laws, such as the EU Data Privacy Directive (95/46/EC) and Swiss Federal Act on Data Protection, regulate the processing of personal data within Europe and between European countries and the United States. Failure to provide adequate privacy protections and maintain compliance with safe harbor mechanisms could jeopardize business transactions across borders and result in significant penalties.

***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 for it is, and will be, available from third-party payers, including governmental payers, such as Medicare and Medicaid, and private health insurers. Many patients will not be capable of paying for CABOMETYX or COMETRIQ themselves and will rely on third-party payers to pay for, or subsidize, their medical needs. 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 often varies based on the type of contract or plan purchased. There has been recent negative publicity regarding the use of specialty pharmacies and drug pricing, 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.

In addition, in some foreign countries, particularly the countries in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, price negotiations with governmental authorities can take six to twelve months or longer after the receipt of regulatory marketing approval 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 clinical trial that compares the cost effectiveness of CABOMETYX to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in the commercialization of CABOMETYX. Third-party payers are challenging the prices charged for medical 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 product 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 United States 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 United States 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 United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

We expect that the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, or PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved product. An expansion in the government's role in the U.S. healthcare industry may cause general downward pressure on the prices of prescription drug products, lower reimbursements for providers using our products, reduce product utilization and adversely affect our business and results of operations. It is unclear whether and to what extent, if at all, other potential developments resulting from the PPACA may provide us with additional revenue to offset the annual excise tax (on certain drug product sales) enacted under the PPACA, subject to limited exceptions. It is possible that the tax burden, if ours is not excepted, would adversely affect our financial performance. The PPACA, among other things, also established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. Moreover, certain politicians, including presidential candidates, have

announced plans to regulate the prices of pharmaceutical products. We cannot know what form any such legislation may take or the market's perception of how such legislation would affect us. Any reduction in reimbursement from government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our current products and/or those for which we may receive regulatory approval in the future.

As a result of the overall trend towards cost-effectiveness criteria and managed healthcare in the United States, third-party payers are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs. They may use tiered reimbursement and may adversely affect demand for CABOMETYX or COMETRIQ by placing a particular product in an expensive tier. They may also refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payers will reimburse for newly approved drugs, which in turn will put pressure on the pricing of drugs. Further, we do not have experience in ensuring approval by applicable third-party payers outside of the United States for coverage and reimbursement of COMETRIQ. We also anticipate pricing pressures in connection with the sale of CABOMETYX and COMETRIQ due to the increasing influence of health maintenance organizations and additional legislative proposals.

***Our competitors may develop products and technologies that impair the value of cabozantinib and cobimetinib.\****

The pharmaceutical, biopharmaceutical and biotechnology industries are highly fragmented and are characterized by rapid technological change. In particular, the area of kinase-targeted therapies is a rapidly evolving and competitive field. 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. In addition, delays in the further development of cabozantinib or cobimetinib for the treatment of additional tumor types, 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. 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 and cobimetinib. In addition, cabozantinib and cobimetinib may compete with existing therapies that have long histories of use, such as chemotherapy and radiation treatments in cancer indications.

*Competition for cabozantinib*

We believe the principal competition for CABOMETYX in advanced RCC includes: Bristol-Myers Squibb's nivolumab; Pfizer's axitinib, sunitinib and temsirolimus; Novartis' everolimus and pazopanib; Bayer's and Onyx Pharmaceuticals' sorafenib; Genentech's bevacizumab; and Eisai's lenvatinib.

The immediate competition we face from Bristol-Myers Squibb's nivolumab is particularly significant. Nivolumab was approved for the treatment of advanced RCC on November 23, 2015, following a rapid review by the FDA. That approval was based in large part on the results of Bristol-Myers Squibb's phase 3 trial comparing nivolumab to everolimus in patients who had received previous antiangiogenic therapy for advanced RCC (Checkmate 025), in which nivolumab met its primary endpoint of showing a statistically-significant improvement in OS over everolimus, a current standard of care for the treatment of second line RCC patients. Nivolumab failed to demonstrate a statistically-significant PFS benefit over everolimus. Nivolumab also demonstrated an acceptable safety profile. Based on publicly available information, it appears nivolumab is being rapidly adopted by physicians for the treatment of advanced RCC.

We believe that the principal competing anti-cancer therapy to COMETRIQ in progressive, metastatic MTC is Genzyme's RET, VEGFR and EGFR inhibitor vandetanib, which has been approved by the FDA and the EMA for the treatment of symptomatic or progressive MTC in patients with unresectable, locally advanced, or metastatic disease. On October 21, 2015, AstraZeneca announced the global completion of the sale of vandetanib to Genzyme, a Sanofi company. We anticipate the potential for increased competition for COMETRIQ in progressive, metastatic MTC as a result of the consolidation of vandetanib into Genzyme's endocrinology portfolio and the company's rare disease expertise. In addition, we believe that COMETRIQ also faces competition as a treatment for progressive, metastatic MTC from off-label use of Bayer's

and Onyx Pharmaceuticals' (a wholly-owned subsidiary of Amgen) multikinase inhibitor sorafenib, Pfizer's multikinase inhibitor sunitinib, Ariad Pharmaceutical's multikinase inhibitor ponatinib, Novartis' multikinase inhibitor pazopanib, and Eisai's multikinase inhibitor lenvatinib.

Should cabozantinib be approved for the treatment of HCC, the other indication for which we have an ongoing phase 3 pivotal trial, we believe its principal competition may include Bayer's and Onyx Pharmaceuticals' sorafenib, Bayer's regorafenib, ArQule's tivantinib, Eisai's lenvatinib, Bristol-Myers Squibb's nivolumab and Merck's pembrolizumab. In particular, Bayer recently announced positive results from a Phase 3 trial that compared regorafenib to placebo in the same HCC patient population that is being enrolled in our Phase 3 trial.

Examples of potential competition for cabozantinib in other cancer indications include: other VEGF pathway inhibitors, including Genentech's bevacizumab; other RET inhibitors including Eisai's lenvatinib and Ariad's ponatinib; and other MET inhibitors, including Amgen's AMG 208, Pfizer's crizotinib, ArQule's tivantinib, and Mirati's MGCD265; and immunotherapies such as Bristol-Myers Squibb's ipilimumab and nivolumab, Merck's pembrolizumab and Roche's atezolizumab.

#### *Competition for cobimetinib*

We believe that cobimetinib's principal competition amongst targeted agents includes Novartis' trametinib and dabrafenib, and Array's encorafenib and binimetinib; and within the class of immunotherapies, Bristol-Myers Squibb's ipilimumab and nivolumab and Merck's pembrolizumab. The second category, immunotherapies, are of particular competitive importance vis-a-vis cobimetinib in advanced melanoma as they are already FDA approved in melanoma patient populations that overlap with those that may be eligible for cobimetinib, they have been rapidly incorporated into the National Comprehensive Cancer Network treatment guidelines, and they are viewed with a high degree of enthusiasm by physicians and key opinion leaders. Ongoing and future trials incorporating immune-oncology agents, including combination trials, may further impact usage of cobimetinib in melanoma and potentially in additional tumor types in which cobimetinib may ultimately gain approval.

***We lack the manufacturing capabilities necessary to enable 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 have the manufacturing capabilities necessary to enable us to produce materials for our clinical trials or for commercial sale of cabozantinib in either its capsule formulation or tablet formulation, and rely on third party contractors to do so. These third parties must comply with applicable regulatory requirements, including the FDA's current Good Manufacturing Practices and the European Commission's Guidelines on Good Distribution Practice. Our current and anticipated future dependence upon these third parties may adversely affect our future profit margins and our ability to develop and commercialize cabozantinib on a timely and competitive basis. These third parties may not be able to produce material on a timely basis or manufacture material at the quality or in the quantity required to meet our development and commercial timelines and applicable regulatory requirements. We may not be able to maintain or renew our existing third party manufacturing and supply arrangements, or enter into new arrangements, on acceptable terms, or at all. Our third party manufacturers and suppliers could terminate or decline to renew our manufacturing and supply arrangements based on their own business priorities, at a time that is costly or inconvenient for us. If we are unable to contract for the production of materials in sufficient quantity and of sufficient quality on acceptable terms, our clinical trials and commercialization efforts may be delayed or otherwise adversely affected. This risk is especially acute during the current period as we continue to ramp up production of CABOMETYX for the treatment of patients advanced RCC in the United States.

Furthermore, if we are required to enter into new manufacturing or supply arrangements, we may not be able to obtain approval from the FDA of any alternate manufacturer or supplier in a timely manner, or at all, which could delay or prevent the clinical development and commercialization of cabozantinib. Failure of our third party manufacturers or suppliers or us to obtain approval from the FDA or to comply with applicable regulations could result in sanctions being imposed on us, including fines, civil penalties, delays in or failure to grant marketing approval of cabozantinib, injunctions, suspension or withdrawal of approvals, license revocation, seizures or recalls of products and compounds, operating restrictions and criminal prosecutions, any of which could have a significant adverse effect on our business. Our third party manufacturers are subject to routine regulatory inspections. Failure of our third party manufacturers to meet these appropriate standards and/or perform manufacturing as required could result in a batch not passing quality inspection or meeting regulatory approval. This could result in product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could have also a significant adverse effect on our business.

***Clinical testing of cabozantinib is a lengthy, costly, complex and uncertain process and may fail to demonstrate safety and efficacy.\****

Cabozantinib is being evaluated in a comprehensive development program for the treatment of advanced HCC and a variety of other indications beyond advanced RCC and MTC. Clinical trials are inherently risky and may reveal that cabozantinib is ineffective or has unacceptable toxicity or other side effects that may significantly decrease the likelihood of regulatory approval in such indications. For example, COMET-1 and COMET-2, our two phase 3 pivotal trials of cabozantinib in mCRPC, failed to meet their respective primary endpoints of 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 by 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 cabozantinib based on existing knowledge of our compounds in development and industry metrics, we may not be able to meet those timelines.

We may experience numerous unforeseen events, during or as a result of clinical testing, that could delay or prevent commercialization of cabozantinib for the treatment of advanced HCC, and other indications, including:

- cabozantinib may not prove to be efficacious or may cause, or potentially cause, 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 cabozantinib;
- patient registration or enrollment in our clinical testing may be lower than we anticipate, resulting in the delay or cancellation of clinical testing; and
- regulators or institutional review boards may withhold authorization of cabozantinib, 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 cabozantinib 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 have limited experience in conducting clinical trials and may not be able to rapidly or effectively continue the further development of cabozantinib 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 cabozantinib 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 cabozantinib. 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.

***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 independently conduct clinical trials for cabozantinib, including our post-marketing commitments in connection with the approvals of CABOMETYX in advanced RCC and COMETRIQ in progressive,

metastatic MTC, and we rely on third parties we do not control such as the federal government (including NCI-CTEP, 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 need to be replaced or if the quality or accuracy of the data they obtain 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 advanced RCC in the United States and the approved MTC indications in the United States and European Union.

***Cabozantinib is subject to a lengthy and uncertain regulatory process that may not result in the necessary regulatory approvals, which could adversely affect our ability to commercialize cabozantinib.***

The activities associated with cabozantinib's research, development and commercialization, are subject to extensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory approval for cabozantinib would prevent us from promoting its use. We have only limited experience in preparing and filing the applications necessary to gain regulatory approvals. The process of obtaining regulatory approvals in the United States 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 NDA supplement can be submitted to the FDA, or MAA to the EMA or any application or submission to regulatory authorities in other jurisdictions, the product candidate must undergo extensive clinical trials, which can take many years and require substantial expenditures.

Any clinical trial may fail to produce results satisfactory to the FDA or regulatory authorities in other jurisdictions. 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. Changes in regulatory approval policy, regulations or statutes governing the process for regulatory review during the development or review periods for cabozantinib may cause delays in the approval or rejection of an application.

Even if the FDA or a comparable authority in another jurisdiction approves cabozantinib, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, distribution, advertising, promotion, marketing and/or production of cabozantinib and may 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 the various post-marketing requirements, including a 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 and to conduct other clinical pharmacology and preclinical studies. 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 civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval.

#### **Risks Related to Our Need for Additional Financing and Our Financial Results**

***If additional capital is not available to us, we may be forced to delay, reduce or eliminate our product development programs or commercialization efforts and we may breach our financial covenants.\****

We may need to access additional capital to:

- fund our operations and clinical trials;
- continue our research and development efforts;
- expand our sales, marketing and distribution capabilities;
- commercialize cabozantinib or any other future product candidates, if any such candidates receive regulatory approval for commercial sale; and

- fund the portion of U.S. sales and marketing costs for cobimetinib that we are obligated to fund under our collaboration with Genentech (a member of the Roche Group), or any similar costs we are obligated to fund under collaborations we may enter into in the future.

As of June 30, 2016, we had \$384.0 million in cash and investments, which included \$298.2 million available for operations, \$81.6 million of compensating balance investments that we are required to maintain on deposit with Silicon Valley Bank, and \$4.2 million of long-term restricted investments. We anticipate that our current cash and cash equivalents, and short-term investments available for operations, and product revenues, will enable us to maintain our operations for a period of at least 12 months following the filing date of this report. Our capital requirements will depend on many factors, and we may need to use available capital resources and raise additional capital significantly earlier than we currently anticipate. Our capital requirements 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 our collaboration with Ipsen;
- the commercial success of COTELLIC and the calculation of 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 outcome of our arbitration demand 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 United States;
- the speed of a potential regulatory approval of cabozantinib for the treatment of advanced RCC in the European Union, following the CHMP's positive opinion, and in other indications both in the United States and abroad;
- future clinical trial results, notably the results from CELESTIAL, our phase 3 pivotal trial in patients with advanced HCC;
- the outcome of discussions with regulatory authorities regarding the development and submission strategy for cabozantinib as a treatment of previously untreated advanced RCC;
- repayment of the Deerfield Notes (see "Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations - Certain Factors Important to Understanding Our Financial Condition and Results of Operations - Deerfield Facility" for a description of these notes) which mature on July 1, 2018, subject to a requirement to make a mandatory prepayment in each of 2017 and 2018 equal to 15% of certain revenues from collaborative arrangements (other than intercompany arrangements) received during the prior fiscal year, subject to a maximum annual prepayment amount of \$27.5 million;
- our ability to repay the Deerfield Notes with our common stock, which we are only able to do under specified conditions;
- repayment of our \$287.5 million aggregate principal amount of the 4.25% Convertible Senior Subordinated Notes due 2019, or the 2019 Notes, (see "Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations - Certain Factors Important to Understanding Our Financial Condition and Results of Operations - Convertible Senior Subordinated Notes" for a description of these notes), which mature on August 15, 2019, unless earlier converted, redeemed or repurchased;
- repayment of our term loan from Silicon Valley Bank, which had an outstanding balance at June 30, 2016, of \$80.0 million and is due in May 2017;
- our ability to control costs;
- our ability to remain in compliance with, or amend or cause to be waived, financial covenants contained in agreements with third parties;
- the cost of clinical drug supply for our clinical trials;
- trends and developments in the pricing of oncologic therapeutics in the United States 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.



***We have a history of net losses. We expect to continue to incur net losses, and we may not achieve or maintain profitability.\****

We have incurred net losses since inception through June 30, 2016, with the exception of the 2011 fiscal year. We anticipate annual net losses for the foreseeable future. For the six months ended June 30, 2016, we incurred a net loss of \$98.4 million and as of June 30, 2016, we had an accumulated deficit of \$2.0 billion. These losses have had, and will continue to have, an adverse effect on our stockholders' deficit and working capital. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses or whether or when we will become profitable, if at all. Excluding fiscal 2011, our research and development expenditures and selling, general and administrative expenses have exceeded our revenues for each fiscal year, and we expect to spend significant additional amounts to fund the continued development and commercialization of cabozantinib. As a result, we expect to continue to incur substantial operating expenses and, consequently, we will need to generate significant additional revenues to achieve future profitability.

Since the launch of our first commercial product in January 2013, through June 30, 2016, we have generated an aggregate of \$115.0 million in net product revenues. Other than sales of CABOMETYX and COMETRIQ, we have derived substantially all of our revenues since inception from collaborative research and development agreements, which depend on royalties, license fees, the achievement of milestones, and research funding we earn from any products developed from the collaborative research.

The amount of our net losses will depend, in part, on: the level of sales of CABOMETYX in the U.S. for the treatment of advanced renal cell carcinoma ("RCC"); our sales of COMETRIQ; achievement of clinical, regulatory and commercial milestones and the amount of royalties, if any, from sales of cabozantinib under our collaboration with Ipsen; our share of the net profits and losses for the commercialization of COTELLIC in the U.S. under our collaboration with Genentech (a member of the Roche group); 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, primarily with respect to expanded commercialization activities for cabozantinib.

***Our significant level of indebtedness could limit cash flow available for our operations and expose us to risks that could adversely affect our business, financial condition and results of operations.***

We have significant indebtedness and substantial debt service requirements as a result of the Deerfield Notes, our loan and security agreement with Silicon Valley Bank and the 2019 Notes. As of June 30, 2016, our total consolidated indebtedness through maturity was \$492.5 million (excluding trade payables). We may also incur additional indebtedness to meet future financing needs. If we incur additional indebtedness, it would increase our interest expense, leverage and operating and financial costs.

Our indebtedness could have significant negative consequences for our business, results of operations and financial condition, including:

- making it more difficult for us to meet our payment and other obligations under the 2019 Notes, the Deerfield Notes, our loan and security agreement with Silicon Valley Bank or our other indebtedness;
- resulting in an event of default if we fail to comply with the covenants contained in our debt agreements, which event of default could result in all of our debt becoming immediately due and payable;
- increasing our vulnerability to adverse economic and industry conditions;
- subjecting us to the risk of increased sensitivity to interest rate increases on our indebtedness with variable interest rates, including borrowings under our loan and security agreement with Silicon Valley Bank;
- limiting our ability to obtain additional financing;
- requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness, thereby reducing the amount of our cash flow available for other purposes, including clinical trials, research and development, capital expenditures, working capital and other general corporate purposes;
- limiting our flexibility in planning for, or reacting to, changes in our business;
- preventing us from raising funds necessary to purchase the 2019 Notes in the event we are required to do so following a "Fundamental Change" as specified in the indenture governing the 2019 Notes, or to settle conversions of the 2019 Notes in cash;
- dilution experienced by our existing stockholders as a result of the conversion of the 2019 Notes or the Deerfield Notes into shares of common stock; and
- placing us at a possible competitive disadvantage with less leveraged competitors and competitors that may have better access to capital resources.

We cannot assure you that we will continue to maintain sufficient cash reserves or that our business will generate cash flow from operations at levels sufficient to permit us to pay principal, premium, if any, and interest on our indebtedness, or that our cash needs will not increase. If we are unable to generate sufficient cash flow or otherwise obtain funds necessary to make required payments, or if we fail to comply with the various requirements of the 2019 Notes, the Deerfield Notes, our loan and security agreement with Silicon Valley Bank, or any indebtedness which we have incurred or may incur in the future, we would be in default, which would permit the holders or the Trustee of the 2019 Notes or other indebtedness to accelerate the maturity of such notes or other indebtedness and could cause defaults under the 2019 Notes, the Deerfield Notes, our loan and security agreement with Silicon Valley Bank or our other indebtedness. Any default under the 2019 Notes, the Deerfield Notes, our loan and security agreement with Silicon Valley Bank, or any indebtedness that we have incurred or may incur in the future could have a material adverse effect on our business, results of operations and financial condition.

If a Fundamental Change, as defined in the indenture governing the 2019 Notes, occurs, holders of the 2019 Notes may require us to purchase for cash all or any portion of their 2019 Notes at a purchase price equal to 100% of the principal amount of the Notes to be purchased plus accrued and unpaid interest, if any, to, but excluding, the Fundamental Change purchase date. We may not have sufficient funds to purchase the notes upon a Fundamental Change. In addition, the terms of any borrowing agreements that we may enter into from time to time may require early repayment of borrowings under circumstances similar to those constituting a Fundamental Change. Furthermore, any repurchase of 2019 Notes by us may be considered an event of default under such borrowing agreements.

***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 June 30, 2016, 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.

**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, Genentech (a member of the Roche group), Bristol-Myers Squibb, Sanofi, Merck (known as MSD outside of the United States and Canada) and Daiichi Sankyo, 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 reasonable costs we are obligated to share, in part, under our collaboration agreement with Genentech;

- collaborators may delay clinical trials, 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, such as the demand for arbitration we filed on June 3, 2016 asserting claims against Genentech for breaches of the collaboration agreement connected with its clinical development, pricing and commercialization of COTELLIC, and cost and revenue allocations arising from COTELLIC's commercialization in the United States;
- 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.

***We may be unable to establish collaborations for selected preclinical and clinical compounds.***

We may pursue new collaborations with leading pharmaceutical and biotechnology companies for the development and ultimate commercialization of selected preclinical and clinical programs and compounds, particularly those drug candidates for which we believe that the capabilities and resources of a partner can accelerate development and help to fully realize their therapeutic and commercial potential. However, we may not be able to close any such additional collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional collaborations because of the numerous risks and uncertainties associated with establishing additional collaborations. If we are unable to close additional collaborations on mutually-advantageous terms with partners qualified to achieve the collaboration's objectives, we may not be able to realize value from a particular drug candidate.

**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. Over the past year, cyber-attacks have 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 United States 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 United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, the patent owner has failed to “work” the invention in that country or the third party has patented improvements). In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. 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 genes and gene fragments, techniques and methodologies relating to model systems and 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**

***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 and commercial 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 and commercial personnel will be critical to support activities related to advancing the development program for cabozantinib and our other compounds, and successfully executing upon our commercialization plan for cabozantinib. Competition is intense for experienced clinical and commercial personnel, and we may be unable to retain or recruit clinical and commercial 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 South San Francisco, 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.

***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.***

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 and the 2019 Notes**

***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;
- 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 our collaboration with Ipsen;
- the outcome of our arbitration with Genentech regarding COTELLIC;

- the progress and scope of other development and commercialization activities for cabozantinib and our other compounds;
- future clinical trial results, notably the results from CELESTIAL, our phase 3 pivotal trial in patients with advanced HCC;
- 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 success rate of our efforts leading to milestone payments and royalties;
- 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;
- 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;
- conflicts or litigation with our collaborators, including the outcome of our arbitration with Genentech regarding COTELLIC;
- 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;
- financing transactions;
- 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. 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 conversion of our convertible notes, or the perception that such sales or conversions may occur, may depress our stock price.***

A substantial number of shares of our common stock is reserved for issuance upon conversion of the 2019 Notes, upon the exercise of stock options, upon vesting of restricted stock unit awards, upon sales under our employee stock purchase program, upon exercise of certain outstanding warrants and upon conversion of the Deerfield Notes. The issuance and sale of substantial amounts of our common stock, including upon conversion of the 2019 Notes or the Deerfield Notes, 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. Trading of the 2019 Notes is likely to influence and be influenced by the market for our common stock. For example, the price of our common stock could be affected by possible sales of common stock by investors who view the 2019 Notes as a more attractive means of equity participation in our company and by hedging or arbitrage trading activity that we expect to occur involving our common stock.

***The accounting method for convertible debt securities that may be settled in cash, such as the 2019 Notes, could have a material effect on our reported financial results.\****

Under Accounting Standards Codification, or ASC, Subtopic 470-20, issuers of certain convertible debt instruments that have a net settlement feature and may be settled in cash upon conversion, including partial cash settlement, are required to separately account for the liability (debt) and equity (conversion option) components of the instrument. As a result of the application of ASC 470-20, we recognized \$143.2 million as the initial debt discount with a corresponding increase to paid-in capital, the equity component, for the 2019 Notes. We will be required to record the amortization of this debt discount over the terms of the 2019 Notes, which may adversely affect our reported or future financial results and the market price of our common stock. In addition, under certain circumstances, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the 2019 Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital. Finally, we use the if-converted method to compute earnings per share, which could be more dilutive than using the treasury stock method.

***Certain provisions applicable to the 2019 Notes and the Deerfield Notes could delay or prevent an otherwise beneficial takeover or takeover attempt.***

Certain provisions applicable to the 2019 Notes and the indenture pursuant to which the 2019 Notes were issued, and the Deerfield Notes and the note purchase agreement governing the Deerfield Notes, could make it more difficult or more expensive for a third party to acquire us. For example, if an acquisition event constitutes a Fundamental Change under the indenture for the 2019 Notes or a Major Transaction under the note purchase agreement governing the Deerfield Notes, holders of the 2019 Notes or the Deerfield Notes, as applicable, will have the right to require us to purchase their notes in cash. In addition, if an acquisition event constitutes a Make-Whole Fundamental Change under the indenture for the 2019 Notes, we may be required to increase the conversion rate for holders who convert their 2019 Notes in connection with such Make-Whole Fundamental Change. In any of these cases, and in other cases, our obligations under the 2019 Notes and the indenture pursuant to which such notes were issued and the Deerfield Notes and the note purchase agreement governing the Deerfield



Notes, could increase the cost of acquiring us or otherwise discourage a third party from acquiring us or removing incumbent management.

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

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

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

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

***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, 2015, 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 NOLs. Furthermore, our ability to utilize our NOLs is conditioned upon our attaining profitability and generating United States federal taxable income. As described above, we have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; thus, we do not know whether or when we will generate the United States federal taxable income necessary to utilize our NOLs. A full valuation allowance has been provided for the entire amount of our NOLs.

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

Not applicable.

**Item 3. Defaults Upon Senior Securities.**

Not applicable.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

Not applicable.

**Item 6. Exhibits.**

(a) Exhibits

See the Exhibit Index immediately following the signature page to this Quarterly Report on Form 10-Q, which is incorporated by reference here.

**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.

August 3, 2016

\_\_\_\_\_  
Date

/s/ CHRISTOPHER J. SENNER

\_\_\_\_\_  
**Christopher J. Senner**

Executive Vice President and Chief Financial Officer

*(Duly Authorized Officer and Principal Financial and Accounting Officer)*

**EXHIBIT INDEX**

Exhibit Number	Exhibit Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit/Appendix Reference	Filing Date	
3.1	Amended and Restated Certificate of Incorporation of Exelixis, Inc.	10-K	000-30235	3.1	3/10/2010	
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Exelixis, Inc.	10-K	000-30235	3.2	3/10/2010	
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Exelixis, Inc.	8-K	000-30235	3.1	5/25/2012	
3.4	Certificate of 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	
4.2	Amended and Restated Secured Convertible Note dated July 1, 2015 in favor of Deerfield Partners, L.P.	10-Q	000-30235	4.2	8/11/2015	
4.3	Amended and Restated Secured Convertible Note dated July 1, 2015 in favor of Deerfield International Master Fund, L.P.	10-Q	000-30235	4.3	8/11/2015	
4.4	Registration Rights Agreement dated January 22, 2014 by and among Exelixis, Inc., Deerfield Partners, L.P. and Deerfield International Master Fund, L.P.	8-K	000-30235	4.2	1/22/2014	
4.5	Form of Warrant to Purchase Common Stock of Exelixis, Inc. issued to OTA LLC	10-Q	000-30235	4.5	11/10/2015	
4.6	Indenture dated August 14, 2012 by and between Exelixis, Inc. and Wells Fargo Bank, National Association	8-K	000-30235	4.1	8/14/2012	
4.7	First Supplemental Indenture dated August 14, 2012 to Indenture dated August 14, 2012 by and between Exelixis, Inc. and Wells Fargo Bank, National Association	8-K	000-30235	4.2	8/14/2012	
4.8	Form of 4.25% Convertible Senior Subordinated Note due 2019	8-K	000-30235	4.2 (Exhibit A)	8/14/2012	
10.1	Exelixis, Inc. 2000 Employee Stock Purchase Plan, as amended and restated	DEF 14A	000-30235	Appendix A	4/13/2016	

Exhibit Number	Exhibit Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit/Appendix Reference	Filing Date	
10.2*	Amended and Restated Collaboration Agreement, dated April 15, 2011, by and between Exelixis, Inc. Exelixis Patent Company, LLC and Bristol-Myers Squibb Company (amending and restating the Collaboration Agreement, dated October 8, 2010, by and between Exelixis, Inc. and Bristol-Myers Squibb Company).					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	XBRL Taxonomy Extension Presentation Linkbase Document					X

‡ This certification accompanies this Quarterly Report on Form 10-Q, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of Exelixis, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of this Quarterly Report on Form 10-Q), irrespective of any general incorporation language contained in such filing.

\* Confidential treatment requested for certain portions of this exhibit.

## AMENDED AND RESTATED COLLABORATION AGREEMENT

**THIS AMENDED AND RESTATED COLLABORATION AGREEMENT** (the “**Agreement**”) is made and entered into as of April 15, 2011 (the “**Effective Date**”) by and between **EXELIXIS, INC.**, a Delaware corporation having its principal place of business at 210 East Grand Avenue, South San Francisco, California 94080 (“**EXEL**”), **EXELIXIS PATENT COMPANY, LLC.**, a Delaware limited liability company having its principal place of business at 210 East Grand Avenue, South San Francisco, California 94080 (“**EPC**”), and **BRISTOL-MYERS SQUIBB COMPANY**, a Delaware corporation headquartered at 345 Park Avenue, New York, New York, 10154 (“**BMS**”). EXEL, EPC and BMS are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**”. EXEL and EPC are sometimes referred to collectively as “**Exelixis**”.

### RECITALS

- A. BMS is a multinational health care company that has expertise and capability in researching, developing and marketing human pharmaceuticals.
- B. EXEL is a drug discovery company that has expertise and proprietary technology relating to compounds that modulate the target known as ROR.
- C. BMS, EXEL and EPC desire to establish a collaboration to apply such Exelixis technology and expertise to the discovery, lead optimization and characterization of Small Molecule Compounds, and to provide for the development and commercialization of novel therapeutic and prophylactic products based on such compounds.
- D. BMS and EXEL are parties to a collaboration agreement that established such collaboration, entered into on October 8, 2010 (such agreement, the “**Collaboration Agreement**”, and the effective date of such agreement, the “**Original Effective Date**”).
- E. On event date herewith, EXEL is assigning to its wholly owned subsidiary, EPC, the patents relating to compounds that modulate ROR.
- F. BMS, EXEL and EPC wishes to amend and restate the Collaboration Agreement to account for such change of patent ownership.

**NOW, THEREFORE**, the Parties agree as follows:

### 1. DEFINITIONS

Capitalized terms used in this Agreement (other than the headings of the **Sections** or **Articles**) have the following meanings set forth in this **Article 1**, or, if not listed in this **Article 1**, the meanings as designated in the text of this Agreement.

**1.1 “Affiliate”** means, with respect to a particular Party, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such Party. For the purposes of the definition in this **Section 1.1**, the word **“control”** (including, with correlative meaning, the terms **“controlled by”** or **“under the common control with”**) means the actual power, either directly or indirectly through one (1) or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of at least fifty percent (50%) of the voting stock of such entity, by contract or otherwise.

**1.2 “ANDA”** means an Abbreviated New Drug Application submitted to the FDA in conformance with applicable laws and regulations, or the foreign equivalent of any such application in any other country.

**1.3 “BMS Licensed Know-How”** means all Information (other than Patents) Controlled by BMS and its Affiliates, including Information Controlled jointly with Exelixis, as of the Original Effective Date or during the term of the Agreement that: (a) relates to a Licensed Compound, a composition containing a Licensed Compound, a formulation containing a Licensed Compound, or the manufacture or use of a Licensed Compound; and (b) is [\*] for Exelixis to exercise the rights licensed to it under the Agreement or to perform its obligations under the Agreement.

**1.4 “BMS Licensed Patents”** means all Patents Controlled by BMS and its Affiliates, including Patents Controlled jointly with EPC, as of the Original Effective Date or during the term of this Agreement that: (a) cover a Licensed Compound, a composition containing a Licensed Compound, a formulation containing a Licensed Compound, or the manufacture or use of a Licensed Compound; and (b) are [\*] for Exelixis to exercise the rights licensed to it under the Agreement or to perform its obligations under the Agreement.

**1.5 “BMS ROR Compound”** means: (a) any Small Molecule Compound that is an ROR Antagonist and is Controlled by BMS and/or its Affiliates as of the Original Effective Date or during the Term, wherein such compound (i) (1) [\*] or [\*] and/or [\*] an ROR Antagonist [\*] the [\*] or (2) is [\*] and [\*] an ROR Antagonist (A) [\*] or [\*] and/or [\*] in the [\*] the [\*] or (B) [\*] or [\*] and/or [\*] in the [\*] the [\*], and (ii) is [\*], a [\*], or a [\*] or [\*]; or (b) any [\*], or [\*] of [\*]. Those ROR Antagonists that are [\*] Controlled by BMS and/or its Affiliates as of the Original Effective Date are set forth in the Disclosure Letter dated as of even date herewith.

**1.6 “Change of Control”** means any transaction in which a Party: (a) sells, conveys or otherwise disposes of all or substantially all of its property or business; or (b)(i) merges, consolidates with, or is acquired by any other Person (other than a wholly-owned subsidiary of such Party); or (ii) effects any other transaction or series of transactions; in each case of clause (i) or (ii), such that the stockholders of such Party immediately prior thereto, in the aggregate, no longer own, directly or indirectly, beneficially or legally, at least fifty percent (50%) of the outstanding voting securities or capital stock of the surviving Person following the closing of

such merger, consolidation, other transaction or series of transactions. As used in this **Section 1.6**, **“Person”** means any corporation, firm, partnership or other legal entity or individual person.

**1.7 “Collaboration”** means all the activities performed by or on behalf of either Exelixis or BMS in the course of performing work contemplated in **Article 3, 4** or **5**.

**1.8 “Collaborative Research Period”** means the period described in **Section 3.2**.

**1.9 “Commercialize”** means to promote, market, distribute, sell (and offer for sale or contract to sell) or provide product support for a Product, including by way of example: (a) detailing and other promotional activities in support of a Product; (b) advertising and public relations in support of a Product, including market research, development and distribution of selling, advertising and promotional materials, field literature, direct-to-consumer advertising campaigns, media/journal advertising, and exhibiting at seminars and conventions; (c) developing reimbursement programs and information and data specifically intended for national accounts, managed care organizations, governmental agencies (e.g., federal, state and local), and other group purchasing organizations, including pull-through activities; (d) co-promotion activities not included in the above; (e) conducting Medical Education Activities and journal advertising; and (f) [\*]. For clarity, **“Commercializing”** and **“Commercialization”** have a correlative meaning.

**1.10 “Controlled”** means, with respect to any compound, material, Information or intellectual property right, that the Party owns or has a license to such compound, material, Information or intellectual property right and has the ability to grant to another Party access, a license or a sublicense (as applicable) to such compound, material, Information or intellectual property right as provided for herein without violating the terms of any agreement or other arrangements with any Third Party existing at the time such Party would be first required hereunder to grant such other Party such access, license or sublicense.

**1.11 “Decision Point [\*]” or “[\*]”** means the point at which [\*] decides whether to [\*] a [\*] to [\*] to [\*], including [\*] of [\*] or [\*] and the [\*] of [\*] and [\*] of [\*] ([\*], etc.) to that effort. At [\*], the following [\*]: (a) [\*] or [\*] with [\*] and [\*] (through [\*]); (b) [\*] to [\*]; (c) [\*] or [\*]; (d) [\*] in [\*]; (e) [\*] for the [\*] through [\*] and [\*]; (f) [\*] for [\*] for [\*]; and (g) [\*].

**1.12 “Derivative”** means, for a particular ROR Antagonist, each ROR Antagonist that is [\*] or [\*] or [\*] that are [\*] of such ROR Antagonist.

**1.13 “Development”** means, with respect to a Product, those activities, including clinical trials, supporting manufacturing activities and related regulatory activities, that are [\*] to: (a) obtain the approval by the applicable Regulatory Authorities of the Drug Approval Application with respect to such Product in the applicable regulatory jurisdiction, whether alone or for use together, or in combination, with another active agent or pharmaceutical product; or (b) maintain such approvals. To avoid confusion, Development [\*]. For clarity, **“Develop”** and **“Developing”** have a correlative meaning.



**1.14 “Diligent Efforts”** means the carrying out of obligations or tasks in a sustained manner consistent with the commercially reasonable efforts a Party devotes to a product or a research, development or marketing project of similar market potential, profit potential or strategic value resulting from its own research efforts. Diligent Efforts requires that the Party: (a) [\*], (b) [\*], and (c) [\*] with respect to such [\*].

**1.15 “Disclosure Letter”** means one or more mutually agreed written letters or memoranda that are delivered by each of EXEL and BMS to the other contemporaneously with or subsequent to the execution of this Agreement and are identified therein as a Disclosure Letter contemplated by this Agreement and any amendments or replacement thereof approved in writing by both Parties.

**1.16 “Dollars” or “\$”** means the legal tender of the United States.

**1.17 “Drug Approval Application” or “DAA”** means: (a) in the United States, an NDA (or a supplemental NDA for following indications), and (b) in any other country or regulatory jurisdiction, an equivalent application for regulatory approval required before commercial sale or use of a Product (or with respect to a subsequent indication) in such country or regulatory jurisdiction.

**1.18 “[\*]” or “[\*]”** means the point at which [\*] decides whether to [\*] a [\*] to [\*] to [\*]. This decision point is known [\*] as “Decision Point [\*]” or “[\*]”. This decision point is typically made [\*] to [\*] prior to the [\*] of the [\*] for such [\*]. For such a [\*], the relevant [\*] for such [\*] shall [\*] include: (a) [\*] of [\*] in [\*]; (b) [\*] that [\*] and is [\*] to be [\*]; (c) [\*] that [\*] includes [\*] and [\*] and [\*] to [\*], [\*], [\*] and [\*]; and (d) [\*], and [\*] and [\*], including [\*] and [\*]. For clarity, [\*] (whether [\*] or [\*] or [\*]) shall be [\*] at [\*]; however, [\*] must be [\*] a [\*]. Typically, the [\*] shall also be [\*] and deemed suitable for [\*].

**1.19 “EMEA”** means BMS’ European, Central and Eastern European, Middle Eastern and African commercial territory, consisting of the following countries and regions: Algeria, Andorra, Austria, Baltic States, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Egypt, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Liechtenstein, Luxembourg, Malta, Morocco, Netherlands, Norway, Poland, Portugal, Romania, Russia, Saudi Arabia, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Tunisia, Turkey, U.K., Ukraine, Vatican City, Lebanon, Jordan, Syria, Kuwait, Bahrain, Oman, UAE and Qatar. The EMEA also includes: (a) the former Soviet Union and commonwealth of independent states such as Georgia, Armenia and central Asian republics; and (b) exports from France to English and French speaking African countries not separately identified in the list. For clarity, the specific list of countries and regions may change to align with any corresponding changes to BMS’ business structures.

**1.20 “EU”** means the European Union, as its membership may be altered from time to time, and any successor thereto. The member countries of the European Union as of the Original Effective Date are Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg,

Malta, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom.

**1.21 “Executive Officers”** means: (a) in the case of Exelixis, the [\*] of EXEL; and (b) in the case of BMS, [\*].

**1.22 “Exelixis ROR Compound”** means:

(a) any Small Molecule Compound that is an ROR Antagonist and is Controlled by Exelixis and/or its Affiliates as of the Original Effective Date or during the Term, wherein such compound (i) [\*] an ROR Antagonist [\*] or [\*] and/or [\*] the [\*]; (ii) [\*] an ROR Antagonist [\*] or [\*] and/or [\*] in the [\*] the [\*] and is [\*] a Small Molecule Compound that [\*] or [\*] and/or [\*] an ROR Antagonist [\*] the [\*]; or (iii) is [\*] or [\*] and such [\*] an ROR Antagonist (A) [\*] or [\*] and/or [\*] in the [\*] the [\*] or (B) [\*] or [\*] and/or [\*] in the [\*] the [\*];

(b) any [\*] or [\*] that is an ROR Antagonist and is [\*] or [\*] and/or [\*] the [\*] or [\*], wherein such [\*] (i) [\*] an ROR Antagonist [\*] or [\*] and/or [\*] the [\*]; or (ii) [\*] an ROR Antagonist [\*] or [\*] and/or [\*] in the [\*] the [\*];

(c) any [\*] or a [\*], wherein such [\*] is [\*] or [\*] and/or [\*] the [\*] or [\*] and such [\*] an ROR Antagonist (i) [\*] or [\*] and/or [\*] in the [\*] the [\*] or (ii) [\*] or [\*] and/or [\*] in the [\*] the [\*]; or

(d) any [\*], or [\*] of [\*] or [\*].

Those ROR Antagonists that are [\*] Controlled by Exelixis and/or its Affiliates as of the Original Effective Date are set forth in the Disclosure Letter dated as of even date herewith.

**1.23 “Exelixis Licensed Know-How”** means all Information (other than Patents) Controlled by Exelixis and its Affiliates, including Information Controlled jointly with BMS, as of the Original Effective Date or during the term of this Agreement that: (a) relates to a Licensed Compound, a composition containing a Licensed Compound, a formulation containing a Licensed Compound, or the manufacture or use of a Licensed Compound; and (b) is [\*] for BMS to exercise the rights licensed to it under the Agreement or to perform its obligations under the Agreement.

**1.24 “Exelixis Licensed Patents”** means all Patents Controlled by Exelixis and its Affiliates, including Patents Controlled jointly with BMS, as of the Original Effective Date or during the term of this Agreement that: (a) cover a Licensed Compound, a composition containing a Licensed Compound, a formulation containing a Licensed Compound, or the manufacture or use of a Licensed Compound; and (b) are [\*] for BMS to exercise the rights licensed to it under the Agreement or to perform its obligations under the Agreement.

**1.25 “FDA”** means the U.S. Food and Drug Administration, and any successor thereto.

**1.26 “GAAP”** means U.S. generally accepted accounting principles, consistently applied.

**1.27 “[\*]”** means, with respect to a particular Product in a country, [\*]: (a) [\*] such Product (or [\*]) and [\*]; (b) is [\*] ([\*] or [\*]); and (c) is [\*] or [\*] a [\*].

**1.28 “IND”** means an Investigational New Drug Application submitted to the FDA in conformance with applicable laws and regulations, or the foreign equivalent of any such application in any other country.

**1.29 “Information”** means information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, including, preclinical data, clinical trial data, databases, practices, methods, techniques, specifications, formulations, formulae, knowledge, know-how, skill, experience, test data including pharmacological, biological, chemical, biochemical, toxicological and clinical test data, analytical and quality control data, stability data, studies and procedures. For clarity, Information does not include any Patents.

**1.30 “Invention”** means any and all inventions and improvements, whether or not patentable, that are conceived or reduced to practice or otherwise made by or on behalf of a Party (and/or its Affiliates) in the performance of its obligations, or the exercise of its rights, under this Agreement.

**1.31 “Joint Invention”** means any Invention invented or discovered jointly by or on behalf of the employee(s), contractor(s) or agent(s) of BMS on one hand, and EXEL and/or EPC on the other hand (and/or their Affiliates).

**1.32 “Joint Research Committee” or “JRC”** means the committee described in **Section 2.1**.

**1.33 “Knowledge”** means, with respect to a Party, the [\*] facts and information [\*], or any [\*] of, or [\*], [\*], [\*] execution of this Agreement. For purposes of this definition, [\*] means any person in the [\*] of a Party.

**1.34 “Launch”** means, for each Product in each country, the first arm’s-length sale to a Third Party for use or consumption by the public of such Product in such country after Regulatory Approval of such Product in such country. A Launch shall not include any Product sold for use in clinical trials, for research or for other non-commercial uses, or that is supplied as part of a compassionate use or similar program.

**1.35 “Licensed Compound”** means any BMS ROR Compound or Exelixis ROR Compound.

**1.36 “LXR Collaboration Agreement”** means the Collaboration Agreement between Exelixis and BMS, executed as of December 5, 2005, as amended.

**1.37 “[\*]”** means [\*] or [\*] to the [\*] that [\*] the [\*] set forth in [\*] of the [\*].

**1.38 “Major European Countries”** means France, Germany, Spain, Italy, and the United Kingdom.

**1.39 “Major Territory”** means each of the following territories: (a) [\*].

**1.40 “Manufacturing”** means all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, inspection, receiving, holding and shipping of Licensed Compounds, Products, or any raw materials or packaging materials with respect thereto, or any intermediate of any of the foregoing, including process and cost optimization, process qualification and validation, commercial manufacture, stability and release testing, quality assurance and quality control. For clarity, “**Manufacture**” has a correlative meaning.

**1.41 “Materials”** means: (a) Licensed Compounds; and (b) biological materials, including but not limited to cell-lines, reagents, genes, vectors and constructs, that are in Exelixis’ Control and that were used by Exelixis in the performance of its obligations under the Research Plan.

**1.42 “NDA”** means a New Drug Application submitted to the FDA in conformance with applicable laws and regulations.

**1.43 “Net Sales”** means the amount invoiced or otherwise billed by BMS, or its Affiliate or sublicensee, for sales or other commercial disposition of a Product to a Third Party purchaser, less the following to the extent included in such billing or otherwise actually allowed or incurred with respect to such sales: (a) discounts, including cash, trade and quantity discounts, price reduction programs, retroactive price adjustments with respect to sales of a product, charge-back payments and rebates granted to managed health care organizations or to federal, state and local governments (or their respective agencies, purchasers and reimbursers) or to trade customers, including but not limited to, wholesalers and chain and pharmacy buying groups; (b) credits or allowances actually granted upon rejections or returns of Products, including for recalls or damaged goods; (c) freight, postage, shipping and insurance charges actually allowed or paid for delivery of Products, to the extent billed; (d) customs duties, surcharges and other governmental charges incurred in connection with the exportation or importation of a Product; (e) bad debts relating to sales of Products that are actually written off by BMS in accordance with GAAP during the applicable calculation period; (f) costs due to the factoring of receivables; and (g) taxes, duties or other governmental charges levied on, absorbed or otherwise imposed on sale of Products, without limitation any fees payable under the Health Care Reform Act of 2010, value-added taxes, or other governmental charges otherwise measured by the billing amount, when included in billing, as adjusted for rebates and refunds, but specifically excluding taxes based on net income of the seller; provided that all of the foregoing deductions are calculated in accordance with GAAP.

Notwithstanding the foregoing, if any Product is sold under a bundled or capitated arrangement with other BMS products, then, solely for the purpose of calculating Net Sales under this Agreement, any discount on such Products sold under such an arrangement shall be [\*] for the applicable accounting period. In case of any dispute as to the applicable [\*] under the preceding sentence, the determination of same shall be calculated and certified by [\*], whose decision shall be binding.

A sale of a Product is deemed to occur upon invoicing. [\*].

For sake of clarity and avoidance of doubt, sales by BMS, its Affiliates or sublicensees of a Product to [\*]. Any Products [\*] considered in determining Net Sales hereunder.

In the event a Product is sold as an end-user product consisting of a combination of active functional elements or as a combined product and/or service, Net Sales allocable to the Product in each such country, for purposes of determining royalty payments on such Product, shall be determined by mutual agreement reached in good faith by the Parties prior to the end of the accounting period in question based on an equitable method of determining such Net Sales that takes into account, on a country-by-country basis, variations in potency, the relative contribution of each active agent, component or service, as the case may be, in the combination, and relative value to the end user of each active agent, component or service, as the case may be. Notwithstanding the foregoing, the Parties agree that, for purposes of this paragraph, drug delivery vehicles, adjuvants, and excipients shall not be deemed to be “**active ingredients**” or “**active functional elements**”.

**1.44** “[\*]” means a [\*] or [\*] to the [\*] that [\*] the [\*] set forth in [\*] of the [\*].

**1.45 “Patent”** means all: (a) unexpired letters patent (including inventor’s certificates and utility models) which have not been held invalid or unenforceable by a court or other applicable governmental authority of competent jurisdiction from which no appeal can be taken or has been taken within the required time period (and which have not been admitted to be invalid or unenforceable through reissue, disclaimer or otherwise, or been abandoned in accordance with or as permitted by the terms of this Agreement or by mutual written agreement), including any substitution, extension, registration, confirmation, reissue, re-examination, supplementary protection certificates, confirmation patents, patent of additions, renewal or any like filing thereof; (b) pending applications for letters patent which have not been canceled, withdrawn from consideration, finally determined to be unallowable by the applicable governmental authority or court for whatever reason (and from which no appeal is or can be taken), and/or abandoned in accordance with or as permitted by the terms of this Agreement or by mutual written consent, including any continuation, division or continuation-in-part thereof and any provisional or other priority applications; and (c) any international counterparts, and counterparts in any country, to clauses (a) and (b) above.

**1.46 “Phase IIb Clinical Trial”** means a clinical trial of a Product on sufficient numbers of patients that is designed to provide a preliminary determination of safety and efficacy of such Product in the target patient population over a range of doses and dose regimens.

**1.47 “Phase III Clinical Trial”** means a clinical trial of a Product on sufficient numbers of patients that is designed to establish that such Product is safe and efficacious for its intended use, and to define warnings, precautions and adverse reactions that are associated with such Product in the dosage range to be prescribed, and to support Regulatory Approval of such Product or label expansion of such Product.

**1.48 “Phase IV Clinical Trial”** means a product support clinical trial of a Product commenced after receipt of Regulatory Approval in the country where such trial is conducted. A Phase IV Clinical Trial may include epidemiological studies, modeling and pharmacoeconomic

studies, and investigator-sponsored clinical trials studying Product that are approved by BMS and that otherwise fit the foregoing definition.

**1.49 “Post-Termination Compound”** means any ROR Antagonist for which [\*] such compound in any of the following time periods after the expiration or termination of the Agreement: (i) within [\*] thereafter in the event the Agreement expires or terminates prior to the [\*] anniversary of the Original Effective Date; (ii) within [\*] thereafter in the event the Agreement expires or terminates on or after the [\*] anniversary and prior to the [\*] anniversary of the Original Effective Date; (iii) within [\*] thereafter in the event the Agreement terminates on or after [\*] anniversary and prior to the [\*] anniversary of the Original Effective Date; and (iv) within [\*] in the event the Agreement terminates on or after the [\*] anniversary of the Original Effective Date. For clarity, Post-Termination Compounds shall not include: (A) any compound with respect to which [\*] such compound [\*] and [\*] the [\*] any [\*] or [\*] or [\*]; or (B) any compound that [\*] or [\*] that is [\*] and that is [\*] under **Article** [\*] of this Agreement.

**1.50 “Product”** means any human pharmaceutical product containing or comprising a Licensed Compound, either alone or with other active ingredients and in all forms, presentations, formulations and dosage forms.

**1.51 “Registrational Trial”** means, with respect to a given Product, either: (a) a Phase III Clinical Trial with such Product; or (b) a Phase IIb Clinical Trial that, at the time of commencement, is expected to be the basis for initial Regulatory Approval of such Product.

**1.52 “Regulatory Approval”** means any and all approvals (including Drug Approval Applications, supplements, amendments, pre- and post-approvals, pricing and reimbursement approvals), licenses, registrations or authorizations of any Regulatory Authority, national, supra-national (e.g., the European Commission or the Council of the EU), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, that are necessary for the manufacture, distribution, use or sale of a Product in a regulatory jurisdiction.

**1.53 “Regulatory Authority”** means the applicable national (e.g., the FDA), supra-national (e.g., the European Commission or the Council of the EU), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity that, in each case, governs the approval of a Product in such applicable regulatory jurisdiction.

**1.54 “Research”** means the following activities: (a) identifying Small Molecule Compounds as [\*] that [\*] and [\*] ROR by [\*]; (b) conducting a [\*] program to [\*] such [\*] to [\*] that [\*] and [\*] ROR (including the conduct of [\*] and [\*] studies, and [\*] studies); and (c) conducting [\*] on [\*] to [\*] for [\*] (including the conduct of [\*] studies, and related [\*] and [\*] activities). To avoid confusion, Research does not include the conduct of Development.

**1.55 “Reverted Compound”** means: (a) any Licensed Compound that has [\*] prior to the effective date of termination of this Agreement; and (b) any Licensed Compound that: (i) has [\*] prior to the effective date of termination of this Agreement; and (ii) are [\*].

**1.56 “Reverted Compounds License Agreement”** has the meaning set forth in **Section 11.5(a)(v)**.

**1.57 “ROR”** means: (a) the RAR-related orphan receptor [\*] gene, otherwise known as the [\*] gene, ([\*]); (b) the RAR-related orphan receptor [\*] (otherwise known as [\*] or [\*]) and RAR-related orphan receptor [\*] (otherwise known as [\*] or [\*]) proteins encoded by such gene (“[\*]”); (c) the RAR-related orphan receptor [\*] (otherwise known as [\*] (otherwise known as [\*]) proteins encoded by such gene (“[\*]”); and (d) all [\*] and [\*] thereof.

**1.58 “ROR Antagonist”** means any Small Molecule Compound that (a) directly binds and antagonizes (or is an inverse agonist of) ROR at the Target Potency Threshold and (b) is specific for ROR, based upon the Target Specificity Threshold.

**1.59 “Small Molecule Compound”** means a small molecule compound [\*] or [\*]. For clarity, [\*], shall be considered Small Molecule Compounds.

**1.60 “Sole Invention”** means any Invention invented or discovered solely by or on behalf of a Party (or its Affiliate) and its employees, contractors and/or agents.

**1.61 “Success Criteria”** has the meaning set forth in **Section 3.3(b)**.

**1.62 “Target Potency Threshold”** means, with respect to a Small Molecule Compound, that such Small Molecule Compound [\*] and [\*] (or [\*] of) the activity of ROR with a half maximal inhibitory concentration (“**IC<sub>50</sub>**”) of less than or equal to [\*] in the [\*] using [\*].

**1.63 “Target Specificity Threshold”** means, with respect to a Small Molecule Compound, that such Small Molecule Compound demonstrates, in a [\*] or [\*], [\*] ROR [\*], [\*] (i.e., the RAR-related orphan receptor [\*] gene, otherwise known as the [\*] gene, and the protein encoded by such gene) (“**ROR** [\*]”).

**1.64 “Territory”** means the world.

**1.65 “Third Party”** means any entity other than: (a) EXEL; (b) EPC; (c) BMS; or (d) an Affiliate of any of the foregoing Party.

**1.66 “United States”** or “**U.S.**” means the United States of America, and its territories, districts and possessions.

**1.67 “Valid Claim”** means: (a) a claim in an issued Patent that has not: (i) expired or been canceled; (ii) been declared invalid by an unreversed and unappealable or unappealed decision of a court or other appropriate body of competent jurisdiction; (iii) been admitted to be invalid or unenforceable through reissue, disclaimer or otherwise; or (iv) been abandoned in accordance with or as permitted by the terms of this Agreement or by mutual written agreement of the Parties; or (b) a claim under an application for a Patent that has been pending [\*], and, in any case, which has not been canceled, withdrawn from consideration, finally determined to be unallowable by the applicable governmental authority or court for whatever reason (and from which no appeal is or can be taken), or abandoned.

## **Additional Definitions**

The following table identifies the location of definitions set forth in various **Sections** of the Agreement.

[\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.



<b>Definition</b>	<b>Location (Section)</b>
<b>Alliance Manager</b>	<b>2.3(a)</b>
<b>Bankrupt Party</b>	<b>14.6(a)</b>
<b>[*]</b>	<b>[*]</b>
<b>[*]</b>	<b>[*]</b>
<b>BMS Independent Program</b>	<b>5.1(b)</b>
<b>[*]</b>	<b>[*]</b>
<b>Confidential Information</b>	<b>10.1</b>
<b>Cost-Terminated Patent Right</b>	<b>7.7(d)(iii)</b>
<b>[*] Notice</b>	<b>[*]</b>
<b>[*] Notice</b>	<b>[*]</b>
<b>EDI</b>	<b>14.11</b>
<b>[*]</b>	<b>[*]</b>
<b>Exelixis Sole Patent</b>	<b>7.8(a)(i)</b>
<b>Indemnatee</b>	<b>13.3</b>
<b>JAMS</b>	<b>14.3(c)</b>
<b>Joint Invention Patents</b>	<b>7.5(b)</b>
<b>Joint Product Patent</b>	<b>7.8(b)(i)(1)</b>
<b>Letter Agreement</b>	<b>14.4</b>
<b>[*]</b>	<b>[*]</b>
<b>Losses</b>	<b>13.1</b>
<b>Other Joint Patent</b>	<b>7.8(b)(ii)(1)</b>
<b>Permitted Use</b>	<b>4.2(b)</b>
<b>Prior CDA</b>	<b>10.4</b>
<b>Proposed Terms</b>	<b>14.3(d)</b>
<b>Research Plan</b>	<b>3.3(a)</b>
<b>ROR Technology</b>	<b>4.1</b>
<b>Royalty Term</b>	<b>8.8</b>
<b>[*]</b>	<b>[*]</b>
<b>Sales Threshold</b>	<b>8.2(b)</b>
<b>Separable Compounds</b>	<b>7.7(a)(v)</b>
<b>Sole Invention Patents</b>	<b>7.5(b)</b>
<b>Support Memorandum</b>	<b>14.3(c)</b>
<b>Term</b>	<b>11.1</b>
<b>TGR5 License Agreement</b>	<b>14.4</b>
<b>[*]</b>	<b>[*]</b>
<b>Title 11</b>	<b>14.6(a)</b>
<b>Transfer Addendum</b>	<b>4.2(d)</b>
<b>Unauthorized Invention</b>	<b>4.2(c)</b>

## 2. GOVERNANCE

### 2.1 Joint Research Committee.

**(a) Membership of JRC.** For the purpose of this Article 2, EXEL and EPC shall be deemed collectively as one (1) “Party”. The JRC shall be composed of four (4) members. Within [\*] after the Original Effective Date, each Party shall appoint two (2) representatives to the JRC. Each Party may replace its appointed JRC representatives at any time upon written notice to the other Party. Each Party shall designate one (1) of its representatives as co-chairperson of the JRC. Each of the co-chairpersons shall be responsible, on an alternating basis with the BMS co-chairperson having responsibility with respect to the initial meeting, for working with the Alliance Managers to schedule meetings, prepare and circulate an agenda in advance of each meeting, and to prepare and issue minutes of each meeting within [\*] thereafter. Any JRC member may add topics to the draft agenda. .

**(b) Decision-making.** The two (2) JRC representatives of each Party shall collectively have one (1) vote, and the JRC shall operate by unanimous consent of all JRC members present and in accordance with the principles set forth in this **Article 2**. The JRC shall not have any authority or jurisdiction to amend, modify, or waive compliance with this Agreement, any of which shall require mutual written agreement of the Parties. In the event of a dispute between the Parties with regard to the performance of the Collaboration, the matter shall be first referred to the Alliance Managers for resolution. If these two (2) individuals are unable to resolve the dispute, then the matter shall be elevated to the [\*] of EXEL and the [\*] of BMS (or in either case a direct report of such individual). If these two (2) individuals are unable to resolve the dispute, then, subject to the last sentence of this **Section 2.1(b)** and to **Section 2.1(c)**, [\*] shall have the final decision for [\*] disputes relating to the [\*] or [\*] of the [\*], so long as such decision does not [\*] or conflict with the terms of the Agreement, the Parties shall mutually agree as to the [\*] of the [\*] of [\*] that [\*] the [\*] under the [\*], and [\*] shall have the final decision with respect to [\*] disputes with respect to the [\*], so long as such decision does not conflict with the terms of the Agreement. Notwithstanding anything to the contrary, no decision by a Party shall (i) require the other Party to: (1) [\*] or [\*] that such other Party [\*] or [\*]; (2) [\*] that are [\*] or [\*] those [\*] the [\*]; or (3) [\*] any [\*] (e.g., [\*] of the [\*] for [\*] in the [\*] for [\*]) in connection with [\*] of [\*] the [\*], or [\*] associated with such [\*]; or (ii) amend, modify, or waive such Party’s compliance with, this Agreement, any of which shall require mutual written agreement of the Parties.

**(c) Exceptions to Decision-making.** Notwithstanding anything to the contrary, [\*] shall not have the final decision with respect to any dispute involving any of the following: (i) [\*] of the [\*] the [\*] and [\*] of [\*] the [\*] and [\*] of [\*]; (ii) changing the [\*]; (iii) changing [\*] for [\*] in a manner that [\*] for [\*] that are [\*] with [\*] for the [\*] the [\*]; (iv) whether the [\*] by [\*] pursuant to [\*] that a [\*] the [\*]; (v) changing the [\*] in a manner that [\*] that are [\*] with [\*] for the [\*] the [\*]; (vi) whether the [\*] by [\*] pursuant to [\*] that a [\*] the [\*]; (vii) changing the [\*] or the [\*]; or (viii) changing the [\*] the [\*] so as to modify [\*] (including [\*]) under the [\*], or the [\*] associated therewith.

**(d) Responsibilities of the JRC.** The JRC shall be responsible for the overall planning and execution of the Collaboration and the approval and oversight of the Research Plan. At its meetings, the JRC shall evaluate the Parties' progress in carrying out the Research Plan and the data generated by the Parties in the course of carrying out the Research Plan, shall discuss and approve project prioritization within the Research Plan, shall discuss and approve any revisions to the Research Plan, and shall perform those activities specifically described in this Agreement. To the extent necessary to carry out its responsibilities, a Party's JRC members shall be granted access to the other Party's Confidential Information relevant to any decision required to be made by the JRC.

**2.2 Meetings of JRC.** During the Collaborative Research Period, the JRC shall meet [\*] by audio or video teleconference and, at a minimum, [\*] in person (which in-person meeting shall be held on an alternating basis in New Jersey and in San Francisco). With the consent of the representatives of each Party serving on the JRC, other representatives of each Party may attend meetings of the JRC as nonvoting observers (provided such representatives: (i) have contractual confidentiality obligations to such Party that are at least as stringent as those set forth in this Agreement; and (ii) are under intellectual property assignment obligations to such Party in accordance with **Section 7.5(c)**). Meetings of the JRC shall be effective only if at least one (1) representative of each Party is present or participating. Each Party shall be responsible for all of its own expenses of participating in JRC meetings. The Parties shall endeavor to schedule meetings of the JRC at least [\*] in advance. Upon the conclusion of the Collaborative Research Period, the JRC shall be discontinued.

### **2.3 Alliance Managers.**

**(a) Appointment.** Each of the Parties shall appoint an individual (each, an "**Alliance Manager**") who possesses a general understanding of the scientific and business issues relevant to this Agreement. Each Party may change its designated Alliance Manager from time to time upon prior written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager by prior written notice to the other Party.

**(b) Responsibilities.** The Alliance Managers shall use good faith efforts to attend all JRC meetings and support the co-chairpersons of the JRC in the discharge of their responsibilities. Alliance Managers shall be nonvoting participants in JRC meetings. An Alliance Manager may bring any matter to the attention of the JRC if such Alliance Manager reasonably believes that such matter warrants such attention. Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment within the JRC. In addition, each Alliance Manager: (a) shall be the point of first referral in all matters of conflict resolution; (b) shall identify and bring disputes to the attention of the JRC in a timely manner; (c) shall plan and coordinate cooperative efforts and internal and external communications; and (d) shall take responsibility for ensuring that governance activities, such as the conduct of required JRC meetings and production of meeting minutes, occur as set forth in this Agreement, and that relevant action items resulting from such meetings are appropriately carried out or otherwise addressed.

### 3. RESEARCH COLLABORATION.

**3.1 Overview.** The general goals and intent of the research portion of the Collaboration are to apply each Party's technology to discover, optimize and characterize ROR Antagonists that may be developed into Products by BMS. Each of EXEL and BMS shall use Diligent Efforts to carry out its research responsibilities in accordance with the allocation of duties set forth in the Research Plan, including responsibilities for [\*], [\*] and [\*] of Licensed Compounds and activities to be conducted by the Parties that lead to the submission by EXEL of data to BMS [\*].

**3.2 Collaborative Research Period.** Subject to termination of this Agreement pursuant to **Section 11.2** or **11.3** (which will in turn terminate the Collaborative Research Period), the Collaborative Research Period shall begin on the Original Effective Date and shall, unless otherwise agreed by the Parties, terminate as follows (such period, the "**Collaborative Research Period**"):

**(a)** In the event that [\*] as of third (3rd) anniversary of the Original Effective Date, then the Collaborative Research Period shall end on such third (3rd) anniversary of the Effective Date.

**(b)** In the event that [\*] prior to the third (3rd) anniversary of the Original Effective Date, then the Collaborative Research Period shall end upon the earlier of (i) the second (2<sup>nd</sup>) anniversary of the date on which in such series of Licensed Compounds has achieved [\*], or (ii) achievement of the first [\*] for a Licensed Compound.

During the Collaborative Research Period, each of EXEL and BMS shall use Diligent Efforts to perform the tasks assigned to it in the Research Plan then in effect. For clarity, upon [\*], Exelixis shall be deemed to have fulfilled its obligations under the Research Plan.

#### **3.3 Research Plan; Success Criteria.**

**(a)** The Parties have agreed in writing upon a detailed plan for the research to be carried out by the BMS and EXEL during the Collaborative Research Period, which is set forth in the Disclosure Letter and incorporated herein by reference (the "**Research Plan**"). The Research Plan includes each of BMS's and EXEL's respective obligations in furtherance of the research portion of the Collaboration and timelines for completion of key stages. The JRC shall review the Research Plan at least [\*] and may propose and approve, subject to **Sections 2.1(b)** and **2.1(c)**, a revised version of the Research Plan that is consistent with the terms of this Agreement. Once approved by the JRC, such revised Research Plan shall replace the prior Research Plan.

**(b)** The Research Plan shall also contain criteria that a Licensed Compound must satisfy in order for BMS to make the [\*] decision (each set of criteria, "**Success Criteria**"). Any Success Criteria that are not reasonably ascertainable or completely known as of the Original Effective Date, or requiring adjustment based on results obtained during the conduct of

the Research Plan, shall be supplemented and/or modified as approved by mutual agreement of the JRC from time to time as appropriate.

### 3.4 Activities and Costs under the Research Plan.

(a) The Parties intend: (i) for EXEL to perform [\*] activities during the “[\*]” phase of the Research Plan, including [\*] of certain [\*], known as “[\*]” and “[\*]” in the [\*], that were [\*] or [\*] pursuant to the [\*] (with [\*] the [\*] to [\*] activities with respect to such [\*] pursuant to the [\*]); (ii) for EXEL to perform the [\*] activities in “[\*]” phase of the Research Plan, which may include [\*] of [\*] that were [\*] and [\*] as [\*] to the [\*]; and (iii) for EXEL and BMS, after [\*], to jointly perform the “[\*]” phase of the Research Plan, in each case as set forth in more detail in the Research Plan. EXEL shall provide no less than the minimum number of FTEs for the periods and activities set forth in the Research Plan, and shall continue to support the Research Plan using Diligent Efforts upon the expiration of any such period until the conclusion of the Collaborative Research Period, and BMS shall provide adequate resources to meet its activities set forth in the Research Plan.

(b) Each of EXEL and BMS shall bear its own internal and out-of-pocket costs and expenses incurred in connection with the conduct of the activities assigned to it under the Research Plan.

3.5 [\*]. Promptly after EXEL and BMS’s activities pursuant to the Research Plan generate data demonstrating that a particular series of Licensed Compounds meets the Success Criteria for [\*], and subsequent to activities in **Section 3.7**, EXEL shall submit such data to BMS. BMS shall promptly (and in good faith) review such data, and, within [\*] of such submission, shall notify EXEL in writing if BMS believes in good faith that such data do not demonstrate that such series of Licensed Compounds [\*], which notice shall specify the deficiencies in such data that cause it not to demonstrate that such series of Licensed Compounds [\*] (such notice, a “[\*] Notice”). If EXEL does not receive [\*] Notice from BMS by the end of such 30-day period, then BMS will, as of the end of such 30-day period, be deemed to have agreed that the series of Licensed Compounds [\*] (“[\*]”) and BMS shall be obligated to [\*] set forth in **Section** [\*] no later than [\*] after the end of such period. If EXEL receives [\*] Notice within such [\*] period and it disagrees with BMS’ assessment of such data, then such dispute shall be resolved by a mutually acceptable independent Third Party expert. Such Third Party expert shall determine, within [\*] of receipt of the data submitted by EXEL to BMS pursuant to this **Section 3.5** and the [\*], whether such data demonstrate that such series of Licensed Compounds [\*], and EXEL and BMS agree that such Third Party expert’s determination on this issue shall be final, binding, and determinative. The Party against whom the Third Party expert rules shall bear all costs of such Third Party determination. If such Third Party expert determines that data submitted by EXEL to BMS pursuant to this **Section 3.5** demonstrate that such series of Licensed Compounds [\*], then BMS will, as of the date of such determination, be deemed to have made a [\*] and BMS shall be obligated to [\*] set forth in **Section** [\*] no later than [\*] after the date of such determination. If such Third Party expert determines that data submitted by EXEL to BMS pursuant to this **Section 3.5** does not demonstrate that such series of

Licensed Compounds [\*], then [\*] will not have occurred and EXEL and BMS shall continue to work under the Research Plan in order to [\*].

**3.6** [\*]. Promptly after the Parties' activities pursuant to the Research Plan generate data demonstrating that a particular Licensed Compound [\*], EXEL shall submit such data to BMS. BMS shall promptly (and in good faith) review such data, and, within [\*] of such submission, shall notify EXEL in writing if BMS believes in good faith that such data do not demonstrate that such Licensed Compound [\*], which notice shall specify the deficiencies in such data that cause it not to demonstrate that such Licensed Compound [\*] (such notice, an "[\*] Notice"). If EXEL does not receive [\*] Notice from BMS by the end of such [\*] period, then BMS will, as of the end of such [\*] period, be deemed to have agreed the Licensed Compound [\*] ("[\*]") and BMS shall be obligated to [\*] set forth in **Section** [\*] no later than [\*] after the end of such period. If EXEL receives [\*] Notice within such [\*] period and it disagrees with BMS' assessment of such data, then such dispute shall be resolved by a mutually acceptable independent Third Party expert. Such Third Party expert shall determine, within [\*] of receipt of the data submitted by EXEL to BMS pursuant to this **Section 3.6** and [\*], whether such data demonstrate that such Licensed Compound [\*], and EXEL and BMS agree that such Third Party expert's determination on this issue shall be final, binding, and determinative. The Party against whom the Third Party expert rules shall bear all costs of such Third Party determination. If such Third Party expert determines that data submitted by EXEL to BMS pursuant to this **Section 3.6** demonstrate that such Licensed Compound [\*], then BMS will, as of the date of such determination, be deemed to have made a [\*] and BMS shall be obligated to [\*] set forth in **Section** [\*] no later than [\*] after the date of such determination. If such Third Party expert determines that data submitted by EXEL to BMS pursuant to this **Section 3.6** does not demonstrate that such Licensed Compound [\*], then [\*] will not have occurred and EXEL and BMS shall continue to work under the Research Plan in order to [\*].

**3.7 Review of Licensed Compounds.** Prior to any determination whether a Licensed Compound meets the Success Criteria for [\*], EXEL shall review the results of all [\*] assays for [\*] conducted by either EXEL or BMS for a compound that is expected to progress to [\*]. BMS shall provide EXEL with the results of all [\*] assays conducted by or on behalf of relating to [\*] for each [\*] Licensed Compound, and sufficient samples of each [\*] Licensed Compound to have such assays conducted. EXEL may use such results and samples for the sole purpose of performing assays to verify that such [\*] Licensed Compound [\*] of [\*] any [\*] for [\*] to any [\*] ("[\*]"). EXEL shall be responsible for having such assays conducted [\*] associated with such assays. If EXEL notifies BMS in writing within [\*] of receiving a sample of a submitted [\*] Licensed Compound that such Licensed Compound [\*], then BMS shall [\*] or [\*] such Licensed Compound, and [\*] to [\*] such Licensed Compound shall [\*] ([\*] to such Licensed Compound); *provided, however*, that BMS [\*] such Licensed Compound [\*] in [\*] to [\*] the [\*] such Licensed Compound. For clarity, (i) nothing in this **Section 3.7** shall be [\*] conducting screening activities, at any time, with respect to Licensed Compounds in order to determine whether Licensed Compounds [\*], and (ii) BMS may [\*] and [\*] with respect to any such submitted [\*] Licensed Compound during such review period prior to receiving any such written notice from EXEL. In the event that EXEL does not provide written notice to BMS with respect to the [\*] submitted [\*] Licensed Compound within such [\*] period, then BMS shall [\*] and [\*] such

Licensed Compound [\*] and [\*] in [\*]. Notwithstanding the foregoing, EXEL shall use commercially reasonable efforts to notify BMS as soon as practicable in the event that EXEL becomes aware in the course of performing its obligations under the Research Plan during the Collaborative Research Period that a Licensed Compound [\*].

**3.8 Obligations of Parties.** EXEL and BMS shall provide the JRC and its authorized representatives with reasonable access during regular business hours to all records, documents, and Information relating to the performance under the Collaboration, which the JRC may reasonably require in order to perform its obligations hereunder, provided that if such documents are under a bona fide obligation of confidentiality to a Third Party, then EXEL or BMS, as the case may be, may withhold access thereto to the extent necessary to satisfy such obligation.

**3.9 Collaboration Guidelines.** Subject to the terms of this Agreement, the activities and resources of each Party shall be managed by such Party, acting independently and in its individual capacity. The relationship between EXEL, EPC and BMS is that of independent contractors, and shall not constitute a partnership, joint venture or agency, and none of the Parties shall have the power to bind or obligate any other Parties in any manner, other than as is expressly set forth in this Agreement.

**3.10 Conduct of Research.** BMS and EXEL shall use Diligent Efforts to conduct their respective tasks throughout the Collaboration and shall conduct the Collaboration in good scientific manner, and in compliance in all material respects with the requirements of applicable laws, rules and regulations and all applicable good laboratory practices to attempt to achieve their objectives as efficiently and expeditiously as reasonably practicable. Each of BMS and EXEL may use its Affiliates or subcontractors, contract manufacturers, services providers or other Third Parties to complete its research responsibilities under the Research Plan, except that EXEL shall not be permitted to use Third Party contractors to complete the respective tasks of the minimum EXEL FTEs specifically set forth in the Research Plan without the approval of the JRC.

**3.11 Records.** Each of EXEL and BMS shall maintain complete and accurate records of all work conducted under the Collaboration and all results, data and developments made pursuant to its efforts under the Collaboration. Such records shall be complete and accurate and shall fully and properly reflect all work done and results achieved in the performance of the Collaboration in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes. Each of EXEL and BMS shall maintain such records for a period of [\*] after such records are created; provided that the following records may be maintained for a longer period, in accordance with each such Party's internal policies on record retention, provided that in no case shall such period be shorter than [\*] from the date of creation of such records: (a) scientific notebooks; and (b) any other records that such other Party reasonably requests be retained in order to ensure the preservation, prosecution, maintenance or enforcement of intellectual property rights. Either such Party shall have the right to review and copy such records of the other such Party at reasonable times to the extent necessary or useful for it to conduct its obligations or enforce its rights under this Agreement.

**3.12 Reports.** During the Collaborative Research Period, each of EXEL and BMS shall report to the JRC no less than [\*] and shall submit to the other such Party and the JRC [\*] written progress report summarizing the work performed under the Collaboration. If reasonably necessary for EXEL or BMS to perform its work under the Collaboration or to exercise its rights under the Agreement, such Party may request that such other Party provide more detailed information and data regarding such results reported by such other Party, and such other Party shall promptly provide the requesting Party with information and data as is reasonably related to such request, including any records created by a Party pursuant to **Section 3.11**. All such reports shall be considered Confidential Information of the Party providing same.

#### **4. TRANSFER OF ROR TECHNOLOGY**

**4.1 General.** For a period beginning on the Original Effective Date and ending [\*] after the end of the Collaborative Research Period, EXEL shall use Diligent Efforts to transfer to BMS, solely in accordance with **Section 4.2**, all items of Materials or Information that are in EXEL's possession and Control and that are [\*] for BMS to research or clinically develop or manufacture Licensed Compounds (such Information and Materials, "**ROR Technology**"); provided that subsequent to such [\*] period, EXEL will use commercially reasonable efforts to transfer Information and Materials that are requested by BMS for purposes of making a regulatory filing or patent application and that are in EXEL's possession and Control (as of the date of such request). BMS may request such a transfer in writing pursuant to **Section 4.2**. Additionally, BMS may request that EXEL provide a reasonable amount of on-site advice or support in connection with the foregoing transfer until the date which is [\*] subsequent to the [\*], and BMS shall reimburse EXEL for reasonable travel costs incurred.

**4.2 Transfer of ROR Technology.** EXEL shall transfer to BMS, upon prior written approval by the Parties, reasonable quantities of Information and Materials included in the ROR Technology solely as described below.

**(a) Ownership.** Except as otherwise provided in the Agreement, all rights, title and interest in and to such Information and Materials that are transferred by EXEL to BMS shall remain with EXEL. All such Information and Materials shall be considered the Confidential Information of EXEL and shall be subject to **Article 10** of the Agreement.

**(b) Permitted Use.** BMS shall use such Information and Materials solely for performing its obligations under the Research Plan and exercising its right to perform the BMS Independent Program, subject to any additional limitations due to Exelixis' obligations to Third Parties relating to such Information or Materials (with such limitations being set forth in the applicable Transfer Addendum) (the "**Permitted Use**"). BMS shall not transfer, deliver or disclose any of the Materials to any Third Party, other than its Affiliates or bona fide collaborators or third party contract service providers, without EXEL's prior written consent, except as otherwise stipulated in the Transfer Addendum. The Materials shall not be used in humans, except as otherwise contemplated by the Agreement. Any unused Materials supplied by EXEL shall be returned to EXEL or destroyed as agreed upon in writing by the Parties.



**(c) Unauthorized Use.** The Parties do not intend for BMS to use the Materials other than for the Permitted Use. If BMS or its Affiliates or other transferees use the Information or Materials outside of the Permitted Use, and any inventions, improvements, discoveries or data arise (or result) from such unauthorized use (such inventions, improvements, discoveries and data, and all intellectual property rights related thereto, collectively the “**Unauthorized Inventions**”), then: (i) BMS shall promptly and fully disclose all such Unauthorized Inventions to EXEL in writing; (ii) BMS shall comply with the terms of any upstream license agreement between either EXEL or EPC on one hand, and a Third Party on the other hand, with respect to such Unauthorized Use of Materials; and (iii) Exelixis may pursue all rights and remedies it may have under this Agreement, or at law or in equity, with respect to any breach of BMS’ obligation of Permitted Use (and creation of any Unauthorized Inventions).

**(d) Transfer Addendum.** Each transfer shall occur through the execution of an agreement substantially in the form of **Exhibit 4.2** (each, a “**Transfer Addendum**”), which is incorporated by reference into the Agreement. After receiving BMS’ written request for a particular item of ROR Technology, EXEL shall prepare and submit a Transfer Addendum listing the Information and Materials to be transferred to BMS. Upon written approval of such Transfer Addendum by the Parties, the Information and Materials shall be transferred to BMS within [\*]. For clarity, the intent of the Parties is to provide BMS with the ability to use Materials and Information for the Permitted Use and without additional restrictions other than those set forth in any applicable agreements between EXEL or EPC on the one hand, and a Third Party on the other hand, and as such, (i) no Transfer Addendum shall contain terms that are inconsistent with this Agreement, and (ii) Exelixis shall not unreasonably withhold its signature on a Transfer Addendum to prevent BMS from obtaining access to Materials or Information where such request by BMS is consistent with **Section 4.1** and this **Section 4.2**.

## **5. RESEARCH, DEVELOPMENT, MANUFACTURING & COMMERCIALIZATION OF PRODUCTS**

### **5.1 Research, Development, & Manufacturing of Products**

**(a) Scope.** After the end of the Collaborative Research Period, BMS shall have sole control and responsibility for the Research (which Research shall solely be conducted pursuant to the BMS Independent Program), Development, Manufacture (including formulation) and Commercialization of all Products. BMS shall bear all costs and expenses associated with such Research, Development, Manufacture (including formulation) and Commercialization of Products.

**(b) BMS Independent Program.** After the end of the Collaborative Research Period, BMS shall have the right to, at its sole expense, to conduct Research upon Licensed Compounds in accordance with, and solely to the extent permitted by, the license set forth in **Section 7.1(b)** (such Research, the “**BMS Independent Program**”). BMS shall provide EXEL with a written description of each ROR Antagonist that is optimized under the BMS Independent Program. Each such ROR Antagonist shall be deemed [\*] unless it qualifies as [\*] on account of satisfying the definition set forth in **Section [\*]**.

**(c) Diligence.** During the BMS Independent Program, BMS shall use Diligent Efforts to conduct Research to advance at least one Licensed Compound to meet the Success Criteria for [\*]. BMS shall use Diligent Efforts to Develop at least one Product in each country in the Major Territory, and Commercialize each Product for each indication for which it receives Regulatory Approval; provided, however, that BMS may satisfy its diligence obligations by sublicensing the Development and Commercialization of a Product to a Third Party pursuant to the terms of this Agreement. EXEL may notify BMS in writing if EXEL in good faith believes that BMS is not meeting its diligence obligations set forth in this **Section 5.1(c)**, and the Parties shall meet and discuss the matter in good faith. EXEL may further request review of BMS' records generated and maintained as required under **Section 5.1(d)** below.

**(d) Records.** BMS shall maintain complete and accurate records of all Research, Development, Manufacturing and Commercialization conducted by it or on its behalf related to each Product, and all Information generated by it or on its behalf in connection with Development under this Agreement with respect to each such Product. BMS shall maintain such records at least until the later of: (i) [\*] after such records are created, or (ii) [\*] after the Launch of the Product to which such records pertain; *provided* that the following records may be maintained for a longer period, in accordance with each Party's internal policies on record retention: (i) scientific notebooks and (ii) any other records that EXEL reasonably requests be retained in order to ensure the preservation, prosecution, maintenance or enforcement of intellectual property rights. Such records shall be at a level of detail appropriate for patent and regulatory purposes. EXEL shall have the right to review and copy such records of BMS at reasonable times to the extent necessary or useful for EXEL to conduct its obligations or enforce its rights under this Agreement.

**(e) Reports.** Beginning [\*] after the end of the Collaborative Research Period, and every [\*] thereafter during the term of the Agreement, BMS shall submit to EXEL a written progress report summarizing the Research, Development, Manufacturing and Commercialization performed by or on behalf of BMS with respect to Products. If reasonably necessary or useful for EXEL to exercise its rights under this Agreement, EXEL may request that BMS provide more detailed Information and data regarding such reports by BMS, and BMS shall promptly provide EXEL with Information and data as is reasonably related to such request, at EXEL's expense. All such reports shall be considered Confidential Information of BMS.

**5.2 Standards of Conduct.** BMS shall perform, or shall ensure that its Affiliates, sublicensees and Third Party contractors perform, all Research, Development, Manufacturing and Commercialization activities in a good scientific and ethical business manner and in compliance with applicable laws, rules and regulations.

## 6. REGULATORY

**6.1 Regulatory Lead Party.** BMS shall have sole responsibility for (and bear all costs and expenses associated with) all regulatory activities regarding Products. BMS shall also have sole responsibility for (and bear all costs and expenses associated with) worldwide pharmacovigilance for each Product. BMS and its Affiliates shall have sole responsibility for all pricing and reimbursement approval proceedings relating to any Product in the Territory.

**6.2 Ownership of Regulatory Dossier.** BMS will own all regulatory filings for such Product in order to facilitate BMS' interactions with Regulatory Authorities. BMS shall prepare and draft all filings (including any supplements or modifications thereto and including the preparation of any electronic submission of a Drug Approval Application) to Regulatory Authorities in each such country for such Product.

**6.3 Recalls in the Territory.** Any decision to initiate a recall or withdrawal of a Product in the Territory shall be made by BMS. In the event of any recall or withdrawal, BMS shall take any and all necessary action to implement such recall or withdrawal in accordance with applicable law, with assistance from EXEL as reasonably requested by BMS. The costs of any such recall or withdrawal in the Territory shall be borne solely by BMS.

## 7. LICENSES; INTELLECTUAL PROPERTY

**7.1 Licenses to BMS.** Subject to the terms of this Agreement:

**(a) Collaborative Research Period (Non-Sublicensable to Non-Affiliates).** During the Collaborative Research Period, EXEL hereby grants to BMS a co-exclusive, worldwide, royalty-free license (with the right to sublicense to its Affiliates, but without the right to sublicense to Third Parties except with prior written consent of Exelixis), under the Exelixis Licensed Know-How, solely to perform, or have performed pursuant to **Section 3.10**, the research tasks assigned to BMS pursuant to the Research Plan. During the Collaborative Research Period, EPC hereby grants to BMS a co-exclusive, worldwide, royalty-free license (with the right to sublicense to its Affiliates, but without the right to sublicense to Third Parties except with prior written consent of Exelixis), under the Exelixis Licensed Patents, solely to perform, or have performed pursuant to **Section 3.10**, the research tasks assigned to BMS pursuant to the Research Plan.

**(b) BMS Independent Program (Sublicensable to Non-Affiliates).** During the period beginning with the end of the Collaborative Research Period and ending on the expiration or earlier termination of this Agreement, EXEL hereby grants to BMS, an exclusive, worldwide, royalty-free license (with the right to sublicense to its Affiliates, Third Party contract research providers and manufacturers, and bona fide collaborators), under the Exelixis Licensed Know-How, to make, have made, import and use for Research any: (i) Licensed Compounds (subject to **Section 3.7**) that have achieved a [\*] by the end of the Collaborative Research Period; (ii) Licensed Compounds (subject to **Section 3.7**) that have achieved a [\*] by the end of the Collaborative Research Period; (iii) Licensed Compounds (subject to **Section 3.7**) that have achieved the [\*] described in the Research Plan by the end of the Collaborative Research Period;

and (iv) [\*] the Licensed Compounds described in [\*], including [\*] that is created under [\*] for [\*]. During the period beginning with the end of the Collaborative Research Period and ending on the expiration or earlier termination of this Agreement, EPC hereby grants to BMS, an exclusive, worldwide, royalty-free license (with the right to sublicense to its Affiliates, Third Party contract research providers and manufacturers, and bona fide collaborators), under the Exelixis Licensed Patents, to make, have made, import and use for Research any: (i) Licensed Compounds (subject to **Section 3.7**) that have achieved a [\*] by the end of the Collaborative Research Period; (ii) Licensed Compounds (subject to **Section 3.7**) that have achieved a [\*] by the end of the Collaborative Research Period; (iii) Licensed Compounds (subject to **Section 3.7**) that have achieved the [\*] described in the Research Plan by the end of the Collaborative Research Period; and (iv) [\*] the Licensed Compounds [\*] in [\*], including [\*] that is created under [\*] for [\*].

**(c) Clinical Development and Commercialization.** EXEL hereby grants to BMS, effective upon BMS' timely payment of the milestone payment set forth in **Section 8.2(a)(i)(2)**, an exclusive, worldwide, royalty-bearing license (with the right to sublicense), under the Exelixis Licensed Know-How, to make, have made, use, Develop, import, sell, offer to sell and have sold Products. EPC hereby grants to BMS, effective upon BMS' timely payment of the milestone payment set forth in **Section 8.2(a)(i)(2)**, an exclusive, worldwide, royalty-bearing license (with the right to sublicense), under the Exelixis Licensed Patents, to make, have made, use, Develop, import, sell, offer to sell and have sold Products.

**(d) Exelixis Retained Rights.** Exelixis retains all rights to use the Exelixis Licensed Know-How and Exelixis Licensed Patents except those expressly granted to BMS on an exclusive basis under the terms of this Agreement. In addition, notwithstanding the exclusive licenses granted to BMS pursuant to **Section 7.1**, Exelixis retains the right under the Exelixis Licensed Patents and the Exelixis Licensed Know-How to make, have made, use, and test Licensed Compounds solely for internal research purposes. To the extent any such Exelixis Licensed Patents are owned by EPC, EPC hereby grants EXEL an exclusive, fully-paid, royalty free license, with the right to grant sublicenses, under the Exelixis Licensed Patents to perform and have performed the research tasks assigned to EXEL pursuant to the Research Plan.

**(e) BMS Covenants.** BMS hereby covenants that BMS shall not (and shall ensure that any of its permitted sublicensees shall not) use any Exelixis Licensed Know-How or Exelixis Licensed Patents for a purpose other than that expressly permitted in **Section 7.1 or 11.5(b)**.

**7.2 License to Exelixis for Collaboration Research.** Subject to the terms of this Agreement, BMS hereby grants Exelixis a co-exclusive, worldwide, royalty-free license (with the right to sublicense to Affiliates, but without the right to sublicense to Third Parties except with prior written consent of BMS), under the BMS Licensed Know-How and BMS Licensed Patents, solely to perform, or have performed pursuant to **Section 3.10**, the research tasks assigned to Exelixis pursuant to the Research Plan. Exelixis hereby covenants that Exelixis shall not (and shall ensure that any of its permitted sublicensees shall not) use any BMS Licensed

Know-How or BMS Licensed Patents for a purpose other than that expressly permitted in this **Section 7.2 or 11.5(a)**.

**7.3 No Additional Licenses.** Except as expressly provided in **Sections 4.2, 7.1, 7.2, and Article 11**, nothing in this Agreement grants either Party any right, title or interest in and to the intellectual property rights of an Party (either expressly or by implication or estoppel). For clarity, the licenses granted in **Section 7.1** by Exelixis to BMS do not give BMS any right or license (a) to incorporate into any Product (e.g., as a combination product) any compound that is Controlled by Exelixis and that is not a Licensed Compound or (b) to perform any research that is directed to identifying, characterizing, developing or otherwise pursuing any Small Molecule Compound that is not a Licensed Compound. For clarity, the licenses granted in **Section 11.5** by BMS to Exelixis do not give Exelixis any right or license (a) to incorporate into any Product (e.g., as a combination product) any compound that is Controlled by Exelixis and that is not a Reverted Compound or (b) to perform any research that is directed to identifying, characterizing, developing or otherwise pursuing any small molecule compound that is not a Reverted Compound.

**7.4 Sublicensing.** Each Party shall provide the other Parties with the name of each permitted sublicensee of its rights under this **Article 7** and a copy of the applicable sublicense agreement; provided that each Party may redact confidential or proprietary terms from such copy, including financial terms. The sublicensing Party shall remain responsible for each permitted sublicensee's compliance with the applicable terms and conditions of this Agreement. Each sublicense granted by a Party of its rights under this **Article 7** to a party who is an Affiliate of such Party at the time such license is granted shall terminate immediately upon such party ceasing to be an Affiliate of such Party.

### **7.5 Ownership.**

(a) The inventorship of all Sole Inventions and Joint Inventions shall be determined under the U.S. patent laws.

(b) BMS shall own the entire right, title and interest in and to any and all of its Sole Inventions, and Patents claiming only such Sole Inventions (and no Joint Inventions) ("**Sole Invention Patents**"). As between EXEL and EPC, EPC shall own the entire right, title and interest in and to any and all of Sole Invention Patents of EXEL and/or EPC. EXEL hereby assigns to EPC its entire right, title and interest in and to its Sole Invention Patents. BMS and Exelixis shall be joint owners in and to any and all Joint Inventions, provided that, as between EXEL and EPC, EPC shall be the joint owner of any and all Patents claiming such Joint Inventions ("**Joint Invention Patents**"), and EXEL hereby assigns to EPC its entire right, title and interest in and to its Joint Invention Patents. BMS and Exelixis (EPC for Joint Invention Patents and EXEL for other Joint Inventions) as joint owners each shall have the right to exploit and to grant licenses under such Joint Inventions, and where exercise of such rights require, under the laws of a country, with the consent of the other Party (such consent not to be unreasonably withheld, delayed or conditioned) unless otherwise specified in this Agreement (including where such rights are exclusively licensed to the other Party hereunder).

(c) All employees, agents and contractors of each Party shall be under written obligation to assign any inventions and related intellectual property to the Party for whom they are employed or are providing services.

(d) The Parties acknowledge and agree that this Agreement shall be deemed to be a “**Joint Research Agreement**” as defined under 35 U.S.C. 103(c).

**7.6 Disclosure.** Each Party shall submit a written report to the other Parties no less frequently than within [\*] of the end of each [\*] describing any Sole Invention or Joint Invention arising during the prior [\*] in the course of the Agreement which it believes may be patentable or at such earlier time as may be necessary to preserve patentability of such invention. Each Party shall provide to the other Parties such assistance and execute such documents as are reasonably necessary to permit the filing and prosecution of such patent application to be filed on such Sole Invention or Joint Invention, or the issuance, maintenance or extension of any resulting Patent.

## **7.7 Patent Prosecution and Maintenance; Abandonment.**

### **(a) Joint Patent Committee.**

(i) **Establishment & Meetings.** Promptly after the Original Effective Date (as defined in the TGR5 License Agreement), the Parties shall establish a committee (the “**Joint Patent Committee**” or “**JPC**”). The JPC shall be composed of at least one (1) representative from each of BMS and EXEL, at least one of which shall be a patent counsel for such Party. Each such Party may change its representative(s) by giving the other such Party at least [\*] prior written notice. The JPC shall meet within [\*] after the Original Effective Date (as defined in the TGR5 License Agreement), and once per [\*] thereafter, or as may be requested by either Party as necessary, by teleconference, videoconference or in person (as determined by the JPC).

(1) **Duties.** As between EXEL and EPC, EXEL shall carry out the day-to-day responsibility for filing, prosecution and maintenance on behalf of EPC under Section 7.1 through 7.8. Promptly after the Original Effective Date (as defined in the TGR5 License Agreement), [\*] shall oversee (subject to **Sections 7.7(a)(ii), (iv) and (v)** below) the preparation, filing, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of all [\*] Patents, [\*] Patents Controlled by [\*], and [\*] Patents that in each case are [\*] (the “[\*] Patents”), provided that, unless otherwise agreed by the Parties, such responsibilities shall be carried out by: (A) [\*] by [\*] the [\*], unless there exists [\*] of [\*] and [\*]; (B) [\*] by [\*], but only in the case where [\*] described in subsection (A) had [\*] of [\*]; or (C) [\*] in conjunction with [\*] described in the preceding subsection (A) or (B), as applicable. [\*], or [\*], shall provide [\*] with an update of the filing, prosecution and maintenance status for each of the [\*] Patents on a periodic basis, and shall use commercially reasonable efforts to consult with and cooperate with [\*] with respect to the filing, prosecution and maintenance of the [\*] Patents, including providing [\*] with drafts of proposed filings to allow [\*] a reasonable opportunity for review and comment before such filings are due. [\*], or [\*], shall provide to [\*] copies of any papers relating to the filing, prosecution and maintenance of the [\*] Patents promptly upon their being filed and received.

(2) **Decisions.** Subsequent to the Original Effective Date (as defined in the TGR5 License Agreement), in the event of a dispute between the Parties with regard to the preparation, filing, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of any [\*] Patent, the matter shall be promptly referred to the [\*] of EXEL and [\*] for BMS. If these two (2) individuals are unable to resolve the dispute promptly, then the matter shall be promptly elevated to the [\*] of EXEL and the [\*] of BMS. If these two (2) individuals are unable to resolve the dispute promptly, then, subject to **Sections 7.7(a)(i)(3), 7.7(a)(i)(4), 7.7(a)(ii),** [\*], and [\*], [\*] shall have the final decision, except if such decision: (A) conflicts with the terms of the Agreement; (B) would result in [\*] described in [\*] or a [\*] of the [\*]; or (C) materially impacts [\*] prosecution of Patents that [\*] a [\*], in which case of **subsection 7.7(a)(i)(2)(A) - (C),** [\*] shall have the final decision.

(3) **Limitation on Subsection 7.7(a)(i)(2)(B).** If [\*] reasonably believes that filing a new patent application covering a [\*] (other than the [\*] of a [\*]) would result in potential claims [\*] for [\*], and if [\*] disputes with [\*] that such patent application should be filed, then such dispute shall be discussed as described in the first two (2) sentences of **Section 7.7(a)(i)(2),** and, if still unresolved, shall be arbitrated pursuant to **Section** [\*], and [\*] shall not have the right to exercise its final-decision making authority pursuant to **Subsection 7.7(a)(i)(2)(B)** unless the dispute is resolved in [\*] favor.

(4) **Limitation on Subsection 7.7(a)(i)(2)(C).** [\*] hereby covenants that it shall not, without the prior written consent of [\*] (which shall not be unreasonably delayed or conditioned), during the term of this Agreement, [\*] the decision-making authority granted to [\*] pursuant to **Subsection 7.7(a)(i)(2)(C)** [\*] that is [\*] as of the Original Effective Date or [\*]. Furthermore, if [\*] the decision-making authority granted to [\*] pursuant to **Subsection 7.7(a)(i)(2)(C)** [\*] by [\*], [\*] or [\*], and such [\*] is [\*] or [\*] a [\*] that is [\*], then [\*] and [\*] shall agree, pursuant to **Section** [\*], on [\*] the decision-making authority granted to [\*] pursuant to **Subsection 7.7(a)(i)(2)(C).**

(ii) **Abandonment.** In no event shall [\*] knowingly permit any of the [\*] Patents to be abandoned in any country, or elect not to file a new patent application claiming priority to a patent application within the [\*] Patents either before such patent application's issuance or within the time period required for the filing of an international (i.e., Patent Cooperation Treaty), regional (including European Patent Office) or national application, without [\*] written consent (such consent not to be unreasonably withheld, delayed or conditioned) or [\*] otherwise first being given an opportunity to assume full responsibility (at [\*] expense) for the continued prosecution and maintenance of such [\*] Patents or the filing of such new patent application. Accordingly, [\*], or [\*], shall provide [\*] with notice of the allowance and expected issuance date of any patent within the [\*] Patents, or any of the aforementioned filing deadlines, and [\*] shall provide [\*] with prompt notice as to whether [\*] desires [\*] to file such new patent application. In the event that [\*] decides either: (A) not to continue the prosecution or maintenance of a patent application or patent within the [\*] Patents in any country; or (B) not to file such new patent application requested to be filed by [\*], [\*] shall provide [\*] with notice of this decision at least [\*] prior to any pending lapse or abandonment thereof, and [\*] shall thereafter have the right to assume responsibility for the filing, prosecution and maintenance of such patent or patent application. In the event that [\*] assumes

such responsibility for such filing, prosecution and maintenance, [\*] shall no longer have the responsibility for such filing, prosecution and maintenance of such patent applications and patents, and [\*] shall cooperate as reasonably requested by [\*] to facilitate control of such filing, prosecution and maintenance by [\*]. In the case where [\*] takes over the filing, prosecution or maintenance of any patent or patent application as set forth above, such patent or patent application shall [\*] be [\*] the [\*], and [\*] shall [\*] such patent or patent application.

**(iii) Filing, Prosecution and Maintenance of Sole Invention Patents Controlled by BMS.** In accordance with this **Section 7.7(a)(iii)**, BMS shall be responsible for the filing, prosecution (including any interferences, reissues and reexaminations) and maintenance of all Sole Invention Patents Controlled by BMS. BMS shall provide to EXEL copies of any papers relating to the filing, prosecution and maintenance of the Sole Invention Patents Controlled by BMS promptly upon their being filed and received.

**(iv) Patent Term Extension.** EXEL and BMS shall each cooperate with each another and shall use commercially reasonable efforts in obtaining patent term extension (including any pediatric exclusivity extensions as may be available) or supplemental protection certificates or their equivalents in any country with respect to patent rights covering the Products. If elections with respect to obtaining such patent term extensions are to be made, [\*] shall have the right to make the election to seek patent term extension or supplemental protection.

**(v) Exelixis Right to Separate Claims.** To the extent that any Sole Invention Patent owned by EPC contains claims that cover compounds that are not Licensed Compounds (such compounds, **“Separable Compounds”**), EXEL shall have the right to separate any claims that cover such Separable Compounds (and not Licensed Compounds) and to file such claims in a separate application (e.g., a continuation, continuation-in-part, or divisional application). EXEL shall notify BMS in writing prior to separating such claims, and such separation shall be at EXEL’s sole expense.

**(b) Payment of Prosecution Costs.** [\*] shall bear the out-of-pocket expenses (including reasonable fees for any outside counsel, [\*]) associated with the filing, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of: (X) Patents covering [\*]; and (Y) the [\*] Patents other than those [\*] Patents that are [\*], *provided* that if any [\*] or [\*] is part of a patent application or patent that is [\*] but [\*] that are [\*], then the Parties shall mutually agree upon an appropriate allocation of the expenses so that [\*] does not bear any portion of the out-of-pocket expenses attributable to [\*].

**(c) Payment of Expenses for Joint Invention Patents.** EXEL and BMS shall mutually agree on the percentage of expenses that each of EXEL and BMS shall bear with respect to Joint Invention Patents for which the cost of filing, prosecuting or maintaining such Joint Invention is not the responsibility of a Party under **Section 7.7(b)** hereof (which, in the absence of any other agreement between EXEL and BMS, shall be divided evenly).

**(d) Non-payment of Expenses.**



(i) If either EXEL or BMS elects not to pay its share of any expenses with respect to [\*] Patent in a given country under any of **Section [\*]**, such Party shall inform such other Party in writing not less than [\*] before any relevant deadline (or, in the event of a shorter period in which to respond to a patent office, as soon as reasonably practicable), and, if such other Party assumes the expenses associated with the [\*] Patent, then the assuming Party (in the case of EXEL, EPC) shall thereby become the sole owner of such [\*] Patent in such country and such other Party shall assign to the assuming Party its rights, title and interests in such [\*] Patent in such country.

(ii) If either EPC or BMS is the assignee or owner of a Patent (other than [\*]) that is licensed to such other Party under any of **Sections 7.1 or 7.2**, and such owning Party elects not to pay its share of expenses pursuant to **Section [\*]** in a given country, such owning Party shall inform such other Party in writing not less than [\*] before any relevant deadline (or, in the event of a shorter period in which to respond to a patent office, as soon as reasonably practicable). If such other Party assumes the expenses associated with the Patent in such country, then the assuming Party shall thereby [\*] such Patent and the owning Party shall [\*] such Patent in such country.

(iii) If either EPC or BMS is the licensee of a Patent (other than [\*]) under any of **Sections 7.1 or 7.2**, and such Party elects not to pay its share of expenses pursuant to **Section [\*]** in a given country, such Party shall inform such other Party (in the case EPC is the licensee, EPC or EXEL shall inform BMS, and in the case BMS is the licensee, BMS shall inform EXEL) in writing not less than [\*] before any relevant deadline (or, in the event of a shorter period in which to respond to a patent office, as soon as reasonably practicable) (such Patent(s) in such countries, as identified in such notice, being a “**Cost-Terminated Patent Right**”), and shall no longer have any rights under such **Sections 7.1 or 7.2**, as applicable, with respect to the relevant Patent in such country, *provided* that all remaining rights and licenses under all other Patent(s) within such licensed Patents would remain in effect. It is also understood that such licensee shall be offered the opportunity to assume its share of the responsibility for the costs of filing, prosecution and maintenance of any Patent(s) claiming priority directly or indirectly from any such Cost-Terminated Patent Right, and that where such expenses are assumed by such licensee, it shall be afforded all the rights and licenses as provided under this Agreement for the licensed Patents (other than the Cost-Terminated Patent Right) with respect to such Patent(s) claiming priority directly or indirectly from any such Cost-Terminated Patent Right.

(e) Each of EXEL and BMS shall provide to such other Party, on [\*] basis, a patent report that includes the serial number, docket number and status of each Patent for which such Party has the right to direct the filing, prosecution and maintenance and which [\*] (in the case of [\*] such [\*] that are [\*]) or [\*]. EXEL and BMS through their patent counsel shall discuss as appropriate (but not more than [\*]) ways in which to allocate such out-of-pocket expenses in an appropriate, cost-effective manner consistent with the purposes of this Agreement [\*].

## 7.8 Enforcement of Patent Rights.

### (a) Enforcement of Exelixis Sole Patents.

(i) **Enforcement by [\*].** In the event that management or in-house counsel for any Party becomes aware of a suspected infringement by a Third Party of a Patent claiming a Sole Invention owned by EPC that claims the composition of matter (including formulation), manufacture or use of one or more Products that is being Developed or Commercialized by BMS or its Affiliate or sublicensee using Diligent Efforts and which is exclusively licensed to BMS under **Section 7.1(c)** (for purposes of this **Section 7.8(a)(i)** only, an “**Exelixis Sole Patent**”), such Party shall notify the other Parties promptly, and following such notification, the Parties shall confer. As between EXEL and EPC, EXEL shall carry out the patent enforcement activities on behalf of EPC under this 7.8, and shall pay costs and expenses on behalf of EPC in connection therewith. Each Party of EXEL and BMS shall provide the same level of disclosure to the other Party’s in-house counsel concerning suspected infringement of an Exelixis Sole Patent as such Party would provide with respect to suspected infringement of its own issued Patent or an exclusively licensed issued Patent claiming a product it is developing or commercializing independent of this Agreement. Where such suspected infringement involves such Third Party’s development, manufacture, use or sale of a product directed against ROR, [\*] shall have the right, but shall not be obligated, to bring an infringement action against any such Third Party or to defend such proceedings at its own expense, in its own name and entirely under its own direction and control. [\*] shall reasonably assist [\*] (at [\*] expense) in such actions or proceedings if so requested, and EPC shall lend its name to such actions or proceedings if requested by [\*] or required by law, and [\*] shall hold [\*] harmless from any liability incurred by [\*] arising out of any such proceedings or actions at [\*] request. [\*] have the right to participate and be represented in any such suit by its own counsel at its own expense. No settlement of any such action or defense which restricts the scope, or adversely affects the enforceability, of any such Exelixis Sole Patent may be entered into by [\*] without the prior consent of [\*] (such consent not to be unreasonably withheld, delayed or conditioned).

(ii) **Enforcement by [\*].** If [\*] elects not to bring any action for infringement or to defend any proceeding described in **Section 7.8(a)(i)** and so notifies [\*], or where [\*] ([\*] such Exelixis Sole Patent) otherwise desires to bring an action or to defend any proceeding directly involving an Exelixis Sole Patent, then [\*] may bring such action or defend such proceeding at its own expense, in [\*] own name and entirely under its own direction and control; *provided* that [\*] must confer with [\*] with respect to any such action or proceeding and obtain the prior written consent of [\*] to commence such action or proceeding, such consent not to be unreasonably withheld, delayed or conditioned; *provided further*, that with respect to any Exelixis Sole Patent that is a Patent [\*] the [\*] (or foreign equivalent(s) of such Patent or the [\*]) by [\*] (a “[\*] Patent”), if [\*] fails to consent to any such action or proceeding, the [\*] for any [\*] such Exelixis Sole Patent shall in no event [\*] by any failure to enforce such Exelixis Sole Patent. [\*] shall reasonably assist [\*] (at [\*] expense) in any action or proceeding being prosecuted or defended by [\*], if so requested by [\*] or required by law, and [\*] shall hold [\*] harmless from any liability incurred by [\*] arising out of any such proceedings or actions. [\*] shall have the right to participate and be represented in any such suit by its own counsel at its

own expense. No settlement of any such action or defense which restricts the scope, or adversely affects the enforceability, of a [\*] Patent, may be entered into by [\*] without the prior consent of [\*] (such consent not to be unreasonably withheld, delayed or conditioned).

**(b) Enforcement of Joint Invention Patents.**

**(i) Joint Product Patents.**

**(1) Enforcement by [\*].** In the event that management or in-house counsel for either EXEL or BMS becomes aware of a suspected infringement of a Patent claiming a Joint Invention that pertains to the composition of matter (including formulation), manufacture or use of one or more Products that is being developed or commercialized by BMS or its Affiliate or sublicensee using Diligent Efforts and which is exclusively licensed to BMS under **Section 7.1(c)** (a “**Joint Product Patent**”), such Party shall notify such other Party promptly, and following such notification, the Parties shall confer. Each Party shall provide the same level of disclosure to such other Party’s in-house counsel concerning suspected infringement of a Joint Product Patent as such Party would provide with respect to suspected infringement of its own issued Patent or an exclusively licensed issued Patent claiming a product it is developing or commercializing independent of this Agreement. [\*] shall have the right, but shall not be obligated, to bring an infringement action or to defend such proceedings at its own expense, in its own name and entirely under its own direction and control. [\*] shall reasonably assist [\*] (at [\*] expense) in such actions or proceedings if so requested, and [\*] shall lend its name to such actions or proceedings if requested by [\*] or required by law, and [\*] shall hold [\*] harmless from any liability incurred by [\*] arising out of any such proceedings or actions. [\*] have the right to participate and be represented in any such suit by its own counsel at its own expense. No settlement of any such action or defense which restricts the scope or affects the enforceability of a Joint Product Patent may be entered into by [\*] without the prior consent of [\*] (such consent not to be unreasonably withheld, delayed or conditioned).

**(2) Enforcement by [\*].** If [\*] elects not to bring any action for infringement or to defend any proceeding described in **Section 7.8(b)(i)(1)** and so notifies [\*], or for any other enforcement by [\*] of a Joint Product Patent which is exclusively licensed to BMS under **Section 7.1(c)**, then [\*] may bring such action or defend such proceeding at its own expense, in [\*] own name and entirely under its own direction and control; *provided* that [\*] must confer with [\*] with respect to any such action or proceeding and obtain the prior written consent of [\*] to commence such action or proceeding, such consent not to be unreasonably withheld, delayed or conditioned; *provided further*, that with respect to any Joint Product Patent that is a [\*] Patent, if [\*] fails to consent to any such action or proceeding, the [\*] for any [\*] such Joint Product Patent shall in no event [\*] by any failure to enforce such Joint Product Patent. [\*] shall reasonably assist [\*] (at [\*] expense) in any action or proceeding being prosecuted or defended by [\*], if so requested by [\*] or required by law, and [\*] shall hold [\*] harmless from any liability incurred by [\*] arising out of any such proceedings or actions. [\*] shall have the right to participate and be represented in any such suit by its own counsel at its own expense. No settlement of any such action or defense which restricts the scope or affects the enforceability of

a Joint Product Patent may be entered into by [\*] without the prior consent of [\*] (such consent not to be unreasonably withheld, delayed or conditioned).

**(ii) Other Joint Patents.**

**(1) Enforcement by [\*].** In the event that management or in-house counsel for either EXEL or BMS becomes aware of a suspected infringement of a Patent that claims a Joint Invention but is not a Joint Product Patent (an “**Other Joint Patent**”), such Party shall notify such other Party promptly, and following such notification, the Parties shall confer. Each of EXEL and BMS shall provide the same level of disclosure to such other Party’s in-house counsel concerning suspected infringement of an Other Joint Patent as such Party would provide with respect to suspected infringement of its own issued Patent or an exclusively licensed issued Patent claiming a product it is developing or commercializing independent of this Agreement. [\*] shall have the right, but shall not be obligated, to prosecute an infringement action or to defend such proceedings at its own expense, in its own name and entirely under its own direction and control. [\*] shall reasonably assist [\*] (at [\*] expense) in such actions or proceedings if so requested, and [\*] shall lend its name to such actions or proceedings if requested by [\*] or required by law, and [\*] shall hold [\*] harmless from any liability incurred by [\*] arising out of any such proceedings or actions. [\*] have the right to participate and be represented in any such suit by their own counsel at its own expense. No settlement of any such action or defense which restricts the scope or affects the enforceability of an Other Joint Patent may be entered into by [\*] without the prior consent of [\*] (such consent not to be unreasonably withheld, delayed or conditioned).

**(2) Enforcement by [\*].** If [\*] elects not to bring any action for infringement or to defend any proceeding described in **Section 7.8(b)(ii)(1)** and so notifies [\*], then [\*] may bring such action or defend such proceeding at its own expense, in its own name and entirely under its own direction and control; *provided* that [\*] must confer with [\*] with respect to any such action or proceeding and obtain the prior written consent of [\*] to commence such action or proceeding, such consent not to be unreasonably withheld, delayed or conditioned; *provided further*, that with respect to any Other Joint Patent that is a [\*] Patent, if [\*] fails to consent to any such action or proceeding, the [\*] for any [\*] such Other Joint Patent shall in no event [\*] by any failure to enforce such Other Joint Patent. [\*] shall reasonably assist [\*] (at [\*] expense) in any action or proceeding being prosecuted or defended by [\*], if so requested by [\*] required by law, and [\*] shall hold [\*] harmless from any liability incurred by [\*] arising out of any such proceedings or actions. [\*] shall have the right to participate and be represented in any such suit by its own counsel at its own expense. No settlement of any such action or defense which restricts the scope or affects the enforceability of an Other Joint Patent may be entered into by [\*] without the prior consent of [\*] (such consent not to be unreasonably withheld, delayed or conditioned).

**(c) General Provisions Relating to Enforcement of Patents.**

**(i) Withdrawal.** If either EXEL or BMS brings such an action or defends such a proceeding under this **Section 7.8** and subsequently ceases to pursue or withdraws from such action or proceeding, it shall promptly notify such other Party and the other

Party (in the case of EXEL, on behalf of EPC) may substitute itself for the withdrawing Party under the terms of this **Section 7.8** (including such prior written consent as provided for under this **Section 7.8**) at its own expense; provided, however, that [\*] right to substitute itself for [\*] pursuant to this **Section 7.8(c)(i)** shall be limited, with respect to [\*] Patents, to actions and proceedings that [\*] initially had the first right to bring or defend pursuant to **Section [\*]**.

(ii) **Recoveries.** In the event either Party exercises the rights conferred in this **Section 7.8** and recovers any damages or other sums in such action, suit or proceeding or in settlement thereof, such damages or other sums recovered shall first be applied to all out-of-pocket costs and expenses incurred by the Parties in connection therewith, including attorneys fees. If such recovery is insufficient to cover all such costs and expenses of both Parties, it shall be shared in proportion to the total such costs and expenses incurred by each Party. If after such reimbursement any funds shall remain from such damages or other sums recovered, such funds shall be[\*].

(d) **Data Exclusivity and Orange Book Listings.** With respect to data exclusivity periods (such as those periods listed in the FDA's Orange Book (including any available pediatric extensions) or periods under national implementations of Article 9.1(a)(iii) of Directive 2001/EC/83, and all international equivalents), BMS shall use commercially reasonable efforts consistent with its obligations under applicable law (including any applicable consent order) to seek, maintain and enforce all such data exclusivity periods available for the Products. With respect to filings in the FDA Orange Book (and foreign equivalents) for issued patents for a Product, upon request by BMS (and at BMS' expense), Exelixis shall provide reasonable cooperation to BMS in filing and maintaining such Orange Book (and foreign equivalent) listings.

(e) **No Action in Violation of Law.** None of the Parties shall be required to take any action pursuant to this **Section 7.8** that such Party reasonably determines in its sole judgment and discretion conflicts with or violates any court or government order or decree applicable to such Party.

(f) **Notification of Patent Certification.** [\*] shall notify and provide [\*] with copies of any allegations of alleged patent invalidity, unenforceability or non-infringement of any [\*] Patent [\*] hereunder pursuant to a Paragraph IV Patent Certification by a Third Party filing an Abbreviated New Drug Application, an application under §505(b)(2) or other similar patent certification by a Third Party, and any foreign equivalent thereof. Such notification and copies shall be provided to [\*] by [\*] as soon as practicable and at least within [\*] after [\*] receives such certification, and shall be sent by facsimile and overnight courier to the address set forth below:

[\*]

**7.9 Defense of Third Party Claims.** If a claim is brought by a Third Party that any activity related to work performed by a Party under the Agreement infringes the intellectual property rights of such Third Party, each Party shall give prompt written notice to the other Parties of such claim, and following such notification, the Parties shall confer on how to respond.

## 8. COMPENSATION

**8.1 Upfront Payment.** BMS shall pay Exelixis an upfront payment of Five Million Dollars (\$5,000,000) on the earlier to occur of the following: (a) [\*] after the Original Effective Date; or (b) [\*] after the Original Effective Date (as defined in the TGR5 License Agreement). Such payment shall be noncreditable and nonrefundable.

### 8.2 Milestone Payments to EPC.

#### (a) Development and Regulatory Milestones.

(i) BMS shall make the milestone payments set forth below to EPC within [\*] after the first achievement of each indicated event by BMS or any of its Affiliates or sublicensees and, subject to **Section 8.2(a)(iii)**, with respect to each of the events described in [\*] below, after the first achievement of each such event with respect to any Licensed Compound. For clarity, with respect to milestones that are triggered by the [\*], such [\*] must be [\*] that is [\*] and [\*] the [\*] or [\*] of the [\*]. All such milestone payments made by BMS to EPC hereunder shall be noncreditable and nonrefundable.

Event	Milestone Payment
(1) BMS DP 2.0 Acceptance	\$2.5 million
(2) [*]	\$[*]
(3) [*]	\$[*]
(4) [*]	\$[*]
(5) [*]	\$[*]
(6) [*]	\$[*]
(7) [*]	\$[*]
(8) [*]	\$[*]
(9) [*]	\$[*]
(10) [*]	\$[*]
(11) [*]	\$[*]
(12) [*]	\$[*]
(13) [*]	\$[*]
(14) [*]	\$[*]

(ii) **Milestone Payment Restrictions.** Each milestone payment set forth in **Section 8.2(a)(i)** shall be paid [\*] with respect to [\*], [\*] the [\*] or [\*] the [\*] in [\*] for [\*], or the [\*] or [\*] for [\*].

(iii) **Milestone Payments for [\*].** If BMS is diligently developing and paying milestones to EPC under **Section 8.2(a)(i)** [\*], the payments [\*] made to EPC under **Sections 8.2(a)(i)** for [\*] shall be [\*] such [\*] the [\*] in [\*], in which case BMS shall pay EPC the [\*] the [\*] in [\*] within [\*] of the [\*] such [\*]; provided, however, that if this Agreement terminates before such [\*], then BMS shall [\*] pay EPC the [\*]. If [\*] the [\*] or [\*], then BMS shall only pay milestones [\*] for the events that [\*] the [\*] such [\*]; however, if a [\*], then BMS shall pay the milestones [\*] a [\*] have been paid [\*]. For clarity, the Parties agree that [\*] shall [\*], [\*], or [\*] of the [\*] the [\*].

(b) **Commercial Milestones.** BMS shall make the milestone payments set forth below to EPC after first achievement of each indicated event by BMS or any of its Affiliates or sublicensees with respect to each Product. Each milestone payment shall be made

[\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

by BMS [\*], [\*] due and payable [\*] after the end of the [\*] in which such milestone event is met. BMS shall pay [\*] to [\*] if, at the time [\*], the [\*] the payment obligation (the “[\*]”) was [\*] for the [\*]. Otherwise, the [\*] shall be [\*], provided that [\*]. BMS shall pay [\*] to EPC [\*] if, at the time [\*], the [\*] for the [\*]. Otherwise, the [\*] shall be [\*], provided that [\*]. All such milestone payments made by BMS to EPC hereunder shall be noncreditable and nonrefundable, and shall be paid only once with respect to each Product, regardless of [\*] or [\*] for that Product, or [\*] or [\*] for that Product.

Event	Milestone Payment
[*]	\$[*]
[*]	\$[*]
[*]	\$[*]

**8.3 Royalty Payments to EPC for Net Sales of Products.** For each Product, BMS shall pay to EPC royalties on Net Sales of such Product by BMS (or its Affiliates or sublicensees) in the Territory at a royalty rate determined by aggregate Net Sales in the Territory of such Product in a calendar year as follows:

<u>Calendar year Net Sales of Products</u>	<u>Royalty Rate for Products Comprising an Exelixis ROR Compound</u>	<u>Royalty Rate for Products Not Comprising an Exelixis ROR Compound</u>
First \$[*]	[*]%	[*]%
Portion above \$[*] and up to and including \$[*]	[*]%	[*]%
Portion above \$[*]	[*]%	[*]%

For clarity, Net Sales shall be [\*]. For the purpose of this **Section 8.3**, all Products [\*] shall be [\*] and the Net Sales of such Products shall be [\*] the [\*], regardless of whether [\*] or [\*], or [\*] or [\*]. All royalty payments made by BMS to EPC hereunder shall be noncreditable and nonrefundable, [\*] royalties to EPC, in which case such [\*] shall be [\*] (or, in the event that [\*], such [\*] shall be [\*]).

#### **8.4 Third Party Royalties**

(a) [\*] all Third Party royalties owed with respect to a Product in the Territory on intellectual property that is intellectual property that: (A) [\*] from a Third Party prior to the Original Effective Date and [\*]; and (B) [\*]. Subject to **Section 8.4(b)**, [\*] Third Party royalties

[\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.



owed on intellectual property in connection with the development and commercialization of a Product in the Territory; *provided* that each Party shall bear all Third Party royalties arising from any infringing activities by such Party prior to the Original Effective Date.

(b) BMS may deduct from the royalties it would otherwise owe to EPC pursuant to **Section 8.3** for a particular Product, an amount equal to [\*] of all royalties payable to a Third Party in consideration for rights necessary or reasonably useful for the manufacture, use or sale of such Product, up to a maximum deduction of [\*] of the royalties due EPC for such Product.

**8.5** [\*]. During the applicable Royalty Term for a particular Product, if the Patents claiming the composition of matter of such Product have expired, and if any [\*]: (a) [\*] in any given country in any year; and (b) such [\*] in such country for such year are, [\*]:

(i) [\*], but [\*] of the [\*] in such country, then [\*]; or

(ii) [\*] of the [\*] in such country, then [\*].

**8.6 Limitation on Deductions.** Notwithstanding anything to the contrary in this Agreement, the operation of **Sections 8.4** and **8.5** for a given Product, whether singularly or in combination with each other, shall not [\*].

**8.7 Quarterly Payments and Reports.** All royalties due under **Section 8.3** shall be paid quarterly, on a country-by-country basis, within [\*] of the end of the relevant quarter for which royalties are due. BMS shall provide to EPC within[\*] after the end of each quarter a report that summarizes the Net Sales of a Product during such quarter, *provided* that to the extent additional information is reasonably required by EPC and/or EXEL to comply with its obligations to any of its licensors, the Parties shall work together in good faith to timely compile and produce such additional information. Such reports shall also include detailed information regarding the calculation of royalties due pursuant to **Section 8.3**, including allowable deductions in the calculation of Net Sales of each Product on which royalties are paid, and, to the extent **Section 8.5** is applicable, the calculation of [\*] and [\*] of [\*].

**8.8 Term of Royalties.** EPC's right to receive royalties under **Section 8.3** shall expire on a country-by-country and Product-by-Product basis upon the later of: (a) [\*]; or (b) [\*] (the "**Royalty Term**"). Upon the expiration of the Royalty Term with respect to a Product in a country, BMS shall have a fully-paid-up perpetual license under **Section 7.1(c)** for the making, using, selling, offering for sale and importing of such Product in such country.

**8.9 Payment Method.** All payments due under this Agreement to EPC shall be made by bank wire transfer in immediately available funds to an account designated by EPC. All payments hereunder shall be made in Dollars.

**8.10 Taxes.** EPC shall pay any and all taxes levied on account of all payments it receives under this Agreement. If laws or regulations require that taxes be withheld, BMS shall: (a) deduct those taxes from the remittable payment; (b) pay the taxes to the proper taxing

authority; and (c) send evidence of the obligation together with proof of tax payment to EXEL within [\*] following that tax payment. The Parties shall discuss appropriate mechanisms for minimizing such taxes to the extent possible in compliance with applicable law.

**8.11 Blocked Currency.** In each country where the local currency is blocked and cannot be removed from the country, royalties accrued in that country shall be paid to EPC in Dollars based on the Dollar reported sales for the quarter (translated for such country per Statement of Financial Standards No. 52), unless otherwise mutually agreed.

**8.12 Sublicenses.** In the event BMS grants any permitted licenses or sublicenses to Third Parties to sell Products that are subject to royalty payments under **Section 8.3**, BMS shall have the responsibility to account for and report sales of any Product by a licensee or a sublicensee on the same basis as if such sales were Net Sales by BMS. BMS shall pay to EPC (or cause the licensee or sublicensee to pay to EPC, with BMS remaining responsible for any failure of the licensee or sublicensee to pay amounts when due under this Agreement): (a) royalties on such sales as if such sales of the licensee or sublicensee were Net Sales of BMS or any of its Affiliates; and (b) milestones payments pursuant to **Section 8.2** based on the achievement by such licensee or sublicensee of any milestone event contemplated in such Sections as if such milestone event had been achieved by BMS or any of its Affiliates hereunder. Any sales by BMS' Affiliates and sublicensees of BMS or such sublicensee's Affiliates, in each case to Third Parties, shall be aggregated with sales by BMS for the purpose of calculating the aggregate Net Sales in **Sections 8.2(b)** and **8.3**.

**8.13 Foreign Exchange.** Conversion of sales recorded in local currencies to Dollars shall be performed in a manner consistent with BMS' normal practices used to prepare its audited financial statements for internal and external reporting purposes, which uses a widely accepted source of published exchange rates.

**8.14 Records.** BMS shall keep (and shall ensure that its Affiliates and sublicensees shall keep) such records as are required to determine, in a manner consistent with GAAP and this Agreement, the sums due under this Agreement, including Net Sales. All such books, records and accounts shall be retained by BMS until the later of (a) [\*] after the end of the period to which such books, records and accounts pertain and (b) the [\*] (or any extensions thereof), or for such longer period as may be required by applicable law. BMS shall require its sublicensees to provide to it a report detailing the foregoing expenses and calculations incurred or made by such sublicensee, which report shall be made available to Exelixis in connection with any audit conducted by Exelixis pursuant to **Section 8.15**.

**8.15 Audits.** Exelixis shall have the right to have an independent certified public accountant, reasonably acceptable to BMS, to have access during normal business hours, and upon reasonable prior written notice, to examine only those records of BMS (and its Affiliates and sublicensees) as may be reasonably necessary to determine, with respect to any calendar year ending not more than [\*] prior to Exelixis' request, the correctness or completeness of any report or payment made under this Agreement. The foregoing right of review may be exercised [\*]. Results of any such examination shall be: (a) limited to information relating to the Products; (b) made available to both Parties; and (c) subject to **Article 10**. Exelixis shall bear the full cost of

the performance of any such audit, unless such audit discloses a variance to the detriment of Exelixis of more than [\*] from the amount of the original report, royalty or payment calculation, in which case BMS shall bear the full cost of the performance of such audit. The results of such audit shall be [\*].

**8.16 Interest.** Any payments or portions thereof due hereunder that are not paid on the date such payments are due under this Agreement shall bear interest at a rate equal to the lesser of: (a) [\*] Rate as published by Citibank, N.A., New York, New York, or any successor thereto, at 12:01 a.m. on the first day of each quarter in which such payments are overdue; or (b) the maximum rate permitted by law, in each case calculated on the number of days such payment is delinquent, compounded monthly.

**8.17 Non-Monetary Consideration.** In the event that BMS or its Affiliate or sublicensee receives any non-monetary consideration in connection with the sale of a Product, BMS' payment obligations under this **Article 8** shall be based on the fair market value of such other consideration. In such case, BMS shall disclose the terms of such arrangement to EPC and EXEL and the Parties shall endeavor in good faith to agree on such fair market value.

**8.18 Payments to or Reports by Affiliates.** Any payment required under any provision of this Agreement to be made to either BMS or EPC or any report required to be made by any Party shall be made to or by an Affiliate of that Party if designated in writing by that Party as the appropriate recipient or reporting entity.

## 9. EXCLUSIVITY

**9.1 Licensed Compounds.** This Agreement will be exclusive with respect to the Development, Manufacture, and Commercialization of [\*] that are intended to [\*] as described below [\*].

(a) **Prior to Commercialization.** Subject to **Sections 9.2, 9.3 and 9.4**, [\*], [\*] (directly or indirectly, and either with or without a *bona fide* collaborator) outside the scope of this Agreement any programs: (i) that [\*] that [\*]; or (ii) where [\*].

(b) **Subsequent to Commercialization.** Subject to **Sections 9.2, 9.3 and 9.4**, [\*], [\*] (directly or indirectly, and either with or without a *bona fide* collaborator) outside the scope of this Agreement any programs to [\*] that [\*], and any [\*] subject to the following terms and conditions:

(i) **Commercial Launch of [\*].** [\*], any product [\*]: (A) that is [\*] and [\*]; or (B) where the [\*] that [\*] (any such product, a "[\*]"), for a [\*] of a [\*].

(ii) **[\*] of a [\*].** In the event of any [\*] of a [\*] that is permitted under **Section [\*]**, the Party [\*] shall [\*] a [\*]: [\*] of any [\*] for a [\*] subsequent to [\*] of a [\*] and [\*] the [\*] the [\*] with respect to such [\*] or [\*] of this Agreement (in either case, [\*]).

**9.2** [\*]. Notwithstanding anything to the contrary set forth in this **Article 9**, if either BMS or EXEL is engaged in [\*] a program that is [\*] that is [\*], and [\*] such program [\*], such Party shall [\*] with such [\*] in order to [\*] so the [\*] the [\*] for [\*].

**9.3 Not Applicable to [\*] or [\*].** The restrictions and obligations in **Section 9.1** shall not apply with respect to either BMS or EXEL for [\*] that are [\*] by such Party [\*] (either with or without a *bona fide* collaborator) or for any [\*].

**9.4 [\*] Right.** [\*] may [\*] with a [\*] that [\*] a [\*] solely with respect to the [\*] of [\*] and/or a [\*] that [\*]: (a) any [\*] product that is [\*] a [\*]; and (b) such [\*] a [\*], on the condition that [\*] to [\*] of [\*] with respect to [\*] as set forth herein (assuming such [\*] and/or a [\*]).

## **10. CONFIDENTIALITY**

**10.1 Nondisclosure of Confidential Information.** For the purpose of this Article 10, unless otherwise set forth herein, EXEL and EPC shall be deemed collectively as one (1) “Party” and shall be referred to as Exelixis. All Information or Materials disclosed by one Party to the other Party pursuant to this Agreement, and, subject to **Section 10.6**, Information that is generated pursuant to this Agreement with respect to Licensed Compounds or Products (for so long as such Licensed Compound or Product is not removed from the Agreement as a result of a Product specific termination pursuant to **Section 11.3**), shall be “**Confidential Information**” for all purposes hereunder. The Parties agree that, during term of this Agreement and for a period of [\*] thereafter, a Party receiving Confidential Information of the other Party shall: (a) use Diligent Efforts to maintain in confidence such Confidential Information (but not less than those efforts as such Party uses to maintain in confidence its own proprietary industrial information of similar kind and value) and not to disclose such Confidential Information to any Third Party without prior written consent of the other Party (such consent not to be unreasonably withheld, delayed or conditioned), except for disclosures made in confidence to any Third Party under terms consistent with this Agreement and made in furtherance of this Agreement or of rights granted to a Party hereunder; and (b) not use such other Party’s Confidential Information for any purpose except those permitted by this Agreement (it being understood that this **Section 10.1** shall not create or imply any rights or licenses not expressly granted under **Article 4, 7 or 11** hereof).

**10.2 Exceptions.** The obligations in **Section 10.1** shall not apply with respect to any portion of the Confidential Information that the receiving Party can show by competent written proof:

(a) Is publicly disclosed by the disclosing Party, either before or after it is disclosed to the receiving Party hereunder; or

(b) Was known to the receiving Party or any of its Affiliates, without obligation to keep it confidential, prior to disclosure by the disclosing Party; or

(c) Is subsequently disclosed to the receiving Party or any of its Affiliates by a Third Party lawfully in possession thereof and without obligation to keep it confidential; or

(d) Is published by a Third Party or otherwise becomes publicly available or enters the public domain, either before or after it is disclosed to the receiving Party, and is not directly or indirectly supplied by the receiving Party in violation of this Agreement; or

(e) Has been independently developed by employees or contractors of the receiving Party or any of its Affiliates without the aid, application or use of the disclosing Party's Confidential Information.

**10.3 Authorized Disclosure.** A Party may disclose the Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following instances; *provided* that notice of any such disclosure shall be provided as soon as practicable to the other Party:

(a) Filing or prosecuting Patents relating to Sole Inventions, Joint Inventions or Products, in each case pursuant to activities under this Agreement;

(b) Regulatory filings;

(c) Prosecuting or defending litigation;

(d) Complying with applicable governmental laws and regulations; and

(e) Disclosure, in connection with the performance of this Agreement, or exercise of its rights hereunder, to Affiliates, potential collaborators, partners, and actual and potential licensees (including potential co-marketing and co-promotion contractors, research contractors and manufacturing contractors), research collaborators, potential investment bankers, investors, lenders, and investors, employees, consultants, or agents, each of whom prior to disclosure must be bound by similar obligations of confidentiality and non-use at least equivalent in scope to those set forth in this **Article 10**.

The Parties acknowledge that the terms of this Agreement shall be treated as Confidential Information of both Parties. Such terms may be disclosed by a Party to individuals or entities covered by **Section 10.3(e)** above, each of whom prior to disclosure must be bound by similar obligations of confidentiality and non-use at least equivalent in scope to those set forth in this **Article 10**. In addition, a copy of this Agreement may be filed by either Party with the Securities and Exchange Commission in connection with any public offering of such Party's securities, in connection with such Party's on-going periodic reporting requirements under the federal securities laws, or as otherwise necessary under applicable law or regulations. In connection with any such filing, such Party shall endeavor to obtain confidential treatment of economic, competitively sensitive, and trade secret information.

**10.4 Prior Confidentiality Agreement.** All Information exchanged between the Parties under the Confidential Disclosure Agreement between EXEL and BMS executed as of [\*], and amended as of [\*] and [\*] (such confidential disclosure agreement, as amended, the "**Prior CDA**") that relates to ROR, ROR Antagonists, [\*] and [\*] ROR Antagonists, Licensed Compounds or Products shall be deemed Confidential Information and shall, commencing upon

the Original Effective Date, be subject to the terms of this **Article 10** rather than the Prior CDA. The Prior CDA shall otherwise remain in full force and effect, including with respect to each Party's rights with respect to breaches thereof, if any, that occurred prior to the Original Effective Date with respect to Information described in the first sentence of this **Section 10.4**.

**10.5 Publicity.** The Parties agree that the public announcement of the execution of this Agreement shall be substantially in the form of the press release attached as **Exhibit 10.5**. Any other publication, news release or other public announcement relating to this Agreement or to the performance hereunder, shall first be reviewed and approved by both Parties; *provided, however*, that any disclosure which is required by law, including disclosures required by the U.S. Securities and Exchange Commission or made pursuant to the requirements of the national securities exchange or other stock market on which such Party's securities are traded, as advised by the disclosing Party's counsel may be made without the prior consent of the other Party, although the other Party shall be given prompt notice of any such legally required disclosure and to the extent practicable shall provide the other Party an opportunity to comment on the proposed disclosure.

**10.6 Publications.** Subject to **Section 10.3**, each Party agrees to provide the other Party the opportunity to review any proposed disclosure which contains Confidential Information of the other Party and would or may constitute an oral, written or electronic public disclosure if made (including the full content of proposed abstracts, manuscripts or presentations) which relate to any Inventions, at least [\*] prior to its intended submission for publication and agrees, upon request, not to submit any such abstract or manuscript for publication until the other Party is given a reasonable period of time to secure patent protection for any material in such publication which it believes to be patentable; *provided, however*, that BMS may publish results of clinical studies relating to Licensed Compounds without the prior review or approval of Exelixis. Both Parties understand that a reasonable commercial strategy may require delay of publication of information or filing of patent applications. The Parties agree to review and consider delay of publication and filing of patent applications under certain circumstances. The Alliance Managers (or the Parties), as appropriate, shall review such requests and recommend subsequent action. Subject to **Section 10.3**, neither Party shall have the right to publish or present Confidential Information of the other Party which is subject to **Section 10.1**. Nothing contained in this **Section 10.6** shall prohibit the inclusion of Confidential Information of the non-filing Party necessary for a patent application, *provided* the non-filing Party is given a reasonable opportunity to review the extent and necessity for its Confidential Information to be included prior to submission of such patent application related to the Agreement. Any disputes between the Parties regarding delaying a publication or presentation to permit the filing of a patent application shall be referred to the Alliance Managers (or the Parties), as appropriate.

## **11. TERM AND TERMINATION**

**11.1 Term.** For the purpose of this Article 11, unless otherwise set forth herein, EPC and EXEL shall be deemed collectively as one (1) "Party" and shall be referred to as Exelixis. This Agreement shall become effective on the Effective Date and shall remain in effect, subject to earlier termination in accordance with **Sections 11.2 or 11.3** or by mutual written agreement,

[\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

until the expiration of all payment obligations under **Article 8**. The period of time between the Original Effective Date until the expiration of this Agreement shall be deemed the **Term**, provided that, for the period of time between the Original aEffective Date and the Effective Date, the terms and conditions of the Collaboration Agreement shall apply..

**11.2 BMS' Right to Terminate.** BMS shall have the right to terminate this Agreement, at any time, [\*]: (a) [\*] prior written notice to each of EXEL and EPC, in the event that such termination is [\*] of the [\*]; or (b) [\*] prior written notice to each of EXEL and EPC, in the event that such termination is [\*] of the [\*].

### **11.3 Termination for Material Breach or Patent Challenge**

**(a) Notice.** If either Party believes that the other is in material breach of this Agreement (including any material breach of a representation or warranty made in this Agreement), then the non-breaching Party may deliver notice of such breach to the other Party. In such notice the non-breaching Party shall identify the actions or conduct that such Party would consider to be an acceptable cure of such breach. For all breaches other than a failure to make a payment set forth in **Article 8**, the allegedly breaching Party shall have [\*] to cure such breach. For any breach arising from a failure to make a payment set forth in **Article 8**, the allegedly breaching Party shall have [\*] to cure such breach.

**(b) Cure Period.** Subject to **Section 11.3(c)**, if the Party receiving notice of breach fails to cure such breach within the [\*] period or [\*] period (as applicable), or the Party providing the notice reasonably determines that the proposed corrective plan or the actions being taken to carry it out is not commercially practicable, the Party originally delivering the notice may terminate this Agreement upon [\*] advance written notice, *provided*, that if the breach [\*] or [\*], the non-breaching Party may [\*] the [\*] with respect to [\*].

**(c) [\*] Material Breach.** If a Party gives notice of termination under **Section 11.3(a)** and the other Party [\*], or if a Party determines under **Section 11.3(b)** that the [\*] or the [\*] is [\*] and such [\*] such [\*], then the [\*]: (i) [\*]; or (ii) [\*] or the [\*], shall in any case [\*]. If [\*] of such [\*] it is [\*] the [\*], then such termination shall [\*] if the breaching Party fails [\*] to cure such breach in accordance with the [\*] within the time period set forth in **Section 11.3(a)** for the applicable breach [\*]. If [\*] of such [\*] it is [\*] the [\*], then [\*] and [\*].

**(d) Termination for Patent Challenge.** Exelixis may terminate this Agreement with respect to a given Product in a given country if BMS or its Affiliates or sublicensees, directly or indirectly, individually or in association with any other person or entity, challenge the validity, enforceability or scope of any Exelixis Licensed Patents that relate to such Product in such country; *provided* that, if BMS, due to a Change of Control transaction, acquires control of a company that is challenging, directly or indirectly, individually or in association with another person or entity, the validity, enforceability or scope of any Exelixis Licensed Patents, BMS shall have [\*] from the date of such acquisition to terminate such challenge to such Exelixis Licensed Patents before Exelixis' right to terminate under this **Section 11.3(d)** becomes effective. For clarity, any dispute as to whether a given Patent is within the scope of Exelixis Licensed Patents, such matter shall be subject to dispute resolution as set forth in **Section 14.3**.

#### 11.4 Survival; Effect of Termination.

(A) In the event of expiration or termination of this Agreement, the following provisions of this Agreement shall survive: **Articles** [\*]; and **Sections** [\*] (with respect to [\*] (and [\*] for such purposes)); the last sentence of **Section** [\*] with respect to [\*] in the event of expiration of this Agreement pursuant to **Section** [\*] and with respect to [\*] in the event of termination of this Agreement [\*], [\*].

(b) Notwithstanding anything to the contrary in this Agreement, in the event of termination of this Agreement pursuant to **Section** [\*], [\*] under this Agreement [\*] of the [\*] shall [\*]. In such case, the non-breaching Party shall continue to hold the licenses granted hereunder, subject to the milestone and royalties set forth herein (which relevant provisions shall survive termination).

(c) In any event, expiration or termination of this Agreement shall not relieve the Parties of any liability which accrued hereunder prior to the effective date of such expiration or termination nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation.

#### 11.5 Licenses and Payments on Expiration or Termination.

##### (a) Research, Development and Commercialization of Reverted Compounds by Exelixis.

(i) Upon termination of this Agreement (other than for Exelixis' uncured material breach pursuant to **Section 11.3**), subject to **Section 11.5(b)**, BMS hereby grants EPC a worldwide, royalty-bearing (solely to the extent provided in the Reverted Compounds License Agreement) license (with the right to sublicense) to clinically develop, make, have made, use, import, sell, offer to sell and have sold products incorporating any Reverted Compounds that are described in **Section 1.55(a)**, under any Information and Patents Controlled by BMS that (A) cover one (1) or more of such Reverted Compounds, and/or any composition containing any of the foregoing, or the manufacture or use thereof or (B) are [\*] to clinically develop, make, have made, use, import, sell, offer to sell and have sold Products incorporating any such Reverted Compound. The license described in this **Section 11.5(a)(i)** shall be [\*] for [\*] and [\*] for [\*].

(ii) Upon expiration of this Agreement pursuant to **Section 11.1** or termination of this Agreement, subject to **Section 11.5(b)** and **Section 11.6**, BMS hereby grants EPC a worldwide, royalty-free license (with the right to sublicense) to clinically develop, make, have made, use, import, sell, offer to sell and have sold products incorporating any Reverted Compounds that are described in **Section 1.55(b)**, under any Information and Patents Controlled by BMS that (A) cover one (1) or more of such Reverted Compounds, and/or any composition containing any of the foregoing, or the manufacture or use thereof or (B) are [\*] to clinically develop, make, have made, use, import, sell, offer to sell and have sold Products incorporating



any such Reverted Compound. The license described in this **Section 11.5(a)(ii)** shall be [\*] for [\*] and [\*] for [\*].

**(iii)** Upon termination of this Agreement, subject to **Section 11.5(b)** and **Section 11.6**, BMS hereby grants EPC a worldwide, royalty-free license (without the right to sublicense except to Third Party contract research providers and manufacturers) to research, identify, derivatize, pre-clinically develop, make, have made and use Licensed Compounds for research purposes, under any BMS Licensed Know-How and BMS Licensed Patents covering one (1) or more Licensed Compounds, and/or any composition containing any of the foregoing, or the manufacture or use thereof. The license described in this **Section 11.5(a)(iii)** shall be: (A) [\*] with respect to [\*]; (B) [\*] for [\*]; and (C) [\*] for [\*]. Notwithstanding anything to the contrary in this Agreement, the foregoing license grant shall not create (by any means, whether expressly, impliedly or by estoppel) any right or license under any other Patents, Information or other intellectual property right that is Controlled by BMS.

**(iv)** Upon termination of this Agreement, subject to **Section 11.5(b)** and **Section 11.6**, BMS hereby grants EPC a [\*], worldwide, royalty-free license (without the right to sublicense except to Third Party contract research providers and manufacturers) to research, identify, derivatize, pre-clinically develop, make, have made and use Licensed Compounds for research purposes, under any Information or Patents Controlled by BMS that are [\*] for the research, identification, derivatization, pre-clinical development, making, having made and use of Licensed Compounds in a manner consistent with the activities performed by (A) the Parties under the Research Plan or (B) BMS pursuant to the BMS Independent Program. Notwithstanding anything to the contrary in this Agreement, the foregoing license grant shall not create (by any means, whether expressly, impliedly or by estoppel) any right or license under any other Patents, Information or other intellectual property right that is Controlled by BMS.

**(v)** Upon termination of this Agreement, BMS shall transfer via assignment, license or sublicense to EPC: (A) all Information reasonably necessary for the development and commercialization of Reverted Compounds; (B) [\*] in BMS' name; (C) [\*] to the extent that [\*]; (D) [\*] Controlled by BMS; and (E) supplies of Product (including any intermediates, retained samples and reference standards) that in each case ((A) through (E)) are existing and in BMS' Control and that [\*] relate to such Reverted Compounds. Any such transfer(s) shall be [\*] of [\*]. BMS and EXEL shall promptly meet, over a [\*] period, to negotiate in good faith the commercially reasonable terms of a license agreement to such Reverted Compounds (the "**Reverted Compounds License Agreement**"), including: (1) the licenses described in **Sections 11.5(a)(i) – (iv)**; (2) [\*] under **Section 11.5(a)(i)**, and [\*] of other Reverted Compounds; (3) a provision requiring BMS to use commercially reasonable efforts to maintain ([\*]) and not to breach any agreements with Third Parties that provide a grant from such Third Party to BMS of rights that are Controlled by BMS and that are licensed to EPC pursuant to the Reverted Compounds License Agreement; and (4) other customary terms and provisions, including terms and provisions relating to diligence, audit rights, and intellectual property maintenance and enforcement, in each case substantially similar to the terms of this Agreement.

**(b) BMS Internal Compound Research License.** Notwithstanding the licenses granted to EPC pursuant to **Section 11(a)**, upon termination or expiration of this Agreement, BMS shall have a non-exclusive, worldwide, royalty-free license (without the right to sublicense except to third party contract research providers and manufacturers), under the Exelixis Licensed Patents and Exelixis Licensed Know-How, to research, identify, derivatize, pre-clinically develop, make, have made and use Licensed Compounds that are BMS ROR Compounds solely for research purposes. Notwithstanding anything to the contrary in this Agreement, the foregoing non-exclusive license grant shall not create (by any means, whether expressly, impliedly or by estoppel) any right or license under any other Patents, Information or other intellectual property right that is Controlled by EPC.

**11.6 Exception for Termination for [\*].** The licenses granted to [\*] under **Sections [\*]** shall be [\*] with respect to any given Product where [\*] termination of Development and/or Commercialization of such Product was due to [\*]. For purposes of this **Section 11.6**, “[\*]” means it is [\*] or [\*] or [\*] that there is [\*] for [\*]: (i) [\*], including [\*]; or (ii) the [\*] of [\*] a Product [\*] or [\*], such as [\*] or [\*] a Product. Notwithstanding anything to the contrary, this **Section 11.6** shall not prevent [\*] (or its sublicensees) from using its licenses in **Sections [\*]** to [\*] by [\*] that was [\*]. [\*] shall provide [\*] with all [\*] for such [\*] but shall not [\*] to [\*] any [\*] relating to such [\*].

**11.7 Interim Supply.** In the event of any termination pursuant to **Section 11.2**, or **Section 11.3** (where BMS is the breaching Party), in each case [\*], at the written request of EPC (or its sublicensee), BMS shall supply, or cause to be supplied, to EPC or such sublicensee sufficient quantities of Product to satisfy EPC (or its sublicensee’s) requirements for Product for a period of up to [\*] following the effective date of termination, as EPC or its sublicensee may require until EPC or its sublicensee can itself assume or transition to a Third Party such manufacturing responsibilities; *provided, however* that EPC or its sublicensee shall use Diligent Efforts to affect such assumption (or transition) as promptly as practicable. Such supply shall be [\*] such Product(s) with respect to development supply, and shall be [\*] such Product(s) with respect to commercial supply. Any such supply will be made pursuant to a supply agreement between the Parties with typical provisions relating to quality, forecasting and ordering to forecast, force majeure and product liability and indemnity. In the event that BMS has one or more agreements with Third Party manufacturers with respect to the manufacture of a Product, at EPC (or its sublicensee’s) request, BMS shall use commercially reasonable efforts to transfer its rights and obligations under such agreement(s) to EPC upon any such termination.

## **12. REPRESENTATIONS AND WARRANTIES AND COVENANTS**

**12.1 Mutual Authority.** EXEL, EPC and BMS each represents and warrants to the other Parties as of the Original Effective Date that: (a) it has the authority and right to enter into and perform this Agreement, (b) this Agreement is a legal and valid obligation binding upon it and is enforceable in accordance with its terms, subject to applicable limitations on such enforcement based on bankruptcy laws and other debtors’ rights, and (c) its execution, delivery and performance of this Agreement shall not conflict in any material fashion with the terms of any other agreement or instrument to which it is or becomes a party or by which it is or becomes

bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having authority over it.

## 12.2 Rights in Technology.

(a) During the term of this Agreement, each Party shall use commercially reasonable efforts to maintain (but without an obligation to renew) and not to breach any agreements with Third Parties that provide a grant of rights from such Third Party to a Party that are Controlled by such Party and are licensed or become subject to a license from such Party to the other Party under **Article 7**. Each Party agrees to provide promptly the other Parties with notice of any such alleged breach or obligation to renew. As of the Original Effective Date, each Party is in compliance in all material respects with any aforementioned agreements with Third Parties.

(b) Each of EPC and BMS represents and warrants that it: (i) has the ability to grant the licenses contained in or required by this Agreement; and (ii) is not currently subject to any agreement with any Third Party or to any outstanding order, judgment or decree of any court or administrative agency that restricts it in any way from granting to another Party such licenses or the right to exercise its rights hereunder.

(c) Each of EPC and BMS represents and warrants that: (i) it has not granted, and covenants that it shall not grant after the Original Effective Date and during the term of this Agreement, any right, license or interest in or to, or an option to acquire any of the foregoing with respect to, the intellectual property rights licensed to another Party hereunder (including the Exelixis Licensed Patents and the BMS Licensed Patents, as the case may be) that is in conflict with the rights (including the rights set forth in **Article 7**) or licenses granted or to be granted (including any conditional license rights) to another Party under this Agreement; and (ii) it has not granted any lien, security interest or other encumbrance (excluding any licenses) with respect to any of the intellectual property rights licensed to another Party hereunder that would prevent it from performing its obligations under this Agreement, or permitted such a lien, security interest or other encumbrance (excluding any permitted licenses) to attach to the intellectual property rights licensed to another Party hereunder.

**12.3 Performance by Affiliates.** The Parties recognize that each may perform some or all of its obligations under this Agreement through Affiliates; *provided, however*, that each Party shall remain responsible and be guarantor of the performance by its Affiliates and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. In particular, if any Affiliate of a Party participates under this Agreement with respect to Licensed Compounds: (a) the restrictions of this Agreement which apply to the activities of a Party with respect to Licensed Compounds shall apply equally to the activities of such Affiliate; and (b) the Party affiliated with such Affiliate shall assure, and hereby guarantees, that any intellectual property developed by such Affiliate shall be governed by the provisions of this Agreement (and subject to the licenses set forth in **Article 7**) as if such intellectual property had been developed by the Party.

**12.4 Third Party Rights.** Each of BMS and EXEL represents and warrants to the other Party that, to its Knowledge as of the Original Effective Date, its performance of work as contemplated by this Agreement shall not infringe the valid patent, trade secret or other intellectual property rights of any Third Party. Each of BMS and EXEL represents and warrants to the other Party that, to its Knowledge as of the Original Effective Date, it will not violate a contractual or fiduciary obligation owed to any Third Party (including misappropriation of trade secrets) by performing its work as contemplated by this Agreement.

**12.5 Notice of Infringement or Misappropriation.** Each of EXEL and IMS represents and warrants to the other Party that, as of the Original Effective Date, it has received no notice of infringement or misappropriation of any alleged rights asserted by any Third Party in relation to any technology that such Party intends, as of the Original Effective Date, to use in connection with the Agreement.

### **13. INDEMNIFICATION AND LIMITATION OF LIABILITY**

**13.1 Mutual Indemnification.** For the purpose of this Article 13, EPC and EXEL shall be deemed collectively as one (1) “Party” and referred to as “Exelixis.” Subject to **Section 13.3**, each Party hereby agrees to indemnify, defend and hold harmless the other Party, its Affiliates, and their respective directors, employees and agents from and against any and all Third Party suits, claims, actions, demands, liabilities, expenses and/or losses, including reasonable legal expenses and reasonable attorneys’ fees (“Losses”) to the extent such Losses result from any: (a) breach of warranty by the indemnifying Party contained in the Agreement; (b) breach of the Agreement or applicable law by such indemnifying Party; (c) negligence or willful misconduct of the indemnifying Party, its Affiliates or (sub)licensees, or their respective directors, employees and agents in the performance of the Agreement; and/or (d) breach of a contractual or fiduciary obligation owed by it to a Third Party (including misappropriation of trade secrets).

#### **13.2 Indemnification.**

**(a) Indemnification by BMS.** Subject to **Section 13.3**, BMS hereby agrees to indemnify, defend and hold harmless Exelixis and its directors, employees and agents from and against any and all Losses to the extent such Losses result from [\*] or [\*] by BMS or its Affiliates, agents or sublicensees, except to the extent such Losses result from any: (a) breach of warranty by Exelixis contained in the Agreement; (b) breach of the Agreement or applicable law by Exelixis; (c) negligence or willful misconduct by Exelixis, its Affiliates or (sub)licensees, or their respective directors, employees and agents in the performance of the Agreement; and/or (d) breach of a contractual or fiduciary obligation owed by Exelixis to a Third Party (including misappropriation of trade secrets).

**(b) Indemnification by Exelixis.** Subject to **Section 13.3**, Exelixis hereby agrees to indemnify, defend and hold harmless BMS and its directors, employees and agents from and against any and all Losses to the extent such Losses result from [\*] or [\*] by Exelixis or its Affiliates, agents or sublicensees, except to the extent such Losses result from any: (a) breach of warranty by BMS contained in the Agreement; (b) breach of the Agreement or applicable law by

BMS; (c) negligence or willful misconduct by BMS, its Affiliates or (sub)licensees, or their respective directors, employees and agents in the performance of the Agreement; and/or (d) breach of a contractual or fiduciary obligation owed by BMS to a Third Party (including misappropriation of trade secrets).

**13.3 Conditions to Indemnification.** As used herein, “**Indemnitee**” shall mean a party entitled to indemnification under the terms of **Sections 13.1** or **13.2**. A condition precedent to each Indemnitee’s right to seek indemnification under such **Sections 13.1** or **13.2** is that such Indemnitee shall:

(a) inform the indemnifying Party under such applicable Section of a Loss as soon as reasonably practicable after it receives notice of the Loss;

(b) if the indemnifying Party acknowledges that such Loss falls within the scope of its indemnification obligations hereunder, permit the indemnifying Party to assume direction and control of the defense, litigation, settlement, appeal or other disposition of the Loss (including the right to settle the claim solely for monetary consideration); *provided*, that the indemnifying Party shall seek the prior written consent (such consent not to be unreasonably withheld, delayed or conditioned) of any such Indemnitee as to any settlement which would materially diminish or materially adversely affect the scope, exclusivity or duration of any Patents licensed under this Agreement, would require any payment by such Indemnitee, would require an admission of legal wrongdoing in any way on the part of an Indemnitee, or would effect an amendment of this Agreement; and

(c) fully cooperate (including providing access to and copies of pertinent records and making available for testimony relevant individuals subject to its control) as reasonably requested by, and at the expense of, the indemnifying Party in the defense of the Loss.

Provided that an Indemnitee has complied with all of the conditions described in **subsections 13.3(a) – (c)**, as applicable, the indemnifying Party shall provide attorneys reasonably acceptable to the Indemnitee to defend against any such Loss. Subject to the foregoing, an Indemnitee may participate in any proceedings involving such Loss using attorneys of the Indemnitee’s choice and at the Indemnitee’s expense. In no event may an Indemnitee settle or compromise any Loss for which the Indemnitee intends to seek indemnification from the indemnifying Party hereunder without the prior written consent of the indemnifying Party (such consent not to be unreasonably withheld, delayed or conditioned), or the indemnification provided under such **Section 13.1** or **13.2** as to such Loss shall be null and void.

**13.4 Limitation of Liability.** EXCEPT FOR AMOUNTS PAYABLE TO THIRD PARTIES BY A PARTY FOR WHICH IT SEEKS REIMBURSEMENT OR INDEMNIFICATION PROTECTION FROM THE OTHER PARTY PURSUANT TO **SECTIONS 13.1 AND 13.2**, AND EXCEPT FOR BREACH OF **SECTION 10.1** HEREOF, IN NO EVENT SHALL EITHER PARTY, ITS DIRECTORS, OFFICERS, EMPLOYEES, AGENTS OR AFFILIATES BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE, EXEMPLARY OR CONSEQUENTIAL DAMAGES,

WHETHER BASED UPON A CLAIM OR ACTION OF CONTRACT, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER TORT, OR OTHERWISE, ARISING OUT OF THE AGREEMENT, UNLESS SUCH DAMAGES ARE DUE TO THE GROSS NEGLIGENCE OR WILLFUL MISCONDUCT OF THE LIABLE PARTY (INCLUDING GROSS NEGLIGENCE OR WILLFUL BREACH WITH REEPCCT TO A PARTY'S REPRESENTATIONS AND WARRANTIES IN **ARTICLE 12**). FOR CLARITY, THE AMOUNT OF THE UPFRONT PAYMENTS DESCRIBED IN **SECTION 8.1** MAY SERVE AS A MEASURE OF A REMEDY IN THE EVENT OF A BREACH WITH REEPCCT TO EXELIXIS' REPRESENTATIONS AND WARRANTIES IN **ARTICLE 12**.

**13.5 Agreement Disclaimer.** EXCEPT AS PROVIDED IN **ARTICLE 12** ABOVE, BMS EXPRESSLY DISCLAIMS ANY AND ALL OTHER WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES WITH REEPCCT TO ANY COMPOUNDS, MATERIALS OR INFORMATION (AND ANY PATENT RIGHTS OBTAINED THEREON) IDENTIFIED, MADE OR GENERATED BY BMS AS PART OF THE COLLABORATION OR OTHERWISE MADE AVAILABLE TO EXELIXIS PURSUANT TO THE TERMS OF THE AGREEMENT. EXCEPT AS PROVIDED IN **ARTICLE 12** ABOVE, EXELIXIS EXPRESSLY DISCLAIMS ANY AND ALL OTHER WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES WITH REEPCCT TO ANY COMPOUNDS, MATERIALS OR INFORMATION (AND ANY PATENT RIGHTS OBTAINED THEREON) IDENTIFIED, MADE OR GENERATED BY EXELIXIS AS PART OF THE COLLABORATION OR OTHERWISE MADE AVAILABLE TO BMS PURSUANT TO THE TERMS OF THE AGREEMENT.

#### **14. MISCELLANEOUS**

**14.1 Dispute Resolution.** For the purpose of Sections 14.1 through 14.3, EPC and EXEL shall be deemed collectively as one (1) "Party" and referred to as Exelixis. Unless otherwise set forth in this Agreement and excluding in particular any dispute described in **Section 14.3(a)**, **Section 14.3(b)**, **Section [\*]** (which will be handled exclusively in accordance with **Section [\*]**), **Section [\*]** (which will be handled exclusively in accordance with **Section [\*]**) and any dispute handled pursuant to **Sections [\*]**, in the event of any dispute, controversy or claim arising out of, relating to or in connection with any provision of the Agreement, the Parties shall try to settle their differences amicably between themselves first, by referring the disputed matter to the Party's respective Executive Officers. Any Party may initiate such informal dispute resolution by sending written notice of the dispute to the other Party, and, within [\*] after such notice, such Executive Officers shall meet for attempted resolution by good faith negotiations. If such Executive Officers are unable to resolve such dispute within [\*] of their first meeting for such negotiations, any Party may seek to have such dispute resolved in any U.S. federal or state court of competent jurisdiction and appropriate venue, *provided*, that if such suit includes a Third

Party claimant or defendant, and jurisdiction and venue with respect to such Third Party appropriately resides outside the U.S., then in any other jurisdiction or venue permitted by applicable law.

**14.2 Governing Law.** Resolution of all disputes, controversies or claims arising out of, relating to or in connection with the Agreement or the performance, enforcement, breach or termination of the Agreement and any remedies relating thereto, shall be governed by and construed under the substantive laws of the State of Delaware, without regard to conflicts of law rules.

### **14.3 Patents and Trademarks; Equitable Relief.**

**(a) General Patent and Trademark Disputes.** Except as set forth in **Sections 14.3(c) and (d)**, any dispute, controversy or claim arising out of, relating to or in connection with: (i) the scope, validity, enforceability or infringement of any Patent rights covering the research, development, manufacture, use or sale of any Product; or (ii) any trademark rights related to any Product, shall in each case be submitted to a court of competent jurisdiction in the territory in which such Patent or trademark rights were granted or arose.

**(b) Equitable Relief.** Any dispute, controversy or claim arising out of, relating to or in connection with the need to seek preliminary or injunctive measures or other equitable relief (e.g., in the event of a potential or actual breach of the confidentiality and non-use provisions in **Article 10**) need not be resolved through the procedure described in **Section 14.1** but may be immediately brought in a court of competent jurisdiction.

**(c) Disputes Related to Subsection [\*].** Any dispute that concerns whether [\*] a [\*] (other than [\*] of a [\*]) would [\*] and that is not resolved by discussion pursuant to **Section [\*]** shall be finally resolved through binding arbitration by JAMS (formerly, the Judicial Arbitration and Mediation Service) (“**JAMS**”), in accordance with its Streamlined Arbitration Rules and Procedures in effect at the time the dispute arises, and applying the substantive law specified in **Section 14.2**. Either Party may initiate arbitration under this **Section 14.3(c)** by written notice to the other Party of its intention to arbitrate, and such notice shall specify in reasonable detail the nature of the dispute. Promptly following receipt of such notice, the Parties shall meet and discuss in good faith and agree on an arbitrator to resolve the issue, which arbitrator shall be neutral and independent of both Parties, shall have significant experience and expertise in [\*] pharmaceutical products, and shall have some experience in mediating or arbitrating issues relating to such [\*]. If the Parties cannot agree on such arbitrator within [\*] of request by a Party for arbitration, then such arbitrator shall be appointed by JAMS, which arbitrator must meet the foregoing criteria. For each arbitration: (i) each Party shall submit to the arbitrator its memorandum (the “**Support Memorandum**”) in support of its position in the dispute; and (ii) the arbitrator shall determine which Party’s position is correct. If the arbitrator’s determination is in [\*] favor, then [\*] would not [\*] under **Section [\*]** for such [\*]; however, if the arbitrator’s determination is in [\*] favor, then [\*] would [\*] under **Section [\*]** for such [\*]. The decision of the arbitrator shall be final and judgment upon such decision may be entered in any competent court or application may be made to any competent court for judicial acceptance of such decision and order of enforcement. The arbitration proceedings shall be conducted at

such location as shall be determined by the arbitrator. The Parties agree that they shall share equally the cost of the arbitration filing and hearing fees, and the cost of the arbitrator. Each Party shall bear its own attorneys' fees and associated costs and expenses.

**(d) Disputes Related to Subsection [\*].** If [\*] and the [\*] that [\*] pursuant to **Subsection [\*]** do not agree upon [\*] that reasonably [\*] within [\*] after the [\*] such [\*], then either party may, by written notification to the other party, submit the matter to binding "baseball" arbitration to determine the terms of such [\*], as follows. Promptly following receipt of such notice, the parties shall meet and discuss in good faith and agree on an arbitrator to resolve the issue, which arbitrator shall be neutral and independent of both parties, shall have significant experience and expertise in [\*] pharmaceutical products and in [\*] as part of collaboration agreements, and shall have some experience in mediating or arbitrating issues relating to such [\*]. If the parties cannot agree on such arbitrator within [\*] of request by a party for arbitration, then such arbitrator shall be appointed by JAMS, which arbitrator must meet the foregoing criteria. Within [\*] after an arbitrator is selected (or appointed, as the case may be), each party will deliver to both the arbitrator and the other party a detailed written proposal setting forth its proposed terms for the [\*] containing the reasonable [\*] (the "**Proposed Terms**" of the party) and a Support Memorandum, not exceeding [\*] in length. The parties will also provide the arbitrator a copy of this Agreement, as may be amended at such time. Within [\*] after receipt of the other party's Proposed Terms and Support Memorandum, each party may submit to the arbitrator (with a copy to the other party) a response to the other party's Support Memorandum, such response not exceeding [\*] in length. Neither party may have any other communications (either written or oral) with the arbitrator other than for the sole purpose of engaging the arbitrator or as expressly permitted in this **Section 14.3(d)**; provided that, the arbitrator may convene a hearing if the arbitrator so chooses to ask questions of the parties and hear oral argument and discussion regarding each party's Proposed Terms. Within [\*] after the arbitrator's appointment, the arbitrator will select one of the two (2) Proposed Terms (without modification) provided by the parties that he or she believes is most consistent with the intention underlying and agreed principles set forth in this Agreement and most accurately reflects industry norms for a transaction of this type. The decision of the arbitrator shall be final, binding, and unappealable and the parties shall promptly [\*] having the terms set forth in the Proposed Terms selected by the arbitrator. For clarity, the arbitrator must select as the only method to determine the [\*] one of the two (2) sets of Proposed Terms, and may not combine elements of both Proposed Terms or take any other action. Except as expressly stated in this **Section 14.3(d)**, such arbitration shall be conducted in accordance with JAMS' Streamlined Arbitration Rules and Procedures then in effect.

**14.4 Entire Agreement; Amendments.** This Agreement, the LXR Collaboration Agreement and the license agreement (for the discovery, development and commercialization of compounds that agonize the target known as TGR5) that is between Exelixis and BMS and that is dated as of the Original Effective Date and amended as of the Effective Date (the "**TGR5 License Agreement**"), set forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto and supersedes and terminates all prior agreements and understandings between the Parties. There are no covenants, promises, agreements, warranties,



representations, conditions or understandings, either oral or written, between the Parties other than as are set forth in this Agreement, the LXR Collaboration Agreement and the TGR5 License Agreement. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party. The Collaboration Agreement shall be effective from the Original Effective Date until the Effective Date and shall govern the Parties' respective rights and obligations during such period of time.

**14.5 Export Control.** This Agreement is made subject to any restrictions concerning the export of products or technical information from the U.S. or other countries which may be imposed upon or related to Exelixis or BMS from time to time. Each Party agrees that it shall not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity.

#### **14.6 Bankruptcy.**

**(a)** For the purpose of this 14.6, EPC and EXEL shall be deemed collectively as one (1) "Party" and referred to as Exelixis. All rights and licenses granted under or pursuant to this Agreement, including amendments hereto, by each Party to the other Party are, for all purposes of Section 365(n) of Title 11 of the U.S. Code ("**Title 11**"), licenses of rights to intellectual property as defined in Title 11. Each Party agrees during the term of this Agreement to create and maintain current copies or, if not amenable to copying, detailed descriptions or other appropriate embodiments, to the extent feasible, of all such intellectual property. If a case is commenced by or against either Party (the "**Bankrupt Party**") under Title 11, then, unless and until this Agreement is rejected as provided in Title 11, the Bankrupt Party (in any capacity, including debtor-in-possession) and its successors and assigns (including a Title 11 Trustee) shall, at the election of the Bankrupt Party made within sixty (60) days after the commencement of the case (or, if no such election is made, immediately upon the request of the non-Bankrupt Party) either (i) perform all of the obligations provided in this Agreement to be performed by the Bankrupt Party including, where applicable, providing to the non-Bankrupt Party portions of such intellectual property (including embodiments thereof) held by the Bankrupt Party and such successors and assigns or otherwise available to them or (ii) provide to the non-Bankrupt Party all such intellectual property (including all embodiments thereof) held by the Bankrupt Party and such successors and assigns or otherwise available to them.

**(b)** If a Title 11 case is commenced by or against the Bankrupt Party and this Agreement is rejected as provided in Title 11 and the non-Bankrupt Party elects to retain its rights hereunder as provided in Title 11, then the Bankrupt Party (in any capacity, including debtor-in-possession) and its successors and assigns (including a Title 11 Trustee) shall provide to the non-Bankrupt Party all such intellectual property (including all embodiments thereof) held by the Bankrupt Party and such successors and assigns or otherwise available to them immediately upon the non-Bankrupt Party's written request therefor. Whenever the Bankrupt Party or any of its successors or assigns provides to the non-Bankrupt Party any of the

intellectual property licensed hereunder (or any embodiment thereof) pursuant to this **Section 14.6**, the non-Bankrupt Party shall have the right to perform the obligations of the Bankrupt Party hereunder with respect to such intellectual property, but neither such provision nor such performance by the non-Bankrupt Party shall release the Bankrupt Party from any such obligation or liability for failing to perform it.

(c) All rights, powers and remedies of the non-Bankrupt Party provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including Title 11) in the event of the commencement of a Title 11 case by or against the Bankrupt Party. The non-Bankrupt Party, in addition to the rights, power and remedies expressly provided herein, shall be entitled to exercise all other such rights and powers and resort to all other such remedies as may now or hereafter exist at law or in equity (including under Title 11) in such event. The Parties agree that they intend the foregoing non-Bankrupt Party rights to extend to the maximum extent permitted by law and any provisions of applicable contracts with Third Parties, including for purposes of Title 11, (i) the right of access to any intellectual property (including all embodiments thereof) of the Bankrupt Party or any Third Party with whom the Bankrupt Party contracts to perform an obligation of the Bankrupt Party under this Agreement, and, in the case of the Third Party, which is necessary for the development, registration and manufacture of Products and (ii) the right to contract directly with any Third Party described in (i) in this sentence to complete the contracted work. Any intellectual property provided pursuant to the provisions of this **Section 14.6** shall be subject to the licenses set forth elsewhere in this Agreement and the payment obligations of this Agreement, which shall be deemed to be royalties for purposes of Title 11.

**14.7 Force Majeure.** Each Party shall be excused from the performance of its obligations under this Agreement to the extent that such performance is prevented by force majeure (defined below) and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, “**force majeure**” shall include conditions beyond the control of the Parties, including an act of God, acts of terrorism, voluntary or involuntary compliance with any regulation, law or order of any government, war, civil commotion, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe. The payment of invoices due and owing hereunder shall in no event be delayed by the payer because of a force majeure affecting the payer.

**14.8 Notices.** Any notices given under this Agreement shall be in writing, addressed to the Parties at the following addresses, and delivered by person, by facsimile (with receipt confirmation), or by FedEx or other reputable courier service. Any such notice shall be deemed to have been given: (a) as of the day of personal delivery; (b) one (1) day after the date sent by facsimile service; or (c) on the day of successful delivery to the other Parties confirmed by the courier service. Unless otherwise specified in writing, the mailing addresses of the Parties shall be as described below.

For EXEL: Exelixis, Inc.  
210 East Grand Avenue  
South San Francisco, CA 94080  
Attention: EVP and General Counsel

With a copy to: Cooley LLP  
3175 Hanover Street  
Palo Alto, CA 94304  
Attention: Marya A. Postner, Esq.

For EPC: Exelixis Patent Company, LLC  
210 East Grand Avenue  
South San Francisco, CA 94080  
Attention: VP, Legal Services

With a copy to: Cooley LLP  
3175 Hanover Street  
Palo Alto, CA 94304  
Attention: Marya A. Postner, Esq.

For BMS: Bristol-Myers Squibb Company  
P.O. Box 4000  
Route 206 and Province Line Road  
Princeton, NJ 08543-4000  
Attention: Senior Vice President, Strategy, Alliances and Transactions  
Phone: 609-252-5333  
Fax: 609-252-7212

With a copy to: Bristol-Myers Squibb Company  
P.O. Box 4000  
Route 206 and Province Line Road  
Princeton, NJ 08543-4000  
Attention: Vice President and Senior Counsel, Corporate and Business Development  
Phone: 609-252-5328  
Fax: 609-252-4232

Furthermore, a copy of any notices required or given under **Article 7** of this Agreement shall also be addressed to the [\*] of [\*] at the address set forth in **Section 7.8(f)**.

**14.9 Maintenance of Records Required by Law or Regulation.** Each Party shall keep and maintain all records required by law or regulation with respect to Products and shall make copies of such records available to the other Parties upon request.

**14.10 Assignment.** For the purpose of this 14.10, EPC and EXEL shall be deemed collectively as one (1) “Party”. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other (such consent not to be unreasonably withheld, delayed or conditioned), except a Party may make such an assignment without the other Party’s consent to an Affiliate or to a Third Party successor to all or substantially all of the business of such Party to which this Agreement relates, whether in a merger, sale of stock, sale of assets or other transaction; *provided* that any such permitted successor or assignee of rights and/or obligations hereunder is obligated, by reason of operation of law or pursuant to a written agreement with the other Party, to assume performance of this Agreement or such rights and/or obligations; and *provided, further*, that if assigned to an Affiliate, the assigning Party shall remain jointly and severally responsible for the performance of this Agreement by such Affiliate. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this **Section 14.10** shall be null and void and of no legal effect.

**14.11 Electronic Data Interchange.** If both Parties elect to facilitate business activities hereunder by electronically sending and receiving data in agreed formats (also referred to as Electronic Data Interchange or “EDI”) in substitution for conventional paper-based documents, the terms and conditions of this Agreement shall apply to such EDI activities.

**14.12 Non-Solicitation of Employees.** For the purpose of this 14.12, EPC and EXEL shall be deemed collectively as one (1) “Party”. [\*], each Party agrees that neither it nor any of its divisions, operating groups or Affiliates shall recruit, solicit or induce any employee of the other Party directly involved in the activities conducted pursuant to this Agreement to terminate his or her employment with such other Party and become employed by or consult for such Party, whether or not such employee is a full-time employee of such other Party, and whether or not such employment is pursuant to a written agreement or is at-will. For purposes of the foregoing, “**recruit**”, “**solicit**” or “**induce**” shall not be deemed to mean: (a) circumstances where an employee of a Party initiates contact with the other Party or any of its Affiliates with regard to possible employment; or (b) general solicitations of employment not specifically targeted at employees of a Party or any of its Affiliates, including responses to general advertisements.

**14.13 Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

**14.14 Severability.** If any of the provisions of this Agreement are held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

**14.15 No Waiver.** Any delay in enforcing a Party’s rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party’s

rights to the future enforcement of its rights under this Agreement, excepting only as to an express written and signed waiver as to a particular matter for a particular period of time.

**14.16 Construction of this Agreement.** Except where the context otherwise requires, wherever used, the use of any gender shall be applicable to all genders, and the word “or” are used in the inclusive sense. When used in this Agreement, “including” means “including without limitation”. References to either Party include the successors and permitted assigns of that Party. The headings of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The Parties have each consulted counsel of their choice regarding this Agreement, and, accordingly, no provisions of this Agreement shall be construed against either Party on the basis that the Party drafted this Agreement or any provision thereof. If the terms of this Agreement conflict with the terms of any Exhibit, then the terms of this Agreement shall govern. The official text of this Agreement and any Exhibits hereto, any notice given or accounts or statements required by this Agreement, and any dispute proceeding related to or arising hereunder, shall be in English. In the event of any dispute concerning the construction or meaning of this Agreement, reference shall be made only to this Agreement as written in English and not to any other translation into any other language.

**14.17 Counterparts.** This Agreement may be executed in two (2) or more counterparts, each of which shall be an original and all of which shall constitute together the same document. Counterparts may be signed and delivered by facsimile, or electronically in PDF format, each of which shall be binding when sent.

*Signature page follows.*

**IN WITNESS WHEREOF**, the Parties have executed this Agreement in duplicate originals by their proper officers. Further, the Parties agree that the signature dates below reflect the actual date of signatures by the Parties and may not be the effective date of this Agreement.

**BRISTOL-MYERS SQUIBB COMPANY EXELIXIS, INC.**

By: /s/ Graham R. Brazier By: /s/ Michael M. Morrissey

Title: Vice President, Business Development Title: President and CEO

Date: 4/20/11 Date: 4/13/11

**EXELIXIS PATENT COMPANY, LLC.**

By: /s/ Michael M. Morrissey

Title: President and CEO

Date: 4/13/11

## Exhibit 4.2

### Form of Transfer Addendum

This Transfer Addendum No. \_\_ (the “**Transfer Addendum**”) to the license agreement between Bristol-Myers Squibb Company and Exelixis, Inc., effective as of \_\_\_\_\_, 2010 (the “**License Agreement**”), is made as of \_\_\_\_\_ **{Note: Please insert date}** (the “**Addendum Effective Date**”), by and between:

Transferring Party: **Exelixis, Inc.**

And

Receiving Party: **Bristol-Myers Squibb Company**

for the transfer of:

**(1) Information:**

**{Note: Please identify any Information other than the Materials that would be transferred, e.g., assay protocols, or else add “N/A” if not applicable.}**

**(2) Materials:**

(i) the following biological materials:

**{Note: Please identify any cell-lines, reagents, genes, vectors and constructs that would be transferred, or else add “N/A” if not applicable.}**

(ii) the following {Licensed Compounds} known as:

**{Note: Please insert identifier of the applicable compounds, or else add “N/A” if not applicable.}**

**Terms and Special Terms**

The Parties agree that the transfer of the above defined Information and Materials pursuant to this Transfer Addendum shall be covered and submitted to the terms and conditions of the License Agreement. Any special terms and conditions identified on Appendix A, attached hereto and incorporated herein, shall also apply to the transfer of the Materials under this Transfer Addendum.

IN WITNESS WHEREOF, this Transfer Addendum is entered into as of the Addendum Effective Date, and it is accepted and agreed to by the Parties' authorized representatives. The date that this Transfer Addendum is signed shall not be construed to imply that the document was made effective on that date.

\_\_\_\_\_  
Name: **{Note: insert name of AM}**                      Name: **{Note: insert name of AM}**

For Exelixis                      For BMS

Title: Alliance Manager                      Title: Alliance Manager

Date: \_\_\_\_\_                      Date: \_\_\_\_\_

[\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.



## **Appendix A to Transfer Addendum Special Terms**

The following special terms and conditions apply to the transfer of the Materials under this Transfer Addendum.

**{Note: Please identify any special terms and conditions, or else add “N/A” if not applicable.}**

## Exhibit 10.5

### Press Release

Contact:  
Charles Butler  
Vice President  
Corporate Communications  
& Investor Relations  
Exelixis, Inc.  
(650) 837-7277  
[cbutler@exelixis.com](mailto:cbutler@exelixis.com)

DeDe Sheel  
Associate Director,  
Investor Relations  
Exelixis, Inc.  
(650) 837-8231  
[dsheel@exelixis.com](mailto:dsheel@exelixis.com)

### EXELIXIS LICENSES PROGRAMS TO BRISTOL-MYERS SQUIBB COMPANY

#### *-Exelixis to receive initial payment of \$60 million-*

SOUTH SAN FRANCISCO, Calif., October XX, 2010 -- Exelixis, Inc. (NASDAQ: EXEL) announced today that it has entered into two new collaboration agreements with Bristol-Myers Squibb Company (NYSE: BMY). Under the first agreement, Exelixis will grant to Bristol-Myers Squibb an exclusive license to its small-molecule TGR5 agonist program including backups. Under the second agreement, the companies will collaborate to discover, optimize, and characterize small-molecule ROR antagonists. The companies have also made minor amendments to their XL281 and liver X receptor (LXR) agreements. Finally, under the companies' cancer collaboration agreement Exelixis has opted to exercise its right to opt out of further co-development of XL139 and will receive an accelerated milestone payment.

Under the terms of the new agreements, Bristol-Myers Squibb will make a combined initial payment of \$60 million to Exelixis. Exelixis will be eligible for potential development and approval milestone payments of up to \$250 million on TGR5 and \$255 million on the ROR antagonists. Exelixis will also be eligible for combined sales performance milestones, and royalties on net sales of products from each of the TGR5 and ROR programs. Bristol-Myers Squibb will receive an exclusive worldwide license to develop and commercialize small molecule TGR5 agonists and ROR antagonists. Under the TGR5 agreement, Bristol-Myers Squibb will have sole responsibility for research, development, manufacturing, and commercialization. Under the ROR agreement, Bristol-Myers Squibb and Exelixis will collaborate on ROR antagonist programs up to a pre-clinical transition point and then Bristol-Myers Squibb will have sole responsibility for the further research, development, manufacture, and commercialization.

Exelixis is granting rights to the ROR program in exchange for Bristol-Myers Squibb waiving rights to receive a third Investigational New Drug (IND) candidate as agreed to under a collaboration signed in 2006 between the two companies in the area of oncology.

After Exelixis opts-out of further co-development of XL139, Bristol-Myers Squibb will receive an exclusive worldwide license to develop and commercialize, and will have sole responsibility for the further development, manufacture, and commercialization of the compound.

“We continue our strong relationship with Bristol-Myers Squibb and are excited for these collaborations to maximize the potential of these novel programs and bring benefits to patients with serious diseases,” said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. “These transactions leverage our discovery expertise with the development expertise of Bristol-Myers Squibb in inflammation and metabolic diseases, and provide important additional resources for us to continue our focus on our clinical stage development pipeline.”

TGR5 is a G-protein coupled bile acid receptor (GPCR) which is highly expressed in the gall bladder and intestine. Through TGR5, bile acids promote the secretion of glucagon-like peptide-1 (GLP-1), a hormone that affects multiple metabolic parameters including increased insulin secretion from the pancreas and lowering of blood glucose. Stimulating GLP-1 secretion by activation of TGR5 has the potential to be complementary to the use of dipeptidyl peptidase-4 (DPP-IV) inhibitors for the treatment of diabetes.

ROR is a member of the nuclear hormone receptor family that is expressed in multiple cell types including T-cells. ROR plays a prominent role in the development and activity of the TH17 subset of T-cells, which secrete IL-17 and are associated with a variety of inflammatory disorders. Small molecule antagonists of ROR inhibit production of these pro-inflammatory cytokines and have broad potential as novel anti-inflammatory compounds.

The TGR5 license agreement and the amendment to the 2007 cancer collaboration agreement are subject to antitrust clearance under the Hart-Scott-Rodino Antitrust Improvements Act and other customary regulatory approvals.

### **About Exelixis**

Exelixis, Inc. is a development-stage biotechnology company dedicated to the discovery and development of novel small molecule therapeutics for the treatment of cancer and other serious diseases. The company is leveraging its biological expertise and integrated research and development capabilities to generate a pipeline of development compounds with significant therapeutic and commercial potential for the treatment of cancer and potentially other serious diseases. Currently, Exelixis’ broad product pipeline includes investigational compounds in phase 3, phase 2, and phase 1 clinical development. Exelixis has established strategic corporate alliances with major pharmaceutical and biotechnology companies, including Bristol-Myers Squibb Company, sanofi-aventis, GlaxoSmithKline, Genentech (a wholly owned member of the Roche Group), Boehringer Ingelheim, and Daiichi-Sankyo. For more information, please visit the company’s web site at <http://www.exelixis.com>.

Exelixis and the Exelixis logo are registered U.S. trademarks.

{Insert Forward-Looking Statements}

**EXELIXIS, INC.**  
**STATEMENT RE COMPUTATION OF RATIO OF EARNINGS TO FIXED CHARGES**  
**(in thousands)**

Our earnings were insufficient to cover fixed charges for the periods presented. The following table sets forth our our deficiency of earnings to cover fixed charges.

	Six Months Ended June 30,	Year Ended December 31,			
	2016	2015	2014	2013	2012
<b>Fixed charges:</b>					
Interest expense	\$ 25,042	\$ 48,673	\$ 48,607	\$ 45,347	\$ 27,088
Interest portion of rental expense	323	755	886	935	2,948
Total fixed charges	<u>\$ 25,365</u>	<u>\$ 49,428</u>	<u>\$ 49,493</u>	<u>\$ 46,282</u>	<u>\$ 30,036</u>
<b>Earnings:</b>					
Net loss before income taxes	\$ (98,362)	\$ (169,682)	\$ (268,724)	\$ (244,856)	\$ (147,538)
Fixed charges per above	25,365	49,428	49,493	46,282	30,036
Earnings	<u>\$ (72,997)</u>	<u>\$ (48,178)</u>	<u>\$ (219,049)</u>	<u>\$ (198,574)</u>	<u>\$ (117,502)</u>
Deficiency of earnings available to cover fixed charges	\$ (98,362)	\$ (97,606)	\$ (268,724)	\$ (244,856)	\$ (147,538)

## CERTIFICATION

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

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

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

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

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

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

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

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

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

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

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

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

/s/ MICHAEL M. MORRISSEY

Michael M. Morrissey, Ph.D.

President and Chief Executive Officer  
(Principal Executive Officer)

Date: August 3, 2016

## CERTIFICATION

I, Christopher J. Senner, certify that:

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

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

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

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

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

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

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

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

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

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

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

/s/ CHRISTOPHER J. SENNER

**Christopher J. Senner**

Executive Vice President and Chief Financial Officer  
(Principal Financial Officer)

Date: August 3, 2016

**CERTIFICATION**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code, Michael M. Morrissey, Ph.D., the President and Chief Executive Officer of Exelixis, Inc. (the "Company"), and Christopher J. Senner, the Executive Vice President and Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended July 1, 2016, to which this Certification is attached as Exhibit 32.1 (the "Quarterly Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned have set their hands hereto as of the 3rd day of August 2016.

/s/ MICHAEL M. MORRISSEY

\_\_\_\_\_  
**Michael M. Morrissey, Ph.D.**

President and Chief Executive Officer  
(Principal Executive Officer)

/s/ CHRISTOPHER J. SENNER

\_\_\_\_\_  
**Christopher J. Senner**

Executive Vice President and Chief Financial Officer  
(Principal Financial Officer)