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

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended March 31, 2017

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

EXELIXIS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**04-3257395**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

210 East Grand Ave.
South San Francisco, CA 94080
(650) 837-7000
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days). Yes ☒ 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

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

As of April 24, 2017, there were 292,512,348 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)
(unaudited)

	March 31, 2017	December 31, 2016*
ASSETS		
Current assets:		
Cash and cash equivalents	$ 183,179	$ 151,686
Short-term investments	241,094	268,117
Trade and other receivables	34,076	40,444
Inventory	3,304	3,338
Prepaid expenses and other current assets	6,297	5,416
Total current assets	467,950	469,001
Long-term investments	47,351	55,601
Long-term restricted cash and investments	4,150	4,150
Property and equipment, net	2,594	2,071
Goodwill	63,684	63,684
Other long-term assets	1,251	1,232
Total assets	$ 586,980	$ 595,739
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,649	$ 6,565
Accrued compensation and benefits	14,490	20,334
Accrued clinical trial liabilities	14,478	14,131
Convertible notes	113,349	109,122
Term loan payable	—	80,000
Current portion of deferred revenue	30,662	19,665
Other current liabilities	24,659	18,969
Total current liabilities	202,287	268,786
Long-term portion of deferred revenue	261,236	237,094
Other long-term liabilities	3,707	541
Total liabilities	467,230	506,421
Commitments		
Stockholders' equity		
Preferred stock, $0.001 par value, 10,000,000 shares authorized and no shares issued	—	—
Common stock, $0.001 par value; 400,000,000 shares authorized; issued and outstanding: 292,302,330 and 289,923,798 at March 31, 2017 and December 31, 2016, respectively	292	290
Additional paid-in capital	2,086,483	2,072,591
Accumulated other comprehensive loss	(326)	(416)
Accumulated deficit	(1,966,699)	(1,983,147)
Total stockholders' equity	119,750	89,318
Total liabilities and stockholders' equity	$ 586,980	$ 595,739

* The condensed consolidated balance sheet as of December 31, 2016 has been derived from the audited financial statements as of that date.

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

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

	Three Months Ended March 31,	
	2017	2016
Revenues:		
Net product revenues	$ 68,877	$ 9,099
Collaboration revenues	12,010	6,328
Total revenues	80,887	15,427
Operating expenses:		
Cost of goods sold	3,203	685
Research and development	23,210	28,926
Selling, general and administrative	34,260	34,857
Restructuring charges	28	94
Total operating expenses	60,701	64,562
Income (loss) from operations	20,186	(49,135)
Other expense, net:		
Interest income and other, net	1,068	202
Interest expense	(4,420)	(10,290)
Total other expense, net	(3,352)	(10,088)
Income (loss) before income taxes	16,834	(59,223)
Income tax expense	134	—
Net income (loss)	$ 16,700	$ (59,223)
Net income (loss) per share, basic	$ 0.06	$ (0.26)
Net income (loss) per share, diluted	$ 0.05	$ (0.26)
Shares used in computing net income (loss) per share, basic	290,870	228,304
Shares used in computing net income (loss) per share, diluted	309,535	228,304

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

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

	Three Months Ended March 31,	
	2017	2016
Net income (loss)	$ 16,700	$ (59,223)
Other comprehensive income [(1)]	90	190
Comprehensive income (loss)	$ 16,790	$ (59,033)

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

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

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

	Three Months Ended March 31,	
	2017	2016
Net income (loss)	$ 16,700	$ (59,223)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	281	229
Stock-based compensation expense	4,713	11,185
Amortization of debt discounts and debt issuance costs	89	3,161
Accrual of interest paid in kind	2,068	1,936
Other	680	440
Changes in assets and liabilities:		
Trade and other receivables	6,541	(4,956)
Inventory	34	144
Prepaid expenses and other current assets	(881)	(985)
Other long-term assets	(19)	241
Accounts payable	(1,916)	(744)
Accrued compensation and benefits	(5,844)	2,413
Accrued clinical trial liabilities	347	(1,936)
Accrued collaboration liability	—	3,736
Deferred revenue	35,139	198,802
Other current and long-term liabilities	10,926	2,367
Net cash provided by operating activities	68,858	156,810
Cash flows from investing activities:		
Purchases of property and equipment	(808)	(682)
Proceeds from sale of property and equipment	4	107
Proceeds from maturities of restricted cash and investments	3,504	2,004
Purchase of restricted cash and investments	(3,504)	(2,004)
Proceeds from sale of investments	37,294	17
Proceeds from maturities of investments	122,507	30,108
Purchases of investments	(124,494)	(49,235)
Net cash provided by (used in) investing activities	34,503	(19,685)
Cash flows from financing activities:		
Proceeds from exercise of stock options	9,675	37
Taxes paid related to net share settlement of equity awards	(1,543)	(1,914)
Principal payments on debt	(80,000)	—
Net cash used in financing activities	(71,868)	(1,877)
Net increase in cash and cash equivalents	31,493	135,248
Cash and cash equivalents at beginning of year	151,686	141,634
Cash and cash equivalents at end of year	$ 183,179	$ 276,882

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 to improve care and outcomes for people with cancer. Since our founding in 1994, three products discovered at Exelixis have progressed through clinical development, received regulatory approval, and entered the commercial marketplace. Two are derived from cabozantinib, an inhibitor of multiple tyrosine kinases including MET, AXL, and VEGF receptors: CABOMETYX™ tablets approved for previously treated advanced kidney cancer and COMETRIQ® capsules approved for progressive, metastatic medullary thyroid cancer. The third product, COTELLIC®, is a formulation of cobimetinib, a selective inhibitor of MEK, marketed under a collaboration with Genentech (a member of the Roche Group), and is approved as part of a combination regimen to treat advanced melanoma.

Basis of Consolidation

The condensed consolidated financial statements include the accounts of Exelixis and those of our wholly-owned subsidiaries. These entities’ functional currency is the 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 (“U.S.”) for interim financial information and pursuant to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (“SEC”). Accordingly, they do not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements. In our opinion, all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation of the results of operations and cash flows for the periods presented have been included.

We have adopted a 52- or 53-week fiscal year policy that generally ends on the Friday closest to December 31st. Fiscal year 2017 will end on December 29, 2017 and fiscal year 2016 ended on December 30, 2016. For convenience, references in this report as of and for the fiscal periods ended March 31, 2017 and April 1, 2016, and as of and for the fiscal years ended December 29, 2017 and December 30, 2016, are indicated as being as of and for the periods ended March 31, 2017 and March 31, 2016, and the years ended December 31, 2017 and December 31, 2016, respectively.

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

Use of Estimates

The preparation of our condensed consolidated financial statements conforms to accounting principles generally accepted in the U.S. which requires management to make judgments, estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosures. On an ongoing basis, management evaluates its estimates including, but not limited to, those related to revenue recognition, including deductions from revenues (such as rebates, chargebacks, sales returns and sales allowances), the period of performance, identification of deliverables and evaluation of milestones with respect to our collaborations, the amounts of revenues and expenses under our profit and loss sharing agreement, recoverability of inventory, certain accrued liabilities including accrued clinical trial liability, and stock-based compensation. We base our estimates on historical experience and on various other market-specific and other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ materially from those estimates.

Correction of an Immaterial Error

During the third quarter of 2016, we identified errors in the Consolidated Balance Sheets and Consolidated Statements of Operations, Comprehensive Loss and Cash Flows for 2015, 2014, 2013, and 2012, and in the unaudited interim Condensed Consolidated Balance Sheets and Condensed Consolidated Statements of Operations, Comprehensive Loss and Cash Flows for all prior interim fiscal periods from September 30, 2012 through June 30, 2016. Specifically, in 2012 we incorrectly calculated 1) the allocation between Additional paid-in capital and Convertible notes of the $287.5 million aggregate principal amount from our 4.25% Convertible Senior Subordinated Notes due 2019 ("2019 Notes"); and 2) the amortization of the debt discount associated with the 2019 Notes during 2012 and all subsequent periods.

Having evaluated the materiality of these errors from a quantitative and qualitative perspective, management has concluded that although the accumulation of these errors was significant to the three and nine months ended September 30, 2016, the correction of these errors would not be material to any individual prior period, and did not have an effect on the trend of financial results, taking into account the requirements of the SEC Staff Accounting Bulletin No. 99, *Materiality* and Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*. Because management has concluded that these errors are not material, we will correct them prospectively when the consolidated balance sheets, statements of operations, comprehensive loss and cash flows for such periods are included in future filings.

Following are the amounts (in thousands, except per share amounts) that should have been reported for the affected line items of the statement of operations, statement of comprehensive loss and statement of cash flows:

	Three Months Ended March 31, 2016
Statement of Operations:	
Interest expense, overstated by $2,124 for the three months ended March 31, 2016	$ (10,290)
Total other expense, net, overstated by $2,124 for the three months ended March 31, 2016	$ (10,088)
Net loss, overstated by $2,124 for the three months ended March 31, 2016	$ (59,223)
Net loss per share, basic and diluted, overstated by $0.01 for the three months ended March 31, 2016	$ (0.26)
Statements of Comprehensive Loss:	
Comprehensive loss, overstated by $2,124 for the three months ended March 31, 2016	$ (59,033)
Statements of Cash Flows [(1)]:	
Net loss, overstated by $2,124 for the three months ended March 31, 2016	$ (59,223)
Accretion of debt discount and debt issuance costs, overstated by $2,124 for the three months ended March 31, 2016	$ 3,161

(1) The error did not impact our net cash provided by or used in operating activities, financing activities or investing activities for any of the periods presented.

These errors did not affect any other caption or total in our unaudited condensed or annual consolidated financial statements as of and for the three months ended March 31, 2016. 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, 2016 for the amounts of the corrections and the amounts that should have been reported for 2015, 2014, 2013, and 2012 in the affected line items of the statements of operations, statements of comprehensive loss and statements of cash flows.

Reclassifications

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

Segment Information

We operate as a single reportable segment.

Stock-Based Compensation

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

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

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

ASU 2016-09 also requires that cash paid to taxing authorities when directly withholding shares for tax withholding purposes should be classified as a financing activity. Previously, we classified such payments as operating cash flows. The change in accounting principle with regards to such cash flows was adopted using a retrospective approach. Accordingly, we reclassified $1.9 million in our Condensed Consolidated Statement of Cash Flows for the three months ended March 31, 2016 to reflect a $1.9 million increase in Cash provided by operating activities and a corresponding increase to Cash used in financing activities.

Recent Accounting Pronouncements

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

The core principle of ASU 2014-09 is that an entity should recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than required under existing U.S. generally accepted accounting pronouncements. We do not expect that ASU 2014-09 will have a material impact on the recognition of revenue from product sales. We are still in the process of evaluating the effect that this guidance will have on revenue recognition from our collaboration agreements such as our arrangements with Ipsen Pharma SAS ("Ipsen"), Takeda Pharmaceutical Company Ltd. ("Takeda") and Genentech. We expect our evaluation to be completed by the end of the second quarter of 2017.

NOTE 2: COLLABORATION AGREEMENTS

Ipsen Collaboration

In February 2016, we entered into a collaboration and license agreement with Ipsen (the "Ipsen Collaboration Agreement") for the commercialization and further development of cabozantinib. Pursuant to the terms of the Ipsen Collaboration Agreement, Ipsen received exclusive commercialization rights for current and potential future cabozantinib indications outside of the U.S., Canada and Japan (the "Ipsen Territory"). The Ipsen Collaboration Agreement was

subsequently amended in December 2016 (the "Amendment") to include commercialization rights in Canada in the Ipsen Territory. We have also agreed to collaborate with Ipsen on the development of cabozantinib for current and potential future indications.

In consideration for the exclusive license and other rights contained in the Ipsen Collaboration Agreement, Ipsen paid us an upfront nonrefundable payment of $200.0 million in March 2016. Additionally, as a result of the Amendment, we received a $10.0 million upfront nonrefundable payment from Ipsen in December 2016 and, as a result of the approval of cabozantinib in second-line renal cell carcinoma ("RCC") by the European Commission ("EC") in September 2016, we received a $60.0 million milestone in November 2016. We are receiving a 2% royalty on the initial $50.0 million of net sales by Ipsen, and are entitled to receive a 12% royalty on the next $100.0 million of net sales by Ipsen. After the initial $150.0 million of sales, we are entitled to receive a tiered royalty of 22% to 26% on annual net sales by Ipsen; these tiers will reset each calendar year. We are primarily responsible for funding cabozantinib-related development costs for those trials in existence at the time we entered into the Ipsen Collaboration Agreement; global development costs for additional trials will be shared between the parties, with Ipsen reimbursing us for 35% of such costs, provided Ipsen opts in to participate in such additional trials. Pursuant to the terms of the Ipsen Collaboration Agreement, we will remain responsible for the manufacture and supply of cabozantinib for all development and commercialization activities. As part of the collaboration agreement, we entered into a supply agreement pursuant to which we will supply finished, labeled product to Ipsen for distribution in the Ipsen Territories at our cost, as defined in the agreement, which excludes the 3% royalty we are required to pay GlaxoSmithKline on Ipsen's Net Sales of any product incorporating cabozantinib.

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

During the quarter ended March 31, 2017, we reclassified $9.0 million of deferred revenue to Other current and long-term liabilities, and accordingly adjusted our amortization of the upfront payment of $200.0 million as a result of a change in operational responsibilities for certain clinical programs in the Ipsen Territory. As of March 31, 2017, we had paid $1.1 million toward the $9.0 million of reimbursements due to Ipsen for these clinical programs.

See "Note 2 - Collaboration Agreements" to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2016 filed with the SEC on February 27, 2017 for additional description of our collaboration agreement with Ipsen.

During the three months ended March 31, 2017 and 2016, collaboration revenues under the Ipsen Collaboration Agreement were as follows (in thousands):

	Three Months Ended March 31,	
	2017	2016
Amortization of upfront payments and deferred milestone	$ 4,305	$ 1,198
Royalty revenue	224	—
Development cost reimbursements	337	—
Product supply agreement revenue	991	—
Cost of supplied product	(991)	—
Royalty payable to GlaxoSmithKline on net sales by Ipsen	(336)	—
Collaboration revenues under the Ipsen Collaboration Agreement	$ 4,530	$ 1,198

As of March 31, 2017, short-term and long-term deferred revenue relating to the Ipsen Collaboration Agreement was $19.0 million and $224.4 million, respectively.

Genentech Collaboration

In December 2006, we out-licensed the development and commercialization of cobimetinib to Genentech pursuant to a worldwide collaboration agreement. Under the terms of our collaboration agreement with Genentech for cobimetinib, we are entitled to a share of U.S. profits and losses received in connection with the commercialization of cobimetinib. 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. In addition, 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 U.S. In 2015, we began fielding 25% of the sales force promoting COTELLIC in combination with Zelboraf as a treatment for patients with BRAF V600E or V600K mutation-positive advanced melanoma.

In January 2017, we announced that Genentech had withdrawn its counterclaim against us in the ongoing JAMS arbitration concerning alleged breaches of the parties' collaboration agreement. Genentech had asserted a counterclaim for breach of contract, which sought monetary damages and interest related to cost allocations under the collaboration agreement. When notifying the arbitral panel, and us, of this unilateral action, Genentech further stated that it is changing the manner in which it allocates promotional expenses of the COTELLIC plus Zelboraf (vemurafenib) combination therapy. Genentech's revised allocation applies retrospectively and prospectively and substantially reduces our exposure to costs associated with promotion of the COTELLIC plus Zelboraf combination in the U.S. Notwithstanding Genentech's change of approach, other significant issues remain in dispute between the parties. As a result, we will continue to press our position before the arbitral panel to obtain a just resolution of these claims. The ultimate outcome and timing of the arbitration is difficult to predict.

During the three months ended March 31, 2017 and 2016, ex-U.S. royalty revenues and U.S. losses under the collaboration agreement with Genentech were as follows (in thousands):

	Three Months Ended March 31,	
	2017	2016
Royalty revenues on ex-U.S. sales of COTELLIC included in Collaboration revenues	$ 2,298	$ 130
U.S. losses included in Selling, general and administrative expenses	$ (626)	$ (7,293)

The U.S. losses under the collaboration agreement include personnel and other costs we have incurred to co-promote COTELLIC plus Zelboraf in the U.S.

Royalty revenues from the collaboration agreement with Genentech are based on amounts reported to us by our collaboration partner and are recorded when such information becomes available to us; for 2017 such information is expected to be available in the current quarter and for 2016 such information was not available until the following quarter, meaning that in 2016 we recorded royalty revenues on a one quarter lag. As a result of this change, during the three months ended March 31, 2017 we recorded royalty revenues earned for both the fourth quarter of 2016 and the first quarter of 2017 of $1.1 million and $1.2 million, respectively.

Takeda Collaboration

On January 30, 2017, we entered into a collaboration and license agreement (the "Takeda Collaboration Agreement") with Takeda for the commercialization and further clinical development of cabozantinib in Japan. Pursuant to the terms of the Takeda Collaboration Agreement, Takeda will have exclusive commercialization rights for current and potential future cabozantinib indications in Japan. The companies have also agreed to collaborate on the clinical development of cabozantinib in Japan. The operation and strategic direction of the parties' collaboration will be governed through a joint executive committee and appropriate subcommittees.

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

Takeda will be responsible for 20% of the costs associated with the global cabozantinib development plan's current and future trials, provided Takeda opts to participate in such future trials, and 100% of costs associated with the cabozantinib development activities that are exclusively for the benefit of Japan. Pursuant to the terms of the Takeda Collaboration Agreement, we will remain responsible for the manufacture and supply of cabozantinib for all development and commercialization activities under the collaboration. As part of the collaboration, the parties will enter into clinical and commercial supply agreements covering the manufacture and supply of cabozantinib for Takeda and a quality agreement setting forth in detail the quality assurance arrangements and procedures for our manufacture of cabozantinib.

The Takeda Collaboration Agreement may be terminated for cause by either party based on uncured material breach by the other party, bankruptcy of the other party or for safety reasons. For clarity, Takeda's failure to achieve specified levels of commercial performance, based upon sales volume and/or promotional effort, during the first six years of the collaboration shall constitute a material breach of the Takeda Collaboration Agreement. We may terminate the agreement if Takeda challenges or opposes any patent covered by the Takeda Collaboration Agreement. At any time prior to August 1, 2023, the parties may mutually agree to terminate the Takeda Collaboration Agreement if Japan's Pharmaceuticals and Medical Devices Agency is unlikely to grant approval of the marketing authorization application in any cancer indication in Japan. After the commercial launch of cabozantinib in Japan, Takeda may terminate the Takeda Collaboration Agreement upon twelve months' prior written notice following the third anniversary of the first commercial sale of cabozantinib in Japan. Upon termination by either party, all licenses granted by us to Takeda will automatically terminate, and the licenses granted by Takeda to us shall survive such termination and shall automatically become worldwide.

The Takeda Collaboration Agreement contains multiple deliverables consisting of intellectual property licenses, delivery of products and/or materials containing cabozantinib to Takeda for all development and commercial activities, research and development services, and participation on the joint executive, development and commercialization committees (as defined in the Takeda Collaboration Agreement). We determined that these deliverables, other than the commercial supply and joint commercialization committee participation, are non-contingent in nature. The commercial supply deliverable was deemed contingent, primarily due to the fact that there is uncertainty around approval in Japan, which is dependent on successful bridging study results. We also determined that the non-contingent deliverables do not have stand-alone value, because each one of them has value only if we meet our obligation as a whole to provide Takeda with research and development services, including clinical supply of cabozantinib under the Takeda Collaboration Agreement. Accordingly, we combined the non-contingent deliverables into a single unit of accounting and allocated the $50.0 million upfront fee to that combined unit of accounting. We also determined that the level of effort required of us to meet our obligations under the Takeda Collaboration Agreement is not expected to vary significantly over the development period of the Takeda Collaboration Agreement. As a result, the upfront payment of $50.0 million, received in the first quarter of 2017, will be recognized ratably over the development period of the Takeda Collaboration Agreement of approximately four years. We determined that the development and regulatory milestones are substantive and will be recognized as revenue in the periods in which they are achieved. We consider the contingent payments due to us upon the achievement of specified sales volumes to be similar to royalty payments. We will record reimbursements for development costs as revenue as the development services represent a part of our ongoing major or central operations.

During the three months ended March 31, 2017, collaboration revenues under the Takeda Collaboration Agreement were as follows (in thousands):

	Three Months Ended March 31, 2017
Amortization of upfront payment	$ 1,887
Development cost reimbursements	795
Collaboration revenues under the Takeda Collaboration Agreement	$ 2,682

As of March 31, 2017, short-term and long-term deferred revenue relating to the Takeda Collaboration Agreement was $11.3 million and $36.8 million, respectively.

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

In February 2017, we entered into a clinical trial collaboration agreement with Bristol-Myers Squibb Company (“BMS Collaboration Agreement”) for the purpose of evaluating the combination of cabozantinib with nivolumab or of cabozantinib with nivolumab and ipilimumab in various tumor types, including, in a pivotal phase 3 trial in first-line advanced RCC, and in potential additional trials in bladder cancer and HCC. Pursuant to the terms of the BMS Collaboration Agreement, each party will grant to the other a non-exclusive, worldwide (within the collaboration territory as defined in the BMS Collaboration Agreement), non-transferable, royalty-free license to use the other party’s compounds in the conduct of each clinical trial. The parties’ efforts will be governed through a joint development committee established to guide and oversee the collaboration’s operation. Each trial will be conducted under a combination Investigational New Drug application, unless otherwise required by a regulatory authority. Each party will be responsible for supplying drug product for the applicable clinical trial and costs for each such trial will be shared equally between the parties, unless two Bristol-Myers Squibb Company (“BMS”) compounds will be utilized in such trial, in which case BMS will bear two-thirds of the costs for such study treatment arms and we will bear one-third of the costs. Unless earlier terminated, the BMS Collaboration Agreement will remain in effect until the completion of all clinical trials under the collaboration, all related trial data has been delivered to both parties and the completion of any then agreed upon analysis. Ipsen has opted in to participate in the phase 3 pivotal trial in first-line advanced RCC and will have access to the results to support potential future regulatory submissions. Ipsen may also participate in future studies at their choosing.

The Roche Group Collaboration

In February 2017, we entered into a clinical trial collaboration agreement with The Roche Group (“Roche”) for the purpose of evaluating the safety and tolerability of cabozantinib in combination with Roche’s atezolizumab in patients with locally advanced or metastatic solid tumors. Based on the dose-escalation results, the trial has the potential to enroll up to four expansion cohorts, including a cohort of patients with previously untreated advanced clear cell RCC and three cohorts of urothelial carcinoma, namely platinum eligible first-line patients, first or second-line platinum ineligible patients and patients previously treated with platinum-containing chemotherapy. Enrollment for this trial is scheduled to begin mid-year 2017. We will be the sponsor of the trial, and Roche will provide atezolizumab. Ipsen will participate in the study and have access to the results for potential future development in its territories.

GlaxoSmithKline Collaboration

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

In connection with the sales of COMETRIQ and CABOMETYX, during the three months ended March 31, 2017 and 2016, we recorded $2.7 million and $0.3 million, respectively, in royalties payable to GlaxoSmithKline. Royalty expense is included in Cost of goods sold for sales by us and as a reduction of Collaboration revenue for sales by Ipsen in the accompanying Condensed Consolidated Statements of Operations.

Other Collaborations

During the three months ended March 31, 2017, we recognized $2.5 million in contract revenues from a contingent payment received from BMS related to its ROR gamma program, and during the three months ended March 31, 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. See “Note 2 - Collaboration Agreements” to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2016 filed with the SEC on February 27, 2017 for a description of our existing collaboration agreements.

NOTE 3: CASH AND INVESTMENTS

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

	March 31, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents	$ 183,179	$ —	$ —	$ 183,179
Short-term investments	241,247	22	(175)	241,094
Long-term investments	47,416	15	(80)	47,351
Long-term restricted cash and investments	4,150	—	—	4,150
Total cash and investments	$ 475,992	$ 37	$ (255)	$ 475,774

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

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

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

	March 31, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$ 44,641	$ —	$ —	$ 44,641
Commercial paper	193,968	—	—	193,968
Corporate bonds	175,244	37	(220)	175,061
U.S. Treasury and government sponsored enterprises	43,321	—	(35)	43,286
Total investments	$ 457,174	$ 37	$ (255)	$ 456,956

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

Gains and losses on the sales of investments available-for-sale were nominal or zero during the three months ended March 31, 2017 and 2016.

All of our investments are subject to a quarterly impairment review. During the three months ended March 31, 2017 and 2016 we did not record any other-than-temporary impairment charges on our available-for-sale securities. As of March 31, 2017, there were 96 investments in an unrealized loss position with gross unrealized losses of $0.3 million and an aggregate fair value of $184.4 million. The investments in an unrealized loss position comprise corporate bonds with an aggregate fair value of $142.2 million and the remainder comprises securities issued by U.S. Treasury and government sponsored enterprises. 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 March 31, 2017 (in thousands):

	Mature within One Year	After One Year through Two Years	Fair Value
Money market funds	$ 44,641	$ —	$ 44,641
Commercial paper	193,968	—	193,968
Corporate bonds	132,355	42,706	175,061
U.S. Treasury and government sponsored enterprises	40,639	2,647	43,286
Total investments	$ 411,603	$ 45,353	$ 456,956

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

NOTE 4. INVENTORY

Inventory consists of the following (in thousands):

	March 31, 2017	December 31, 2016
Raw materials	$ 692	$ 863
Work in process	2,462	2,343
Finished goods	774	738
Total	3,928	3,944
Less: non-current portion included in Other assets	(624)	(606)
Inventory	$ 3,304	$ 3,338

We generally relieve inventory on a first-expiry, first-out basis. A portion of the manufacturing costs for inventory was incurred prior to regulatory approval of CABOMETYX and COMETRIQ and, therefore, was expensed as research and development costs when those costs were incurred, rather than capitalized as inventory. Write-downs related to excess and

expiring inventory are charged to either Cost of goods sold or the cost of supplied product included in Collaboration revenues. Such write-downs were $0.5 million for the three months ended March 31, 2017; these amounts were nominal for the comparable period in 2016. The non-current portion of inventory consists of raw materials and a portion of active pharmaceutical ingredient which is included in work in process.

NOTE 5. DEBT

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

	March 31, 2017	December 31, 2016
Secured Convertible Notes due 2018 ("Deerfield Notes")	$ 113,349	$ 109,122
Term loan payable	—	80,000
Total debt	$ 113,349	$ 189,122

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

Deerfield Notes

As of March 31, 2017 and December 31, 2016, the outstanding principal balance on the Deerfield Notes was $113.9 million and $109.8 million, respectively, which, subject to certain limitations, is payable in cash or in stock at our discretion. 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.

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 prepaid 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.

The Deerfield Notes are classified as a current liability as of March 31, 2017 and December 31, 2016 because we intend to repay the Deerfield Notes on or about July 1, 2017 at the Prepayment Price. We expect that cash and cash equivalents and short-term investments held at March 31, 2017 will be used to repay the Deerfield Notes.

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

	Three Months Ended March 31,	
	2017	2016
Stated coupon interest	$ 2,068	$ 1,936
Interest paid in kind	2,068	1,936
Amortization of debt discount and debt issuance costs	89	93
Total interest expense	$ 4,225	$ 3,965

The balance of unamortized fees and costs was $0.4 million as of both March 31, 2017 and December 31, 2016, which is recorded as a reduction of the carrying amount of the Deerfield Notes on the accompanying Condensed Consolidated Balance Sheets. We are amortizing the remaining unamortized debt discount and debt issuance costs through the July 1, 2018 maturity date using the effective interest method at an effective interest rate of 15.2%.

Although we currently intend to repay the Deerfield Notes on or about July 1, 2017, if we do not prepay the Deerfield Notes by December 31, 2017, we may be required to make an additional mandatory prepayment in January 2018 equal to 15% of certain revenues from collaborative arrangements, which we refer to as Development/Commercialization Revenue, received during the fiscal year ending December 31, 2017, subject to a maximum prepayment amount of $27.5 million. However, we will only be obligated to make any such annual mandatory prepayment if the holders of the Deerfield Notes provide notice to us of their election to receive the prepayment. 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 sale of our intellectual property, subject to limited exceptions, 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. Pursuant to this requirement, if we do not prepay the Deerfield Notes by December 31, 2017, we may be required to make a mandatory prepayment of $8.2 million in January 2018.

Silicon Valley Bank Loan and Security Agreement

On March 29, 2017, we repaid all amounts outstanding under our term loan with Silicon Valley Bank which was initiated in June 2010 under our loan and security agreement with Silicon Valley Bank. The payment included $80.0 million in principal plus $0.1 million in accrued and unpaid interest. There was no gain or loss on the extinguishment of debt as a result of the repayment of the term loan. As of December 31, 2016, the outstanding principal balance due under the term loan was $80.0 million. Prior to our early repayment of the term loan, the principal amount outstanding under the term loan had accrued interest at 1.0% per annum, which was due and payable monthly.

In accordance with the terms of the loan and security agreement, we were required to maintain an amount equal to at least 100%, but not to exceed 107%, of the outstanding principal balance of the term loan on deposit in one or more investment accounts with Silicon Valley Bank or one of its affiliates as support for our obligations under the loan and security agreement. We were entitled to retain income earned or the amounts maintained in such accounts. The total collateral balance as of December 31, 2016 was $81.6 million and is reflected in our Condensed Consolidated Balance Sheet in Short-term investments as the amounts were not restricted as to withdrawal. As a result of our repayment of the term-loan, the compensating balance requirement was terminated as of March 29, 2017.

NOTE 6. FAIR VALUE MEASUREMENTS

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

	March 31, 2017		
	Level 1	Level 2	Total
Money market funds	$ 44,641	$ —	$ 44,641
Commercial paper	—	193,968	193,968
Corporate bonds	—	175,061	175,061
U.S. Treasury and government sponsored enterprises	—	43,286	43,286
Total financial assets	$ 44,641	$ 412,315	$ 456,956

	December 31, 2016		
	Level 1	Level 2	Total
Money market funds	$ 71,457	$ —	$ 71,457
Commercial paper	—	165,375	165,375
Corporate bonds	—	152,407	152,407
U.S. Treasury and government sponsored enterprises	—	70,727	70,727
Total financial assets	$ 71,457	$ 388,509	$ 459,966

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

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

	March 31, 2017		December 31, 2016	
	Carrying Amount	Fair Value	Carrying Amount	Fair Value
Deerfield Notes	$ 113,349	$ 121,895	$ 109,122	$ 121,220
Term loan payable	$ —	$ —	$ 80,000	$ 79,784

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

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 are Level 2 inputs.
- We estimate the fair value of our debt instruments using the net present value of the payments. For the Deerfield Notes, we used a discount rate of 9.5%, which we estimate as our current borrowing rate for similar debt as of March 31, 2017, which is a Level 3 input. For the term loan payable, we used 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.

NOTE 7. 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 March 31,	
	2017	2016
Research and development expense	$ 1,478	$ 5,564
Selling, general and administrative expense	3,235	5,621
Total stock-based compensation expense	$ 4,713	$ 11,185

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

	Three Months Ended March 31,	
	2017	2016
Stock options	$ 9.92	$ 2.51
ESPP	$ 3.71	$ 2.31

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

	Stock Options	
	Three Months Ended March 31,	
	2017	2016
Risk-free interest rate	1.62%	1.16%
Dividend yield	—%	—%
Expected volatility	64%	79%
Expected life	4.0 years	4.3 years

	Employee Stock Purchase Plan	
	Three Months Ended March 31,	
	2017	2016
Risk-free interest rate	0.62%	0.51%
Dividend yield	—%	—%
Expected volatility	68%	81%
Expected life	6 months	6 months

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

A summary of stock option activity for the three months ended March 31, 2017 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, 2016	24,999,665	$ 4.91		
Granted	288,120	$ 20.16		
Exercised	(2,297,358)	$ 4.29		
Forfeited	(141,021)	$ 7.23		
Options outstanding at March 31, 2017	22,849,406	$ 5.15	4.46 years	$ 377,392
Exercisable at March 31, 2017	16,456,810	$ 4.02	3.94 years	$ 290,400

As of March 31, 2017, a total of 1,548,149 shares were available for grant under our stock option plans

A summary of restricted stock unit (“RSU”) activity for the three months ended March 31, 2017 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, 2016	2,469,791	$ 8.69		
Awarded	135,750	$ 20.06		
Vested and released	(178,898)	$ 4.42		
Forfeited	(73,495)	$ 10.36		
Awards outstanding at March 31, 2017	2,353,148	$ 9.62	1.87 years	$ 50,993

NOTE 8. INCOME TAXES

During the first quarter, we recorded income tax expense of $0.1 million, which is comprised of our computed income tax expense of $1.0 million reduced by $0.9 million of excess benefits associated with equity compensation. The income tax expense for the three months ended March 31, 2017 primarily relates to state taxes in jurisdictions outside of California, for which we have a limited operating history.

NOTE 9. NET INCOME (LOSS) PER SHARE

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

	Three Months Ended March 31,	
	2017	2016
Net income (loss)	$ 16,700	$ (59,223)
Net income allocated to participating securities - 2014 Warrants	(57)	—
Net income allocable to common stock for basic net income (loss) per share	16,643	(59,223)
Adjustment to net income allocated to participating securities	3	—
Net income allocable to common stock for diluted net income (loss) per share	$ 16,646	$ (59,223)
Weighted-average shares of common stock outstanding	290,870	228,304
Dilutive securities:		
Outstanding stock options, unvested RSUs and ESPP contributions	18,665	—
Weighted-average shares of common stock outstanding and dilutive securities	309,535	228,304
Net income (loss) per share, basic	$ 0.06	$ (0.26)
Net income (loss) per share, diluted	$ 0.05	$ (0.26)

The 2014 Warrants are participating securities and the warrant holders do not have a contractual obligation to share in our losses. See “Note 8 - Common Stock and Warrants” to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2016 filed with the SEC on February 27, 2017 for a description of the 2014 Warrants.

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

	March 31	
	2017	2016
2019 Notes	—	54,118
Deerfield Notes	33,890	33,890
Outstanding stock options, unvested RSUs and ESPP contributions	1,396	31,364
Warrants	—	1,000
Total potentially dilutive shares	35,286	120,372

The 2019 Notes were converted and redeemed between August and November 2016.

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, commercial paper, corporate bonds with high credit quality, and U.S. Treasury and government sponsored enterprises. All investments are maintained with financial institutions that management believes are creditworthy.

Trade and other receivables are unsecured and are concentrated in the pharmaceutical and biotechnology industries. Accordingly, we may be exposed to credit risk generally associated with pharmaceutical and biotechnology companies. We have incurred no bad debt expense since inception. As of March 31, 2017, 21%, 18%, 16%, and 12% of our trade receivables are with Diplomat Specialty Pharmacy, Caremark L.L.C., affiliates of McKesson Corporation, and Accredo Health, Incorporated, respectively. All of these customers have historically paid promptly.

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

	Three Months Ended March 31,	
	2017	2016
Diplomat Specialty Pharmacy	25%	55%
Caremark L.L.C.	17%	—%
Affiliates of McKesson Corporation	14%	—%
Accredo Health, Incorporated	12%	—%
Merck	—%	32%

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

The following table shows the revenues earned by geographic region. Net product revenues are attributed to regions based on the delivery location. Collaboration revenues are attributed to regions based on where the collaboration partner is headquartered (dollars in thousands):

	Three Months Ended March 31,	
	2017	2016
U.S.	$ 73,675	$ 13,594
Europe	4,530	1,833
Japan	2,682	—

We recorded losses of $0.1 million and $0.2 million relating to foreign exchange fluctuations for three months ended March 31, 2017 and 2016, respectively.

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

The following discussion and analysis contains forward-looking statements. These statements are based on Exelixis, Inc.'s ("Exelixis," "we," "our" or "us") current expectations, assumptions, estimates and projections about our business and our industry, and involve known and unknown risks, uncertainties and other factors that may cause our or our industry's results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied in, or contemplated by, the forward-looking statements. Words such as "expect," "potential," "will," "goal," "would," "intend," "continues," "objective," "anticipate," "initiate," "believe," "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, 2016, filed with the Securities and Exchange Commission, or SEC, on February 27, 2017. Operating results are not necessarily indicative of results that may occur in future periods. We undertake no obligation to update any forward-looking statement to reflect events after the date of this report.

Overview

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

While our commercialization efforts for CABOMETYX and COMETRIQ are focused in the U.S., we have licensed development and commercialization rights to cabozantinib outside of the U.S. to Ipsen Pharma SAS, or Ipsen, and Takeda Pharmaceutical Company Ltd., or Takeda. Ipsen has been granted rights to cabozantinib outside of the U.S. and Japan, and Takeda has been granted rights to cabozantinib in Japan. We are also closely working with Ipsen and Takeda on the further global development and commercialization of cabozantinib in other potential indications.

Beyond the U.S. Food and Drug Administration, or FDA, approved indications of cabozantinib for second-line advanced renal cell carcinoma, or RCC, and progressive, metastatic 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 CELESTIAL, our company-sponsored phase 3 trial of cabozantinib in advanced hepatocellular carcinoma, or HCC, for which we anticipate the planned second interim analysis with 75% of all required events to take place in the second half of 2017, and CABOSUN, a randomized phase 2 trial comparing cabozantinib to sunitinib in the first-line treatment of intermediate- or poor-risk RCC patients, 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 progression-free survival compared with sunitinib. Based on these results, we are working towards the submission of a supplemental New Drug Application, or sNDA, in the third quarter of 2017 for cabozantinib as a treatment for first-line advanced RCC.

Cabozantinib has demonstrated clinical activity as a single agent in advanced RCC, and we are interested in further examining its potential in combination with immunotherapies to determine if outcomes for patients may be further improved. Building on preclinical and clinical observations that cabozantinib creates a more immune-permissive tumor environment potentially resulting in the cooperative activity of cabozantinib in combination with immune checkpoint inhibitors, we, in collaboration with Bristol-Myers Squibb Company, or BMS, plan to evaluate the combination of cabozantinib with nivolumab or with nivolumab and ipilimumab in various tumor types. This is expected to include a phase 3 trial in first-line advanced RCC, as well as studies in bladder cancer and HCC. We are also planning to initiate a phase 1b dose escalation study mid-year 2017 that will evaluate the safety and tolerability of cabozantinib in combination with Roche's atezolizumab in patients with locally advanced or metastatic solid tumors.

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 cobimetinib under our collaboration agreement with Genentech. Genentech is now conducting two phase 3 pivotal trials exploring the combination of cobimetinib with atezolizumab in melanoma and colorectal carcinoma, and has announced plans to initiate a third phase 3 trial of cobimetinib in combination with atezolizumab in a distinct melanoma population in the second quarter of 2017. Roche recently announced that enrollment in the phase 3 trial of cobimetinib plus atzolizumab in colorectal carcinoma (IMblaze370) was completed in the first quarter of 2017.

First Quarter 2017 Business Development Updates and Financial Highlights

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

Business Development Updates

- In January 2017, we entered into a collaboration and license agreement with Takeda for the commercialization and further clinical development of cabozantinib in Japan.
- In February 2017, we announced results from a phase 1 trial evaluating the combination of cabozantinib with nivolumab or cabozantinib with nivolumab and ipilimumab in refractory metastatic urothelial carcinoma and other genitourinary tumors being conducted under our CRADA with NCI-CTEP. The primary endpoint of the trial was to determine the dose limiting toxicity and recommended phase 2 doses of the doublet and triplet combinations. The recommended doses for the ongoing expansion cohorts, based on encouraging tolerability, safety and activity profile were determined to be cabozantinib 40 mg daily plus nivolumab 3 mg/kg once every 2 weeks for the doublet and cabozantinib 40 mg daily, nivolumab 3 mg/kg plus ipilimumab 1 mg/kg every 3 weeks for 4 doses, then nivolumab 3 mg/kg every 2 weeks for the triplet.
- In February 2017, we entered into a clinical trial collaboration agreement with BMS for the purpose of evaluating the combination of cabozantinib with nivolumab or cabozantinib with nivolumab and ipilimumab in various tumor types, including a planned phase 3 trial in first-line advanced RCC, and potential additional trials in bladder cancer and HCC. Ipsen has opted in to participate in the phase 3 pivotal trial in

first-line advanced RCC and will have access to the results to support potential future regulatory submissions. Ipsen may also participate in future studies at their choosing.

- In February 2017, we entered into a clinical trial collaboration with Roche pursuant to which we will evaluate cabozantinib and atezolizumab in locally advanced or metastatic solid tumors. Ipsen will participate in the study and have access to the results for potential future development in its territories.
- In March 2017, the FDA granted orphan drug designation to cabozantinib for the treatment of HCC.

Financial Highlights

- Net income for the first quarter 2017 was $16.7 million, or $0.06 per share, basic, and $0.05 per share, diluted, compared to a net loss of $(59.2) million, or $(0.26) per share, basic and fully diluted, for the first quarter of 2016.
- Total revenues for the first quarter 2017 increased to $80.9 million, compared to $15.4 million for the first quarter of 2016.
- Cost of goods sold for the first quarter 2017 increased to $3.2 million, compared to $0.7 million for the first quarter of 2016.
- Research and development expenses for the first quarter 2017 decreased to $23.2 million, compared to $28.9 million for the first quarter of 2016.
- Selling, general and administrative expenses for the first quarter 2017 decreased to $34.3 million, compared to $34.9 million for the first quarter of 2016.
- Total other expense, net for the first quarter 2017 decreased to $3.4 million, compared to $10.1 million for the first quarter of 2016.
- Cash and investments decreased to $475.8 million at March 31, 2017 as compared to $479.6 million at December 31, 2016.
- In March 2017, we repaid all amounts outstanding under our term loan with Silicon Valley Bank, which was initiated in 2010 with an original maturity date of May 31, 2017.

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

Although we reported net income of $16.7 million for the three months ended March 31, 2017, we may not be able to maintain or increase profitability on a quarterly or annual basis and we are otherwise unable to accurately predict the extent of long-range future profits or losses. Excluding fiscal 2011 and the three months ended March 31, 2017, 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 during 2017. In addition, we intend to expand our product pipeline through the measured resumption of drug discovery and the evaluation of in-licensing and acquisition opportunities that align with our oncology drug expertise, which efforts could involve substantial costs. As a result, we are unable to predict the extent of any future profits or losses because we expect to continue to incur substantial operating expenses and, consequently, we will need to generate substantial revenues to maintain or increase profitability.

Challenges and Risks

We anticipate that we will continue to face a number of challenges and risks to our business that may impact our ability to execute on our 2017 business objectives. In particular, we anticipate that for the foreseeable future our ability to generate meaningful revenue to fund our commercial operations and our development and discovery programs is dependent upon the successful commercialization of CABOMETYX for the treatment of advanced RCC in territories where it has been or may be approved. The commercial potential of CABOMETYX for the treatment of advanced RCC remains subject to a variety of factors, most importantly, CABOMETYX's perceived benefit/risk profile as compared to the benefit/risk profiles of other treatments available or currently in development for the treatment of advanced RCC. Our ability to generate meaningful product revenue from CABOMETYX is also affected by a number of other factors, including the extent to which coverage and reimbursement for CABOMETYX is available from government and other third-party payers. Obtaining and maintaining appropriate coverage and reimbursement for CABOMETYX is increasingly challenging due to, among other things, efforts by payors to contain and slow increases in healthcare costs in the U.S. and worldwide, as well as increasing policy interest in the U.S. with respect to controlling pharmaceutical drug pricing practices. Our ability to fulfill the commercial potential of cabozantinib also depends on our ability to expand the compound's use by generating data in clinical development that will support regulatory approval of cabozantinib in additional indications. Our immediate focus in this regard is a potential regulatory approval of our sNDA for cabozantinib for first-line advanced RCC based upon data from CABOSUN. This approval represents a greater challenge than others because CABOSUN was not originally designed as a registrational trial. However, given the positive nature of CABOSUN results, we are planning to submit a sNDA to the FDA. Achievement of our 2017 business objectives will also depend on our ability to adapt our development and commercialization strategy to navigate the increasing prevalence of immunotherapy, which is both a competitive threat and a potential opportunity due to interest in the use of combination therapy to treat cancer. Furthermore, our research and development objectives may be curtailed as a result of operational challenges related to organizational growth as we resume drug discovery activities, and we may be unable to successfully identify appropriate candidates for in-licensing or acquisition.

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

Fiscal Year Convention

We have adopted a 52- or 53-week fiscal year policy that generally ends on the Friday closest to December 31st. Fiscal year 2017 will end on December 29, 2017 and fiscal year 2016 ended on December 30, 2016. For convenience, references in this report as of and for the fiscal periods ended March 31, 2017 and April 1, 2016, and as of and for the fiscal years ended December 29, 2017 and December 30, 2016, are indicated as being as of and for the periods ended March 31, 2017 and March 31, 2016, and the years ended December 31, 2017 and December 31, 2016, respectively.

Results of Operations

Revenues

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

	Three Months Ended March 31,	
	2017	2016
Product revenues:		
Gross product revenues	$ 77,959	$ 10,614
Discounts and allowances	(9,082)	(1,515)
Net product revenues	68,877	9,099
Collaboration revenues:		
License revenues [(1)]	6,192	1,198
Contract revenues [(2)]	2,500	5,000
Royalty and product supply revenues, net	2,186	130
Development cost reimbursements	1,132	—
Total collaboration revenues	12,010	6,328
Total revenues	$ 80,887	$ 15,427
Dollar change	$ 65,460	
Percentage change	424%	

(1) Includes amortization of upfront payments.
(2) Includes milestone payments.

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

	Three Months Ended March 31,	
	2017	2016
CABOMETYX	$ 62,359	$ —
COMETRIQ	6,518	9,099
Net product revenues	$ 68,877	$ 9,099
Dollar change	$ 59,778	
Percentage change	657%	

The increase in net product revenues for the three months ended March 31, 2017, as compared to the comparable period in 2016, was primarily due to 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. The 28% decrease in net product revenues for COMETRIQ for the three months ended March 31, 2017, as compared to the comparable period in 2016, was primarily due to a 24% decrease in the number of COMETRIQ units sold in the U.S., as well as a decrease in units sold related to the termination of our agreement with SOBI, which was partially offset by an increase in the average selling price of the product. The decrease in COMETRIQ sales volume was primarily driven by the adoption of CABOMETYX by our customers.

License revenues for the three months ended March 31, 2017 consisted of the recognition of $4.3 million and $1.9 million of the upfront payments and non-substantive milestone received in 2016 in connection with our collaboration agreements with Ipsen and Takeda, respectively. License revenues during the comparable period in 2016 were $1.2 million and solely related to the collaboration agreement with Ipsen.

Contract revenues for the three months ended March 31, 2017 reflect recognition of the $2.5 million milestone earned from BMS related to the ROR Gamma program. Contract revenues for the comparable period in 2016 reflect a $5.0 million milestone earned from Merck related to its worldwide license of our phosphoinositide-3 kinase-delta program.

Royalty and product supply revenues, net, for the three months ended March 31, 2017 and 2016 primarily consisted of royalties on ex-U.S. net sales of COTELLIC under our collaboration agreement with Genentech for cobimetinib totaling $2.3 million and $0.1 million, respectively.

Development cost reimbursements for the three months ended March 31, 2017 consisted of $0.8 million and $0.3 million of reimbursements pursuant to our collaboration and license agreements with Takeda and Ipsen, respectively. There was no such development cost reimbursements during the comparable period in 2016.

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

	Three Months Ended March 31,	
	2017	2016
Diplomat Specialty Pharmacy	$ 19,850	$ 8,464
Caremark L.L.C.	13,819	—
Affiliates of McKesson Corporation	11,278	—
Accredo Health, Incorporated	9,440	—
Merck	—	5,000
Others, individually less than 10% of total revenues for all periods presented	26,500	1,963
Total revenues	$ 80,887	$ 15,427

We recognize net product revenue net of discounts and allowances that are further described in “Note 1. Organization and Summary of Significant Accounting Policies” to our “Notes to Consolidated Financial Statements” contained in Part II, Item 8 of our Annual Report on Form 10-K filed with the SEC on February 27, 2017. The activities and ending reserve balances for each significant category of discount and allowance were as follows (dollars in thousands):

	Chargebacks and discounts for prompt payment	Other customer credits and co-pay assistance	Rebates	Returns	Total
Balance at December 31, 2016	$ 1,802	$ 794	$ 2,627	$ 351	$ 5,574
Provision related to sales made in:					
Current period	5,461	1,640	2,331	—	9,432
Prior periods	—	—	(350)	—	(350)
Payments and customer credits issued	(5,548)	(1,693)	(1,589)	—	(8,830)
Balance at March 31, 2017	$ 1,715	$ 741	$ 3,019	$ 351	$ 5,826

Chargebacks and discounts for prompt payment are recorded as a reduction of trade receivables and the remaining reserve balances are classified as Other current liabilities in the accompanying Condensed Consolidated Balance Sheets. Amounts presented as of December 31, 2016 have been restated to reflect that classification.

The increase in the reserve balance at March 31, 2017 was primarily the result of an increase in product sales volume. We expect our discounts and allowances as a percentage of gross product revenue to increase during the remainder of 2017 as our business evolves.

Cost of Goods Sold

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

	Three Months Ended March 31,	
	2017	2016
Cost of goods sold	$ 3,203	$ 685
Gross margin	95%	92%

Cost of goods sold is related to our product revenues and consists primarily of a 3% royalty payable to GlaxoSmithKline on net sales of any product incorporating cabozantinib, indirect labor costs, the cost of manufacturing, write-downs related to expiring and excess inventory, and other third party logistics costs. Portions of the manufacturing costs

for inventory were incurred prior to the regulatory approval of CABOMETYX and COMETRIQ and, therefore, were expensed as research and development costs when those costs were incurred, rather than capitalized as inventory. The sale of products containing previously expensed materials resulted in a 10% and 3% reduction in the Cost of goods sold during the three months ended March 31, 2017 and 2016, respectively. As of March 31, 2017, our inventory includes approximately $1.0 million of materials that were previously expensed, are not capitalized, and will not be charged to Costs of goods sold in future periods. Cost of goods sold also includes write-downs related to excess and expiring inventory. Such write-downs were $0.4 million for the three months ended March 31, 2017 and nominal for the comparable period in 2016.

The increase in Cost of goods sold was primarily related to the growth in sales of CABOMETYX due to the commercial launch of CABOMETYX in late April 2016.

Gross margin percentage is net product revenues less cost of goods sold, divided by net product revenues. The increase in gross margin for the three months ended March 31, 2017, as compared to the comparable period in 2016, was related to the change in product mix as CABOMETYX has a lower manufacturing cost than COMETRIQ.

Research and Development Expenses

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

	Three Months Ended March 31,	
	2017	**2016**
Research and development expenses	$ 23,210	$ 28,926
Dollar change	$ (5,716)	
Percentage change	(20)%	

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

The decrease in research and development expenses for the three months ended March 31, 2017, as compared to the comparable period in 2016, was primarily related to clinical trial costs, which includes services performed by third-party contract research organizations and other vendors who support our clinical trials, and stock-based compensation; these decreases were partially offset by an increase in personnel expenses. The decrease in clinical trial costs was $4.4 million for the three months ended March 31, 2017, as compared to the comparable period in 2016. 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 was partially offset by increases in costs related to CABOSUN, a randomized phase 2 trial of cabozantinib in patients with previously untreated advanced RCC with intermediate- or poor-risk disease conducted by The Alliance under our CRADA with NCI-CTEP. Stock-based compensation decreased by $4.1 million for the three months ended March 31, 2017 as compared to the comparable period in 2016, primarily due to the 2016 recognition of stock-based compensation expense pertaining to the performance-based stock-options tied to the acceptance and anticipated approval of our CABOMETYX New Drug Application, or NDA, filing with the FDA and a 2016 bonus to our employees in the form of fully-vested restricted stock units. These decreases were partially offset by personnel expenses which increased by $3.2 million for the three months ended March 31, 2017 as compared to the comparable period in 2016, primarily due to the hiring of medical science liaisons as a result of the launch of CABOMETYX and an increase in the accrual for bonuses.

We are focusing our development and commercialization efforts primarily on cabozantinib to maximize the therapeutic and commercial potential of this compound, and as a result, we expect our near-term research and development expenses to relate to the clinical development of cabozantinib. We expect to continue to incur significant development costs for cabozantinib in future periods as we evaluate its potential in a broad development program comprising approximately 45 ongoing or planned clinical trials across multiple indications. The most notable study of this program is CELESTIAL, our company-sponsored phase 3 trial of cabozantinib in advanced HCC. 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. As a result, we expect our research and development expenses to increase as we continue to develop cabozantinib and our pipeline.

The length of time required for clinical development of a particular product candidate and our development costs for that product candidate may be impacted by the scope and timing of enrollment in clinical trials for the product candidate, our decisions to develop a product candidate for additional indications, and whether we pursue development of the product candidate or a particular indication with a collaborator or independently. For example, cabozantinib is being developed in

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

In any event, our potential therapeutic products are subject to a lengthy and uncertain regulatory process that may not result in receipt of the necessary regulatory approvals. Failure to receive the necessary regulatory approvals would prevent us from commercializing the product candidates affected, including cabozantinib in any additional indications. In addition, clinical trials of our potential product candidates may fail to demonstrate safety and efficacy, which could prevent or significantly delay regulatory approval. A discussion of the risks and uncertainties with respect to our research and development activities, including completing the development of our product candidates, and the consequences to our business, financial position and growth prospects can be found in “Risk Factors” in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Selling, General and Administrative Expenses

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

	Three Months Ended March 31,	
	2017	**2016**
Selling, general and administrative expenses	$ 34,260	$ 34,857
Dollar change	$ (597)	
Percentage change	(2)%	

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

The decrease in selling, general and administrative expenses for the three months ended March 31, 2017, as compared to the comparable period in 2016, was primarily related to decreases in marketing costs and stock-based compensation; those decreases were almost entirely offset by increases in personnel expenses and legal and accounting costs. Marketing costs decreased by $6.7 million for the three months ended March 31, 2017, as compared to the comparable period in 2016, primarily due to a decrease in losses under our collaboration agreement with Genentech. Stock-based compensation decreased by $2.4 million for the three months ended March 31, 2017, as compared to the comparable period in 2016, primarily due to the 2016 recognition of stock-based compensation expense pertaining to the performance-based stock-options tied to the acceptance and anticipated approval of our CABOMETYX NDA filing with the FDA and a 2016 bonus to our employees in the form of fully-vested restricted stock units. Personnel expenses increased by $6.6 million for the three months ended March 31, 2017, as compared to the comparable period in 2016, primarily due to an increase in headcount connected with the build-out of our U.S. commercial organization as a result of the launch of CABOMETYX, as well as an increase in incentive compensation and the accrual for bonuses. Legal and accounting expenses increased by $1.3 million for the three months ended March 31, 2017, as compared to the comparable period in 2016, primarily due to increases in legal costs related to our dispute with Genentech.

Other Expense, Net

Certain historical amounts in Other expense, net have been revised to reflect the correction of the accounting for non-cash interest expense associated with our previously-outstanding 4.25% Convertible Senior Subordinated Notes due 2019, or the 2019 Notes. See “Note 1 - Organization and Summary of Significant Accounting Policies - Correction of an Immaterial Error” in the Notes to the Condensed Consolidated Financial Statements for additional information on the correction.

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

	Three Months Ended March 31,	
	2017	2016
Interest income and other, net	$ 1,068	$ 202
Interest expense	(4,420)	(10,290)
Total other expense, net	$ (3,352)	$ (10,088)
Dollar change	$ 6,736	
Percentage change	(67)%	

Other expense, net consists primarily of interest expense incurred on our debt and interest income earned on our cash and investments.

Interest expense decreased by $5.9 million for the three months ended March 31, 2017, as compared to the comparable period in 2016, primarily due to conversions and the redemption of the 2019 Notes during the third and fourth quarters of 2016. We expect our interest expense will continue to decrease as a result of interest savings from the repayment of the Silicon Valley Bank term loan in March 2017 and the anticipated prepayment of the Secured Convertible Notes due 2018, or the Deerfield Notes, on or about July 1, 2017.

Interest income increased by $0.7 million for the three months ended March 31, 2017, as compared to the comparable period in 2016, primarily due to both an increase in our investment balances and an increase in the yield earned on those investments.

Income Tax Expense

Income tax expense was as follows (dollars in thousands):

	Three Months Ended March 31,	
	2017	2016
Income tax expense	$ 134	$ —

Income tax expense for the three months ended March 31, 2017 primarily relates to state taxes in jurisdictions outside of California, for which we have a limited operating history. Our historical losses are sufficient to fully offset any federal taxable income.

Liquidity and Capital Resources

We have incurred net losses in every fiscal year since our inception, with the exception of the 2011 fiscal year, and as of March 31, 2017, we had an accumulated deficit of $2.0 billion. Although we reported net income of $16.7 million for the three months ended March 31, 2017, we may not be able to maintain or increase profitability on a quarterly or annual basis and we are otherwise unable to accurately predict the extent of long-range future profits or losses. Excluding fiscal 2011 and the three months ended March 31, 2017, 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 during 2017. In addition, we intend to expand our product pipeline through the measured resumption of drug discovery and the evaluation of in-licensing and acquisition opportunities that align with our oncology drug expertise, which efforts could involve substantial costs. As a result, we are unable to predict the extent of any future profits or losses because we expect to continue to incur substantial operating expenses and, consequently, we will need to generate substantial revenues to maintain or increase profitability.

Since the launch of our first commercial product in January 2013, through March 31, 2017, we have generated an aggregate of $278.5 million in net product revenues, including $68.9 million for the three months ended March 31, 2017. Other than sales of CABOMETYX and COMETRIQ, we have derived substantially all of our revenues since inception from collaborative arrangements, including upfront and milestone payments and research funding we earn from any products developed from the collaborative research. The amount of our net profits or losses will depend, in part, on: the level of sales of CABOMETYX and COMETRIQ in the U.S.; achievement of clinical, regulatory and commercial milestones and the amount of royalties, if any, from sales of CABOMETYX and COMETRIQ under 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; the

amount of royalties from COTELLIC sales outside the U.S. under our collaboration with Genentech; other license and contract revenues; and the level of our expenses, including commercialization activities for cabozantinib and any pipeline expansion efforts.

As of March 31, 2017, we had $475.8 million in cash and investments, which included $471.6 million available for operations 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, product revenues and collaboration revenues, will enable us to maintain our operations for a period of at least 12 months following the filing date of this report. The sufficiency of our cash resources depends on numerous assumptions, including assumptions related to product sales and operating expenses, as well as the other factors set forth in "Risk Factors" under the headings "Risks Related to our Capital Requirements and Financial Results," in Part II, Item 1A of this Quarterly Report on Form 10-Q. Our assumptions may prove to be wrong or other factors may adversely affect our business, and as a result we may not have the cash resources to fund our current and future operating plans, which could have a material adverse effect on our business. In addition, we intend to prepay the Deerfield Notes in full on or about July 1, 2017, which will require the use of a substantial portion of our cash resources. Our commitment of cash resources to the prepayment of the Deerfield Notes could limit our ability to fund our current and future operating plans, which in turn could require us to raise additional funds, which we may be unable to do. We may also choose to raise additional funds through the issuance of equity or debt to meet our business objectives.

Sources and Uses of Cash

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

	Three Months Ended March 31,	
	2017	**2016**
Net cash provided by operating activities:		
Net income (loss)	$ 16,700	$ (59,223)
Adjustments to reconcile net income (loss) to net cash used in operating activities	7,831	16,951
Changes in operating assets and liabilities	44,327	199,082
Net cash provided by operating activities	68,858	156,810
Net cash provided by (used in) investing activities	34,503	(19,685)
Net cash used in financing activities	(71,868)	(1,877)
Net increase in cash and cash equivalents	31,493	135,248
Cash and cash equivalents at beginning of period	151,686	141,634
Cash and cash equivalents at end of period	$ 183,179	$ 276,882

Operating Activities

Cash flows provided by operating activities represents the cash receipts and disbursements related to all of our activities other than investing and financing activities. Cash provided by operating activities is derived by adjusting our net income (loss) for: non-cash operating items such as depreciation and amortization, non-cash interest expense and share-based compensation charges; and changes in operating assets and liabilities which reflect timing differences between the receipt and payment of cash associated with transactions and when they are recognized in our Condensed Consolidated Results of Operations. Our operating activities provided cash of $68.9 million for the three months ended March 31, 2017, compared to $156.8 million for the same period in 2016. The decrease in cash provided by operating activities was primarily due to the upfront nonrefundable payment of $200.0 million received from Ipsen in the three months ended March 31, 2016 in consideration for the exclusive license and other rights contained our collaboration and license agreement with Ipsen. That decrease was partially offset by a $59.8 million increase in net product revenues and the upfront nonrefundable payment of $50.0 million received from Takeda in the three months ended March 31, 2017 in consideration for the exclusive license and other rights contained in our collaboration and license agreement with Takeda.

Investing Activities

Our investing activities provided cash of $34.5 million for the three months ended March 31, 2017, compared to $19.7 million of cash used for investing activities during same period in 2016.

Cash provided by investing activities for the three months ended March 31, 2017 was primarily due to cash provided by the maturity of investments of $126.0 million and the sale of investments of $37.3 million, less cash used for investment purchases of $128.0 million.

Cash used in investing activities for the three months ended March 31, 2016 was primarily due to the use of cash for investment purchases of $51.2 million, less cash provided by the maturity of unrestricted and restricted investments of $32.1 million.

Financing Activities

Cash used in financing activities was $71.9 million for the three months ended March 31, 2017, compared to $1.9 million for the same period in 2016.

Cash used in financing activities for the three months ended March 31, 2017 was primarily a result of the full repayment of the $80.0 million outstanding under our term loan with Silicon Valley Bank, partially offset by $9.7 million in proceeds from the exercise of stock options.

Cash used in financing activities for the three months ended March 31, 2016 was primarily related to employees' tax withholding paid to taxing authorities from shares withheld on stock awards.

Over the next 15 months, we are required to make significant payments on the Deerfield Notes. See "Note 5 - Debt" in the Notes to the Condensed Consolidated Financial Statements for a description of those payment obligations. We intend to repay the Deerfield Notes early, on or about July 1, 2017, 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 prepaid 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.

Contractual Obligations

We have contractual obligations in the form of debt, operating leases, purchase obligations and other long-term liabilities. On March 29, 2017, we repaid all amounts outstanding under our term loan with Silicon Valley Bank which was initiated in June 2010 under our loan and security agreement with Silicon Valley Bank. See "Note 5 - Debt" in the accompanying Notes to the Condensed Consolidated Financial Statements for more information on our loan and security agreement with Silicon Valley Bank. There were no other material changes outside of the ordinary course of business in our contractual obligations from those as of December 31, 2016.

Off-Balance Sheet Arrangements

As of March 31, 2017, we did not have any material off-balance-sheet arrangements, as defined by applicable SEC regulations.

Critical Accounting Estimates

The preparation of our Condensed Consolidated Financial Statements conforms to accounting principles generally accepted in the U.S. which requires management to make judgments, estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosures. An accounting policy is considered to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, and if different estimates that reasonably could have been used, or changes in the accounting estimates that are reasonably likely to occur periodically, could materially impact our Condensed Consolidated Financial Statements. On an ongoing basis, management evaluates its estimates including, but not limited to, those related to revenue recognition, including deductions from revenues (such as rebates, chargebacks, sales returns and sales allowances), the period of performance, identification of deliverables and evaluation of milestones with respect to our collaborations, the amounts of revenues and expenses under our profit and loss sharing agreement, recoverability of inventory, certain accrued liabilities including accrued clinical trial liability, and stock-based compensation. We base our estimates on historical experience and on various other market-specific and other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our senior management has discussed the development, selection and disclosure of these estimates with the Audit Committee of our Board of Directors. Actual results could differ materially from those estimates.

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

There have been no significant changes in our critical accounting policies and estimates during the three months ended March 31, 2017, as compared to the critical accounting policies and estimates disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2016 filed with the SEC on February 27, 2017.

Recent Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio and our long-term debt. As of March 31, 2017, a decrease in the interest rates of one percentage point would have had a net positive change in the fair value of interest rate sensitive assets and liabilities of $0.4 million as compared to a net adverse change in the fair value of $(0.3) million as of December 31, 2016.

In addition, we have exposure to fluctuations in certain foreign currencies in countries in which we conduct clinical trials. As of March 31, 2017, and December 31, 2016, approximately $1.9 million and $2.2 million, respectively, of our accrued clinical trial liability was owed in foreign currencies. An adverse change of one percentage point in the foreign currency exchange rates would not have resulted in a material impact as of either of the dates presented. We recorded losses of $0.1 million and $0.2 million relating to foreign exchange fluctuations for three months ended March 31, 2017 and 2016, 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 U.S.

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 Zelboraf® (vemurafenib) and launched by Genentech in the U.S. 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.

On July 13, 2016, Genentech asserted a counterclaim for breach of contract seeking monetary damages and interest related to the cost allocations under the collaboration agreement. On December 29, 2016, Genentech withdrew its counterclaim against us and stated that it would unilaterally change its approach to allocation of promotional expenses arising from commercialization of the COTELLIC plus Zelboraf combination therapy, both retrospectively and prospectively. We believe this revised allocation approach has substantially reduced our exposure to costs associated with promotion of the COTELLIC plus Zelboraf combination in the U.S. Notwithstanding Genentech's change of approach, other significant issues remain in dispute between the parties. Genentech's action does not address the claims in our demand for arbitration related to Genentech's clinical development of cobimetinib, or pricing and promotional costs for COTELLIC in the U.S., nor does it fully resolve claims over revenue allocation. And, Genentech has not clarified how it intends to allocate promotional costs incurred with respect to the promotion of other combination therapies that include cobimetinib for other indications that may be developed or are in development and may be approved. As a result, we will continue to press our position before the arbitral panel to obtain a just resolution of these claims. The ultimate outcome and timing of the arbitration is difficult to predict.

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

Item 1A. Risk Factors

In addition to the factors discussed elsewhere in this report and our other reports filed with the SEC, the following are important factors that could cause actual results or events to differ materially from those contained in any forward-looking statements made by us or on our behalf. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not currently known to us or that we deem immaterial also may impair our business operations. If any of the following risks or such other risks actually occurs, our business could be harmed.

We have marked with an asterisk (*) those risk factors below that reflect substantive changes in risks facing us from the risk factors included in our Annual Report on Form 10-K for the fiscal year ended December 30, 2016 filed with the Securities and Exchange Commission on February 27, 2017.

Risks Related to Our Business and Industry

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

Our mission is to maximize the clinical and commercial potential of cabozantinib and cobimetinib and position Exelixis for future growth through the resumption of our discovery efforts and expansion of our development pipeline. We anticipate that for the foreseeable future our ability to generate meaningful revenue to fund our commercial operations and our development and discovery programs is dependent upon the successful commercialization of CABOMETYX for the

treatment of advanced RCC in territories where it has been or may soon be approved. The commercial potential of CABOMETYX for the treatment of advanced RCC remains subject to a variety of factors, most importantly, CABOMETYX's perceived benefit/risk profile as compared to the benefit/risk profiles of other treatments available or currently in development for the treatment of advanced RCC. If revenue from CABOMETYX decreases, we may need to reduce our operating expenses or raise additional funds to execute our business plan, which would have a material adverse effect on our business and financial condition, results of operations and growth prospects. Furthermore, as a consequence of our exclusive collaboration agreement with Ipsen, we rely heavily upon Ipsen's regulatory, commercial, medical affairs, and other expertise and resources for commercialization of CABOMETYX in territories outside of the U.S. and Japan. If Ipsen is unable to, or does not invest the resources necessary to, successfully commercialize CABOMETYX for the treatment of advanced RCC in the European Union and other international territories where it may be approved, this could reduce the amount of revenue we are due to receive under our collaboration agreement with Ipsen, thus resulting in harm to our business and operations.

We also believe that there are commercial opportunities for cabozantinib in therapeutic indications beyond advanced RCC, and we are dedicating substantial proprietary resources to developing cabozantinib into a potentially broad and significant oncology franchise. Even following the approval of CABOMETYX for the treatment of advanced RCC in the U.S. and European Union, our success remains contingent upon, among other things, successful clinical development, regulatory approval and market acceptance of cabozantinib in additional indications, such as first-line RCC, advanced HCC, non-small cell lung cancer, and other forms of cancer. With the planned second interim analysis from CELESTIAL anticipated in the second half of 2017, and a final analysis, if needed in 2018, we expect growth of the cabozantinib oncology franchise to be most immediately impacted by the clinical trial results of cabozantinib in advanced HCC. However, the historical rate of failures for product candidates in clinical development is high. Should we prove unsuccessful in the further development of cabozantinib beyond MTC or advanced RCC, we may be unable to execute our business plan and our revenues and financial condition would be materially adversely affected.

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

The terms of our collaboration agreement provide Genentech with exclusive authority over the global development and commercialization plans for cobimetinib and the execution of those plans. We have no effective influence over those plans and are heavily dependent on Genentech's decision making. The collaboration agreement provides that we are entitled to a share of U.S. profits and losses received in connection with commercialization of cobimetinib. We are also entitled to low double-digit royalties on ex-U.S. net sales 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. In connection with the commercialization of COTELLIC, we believed 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 in connection with COTELLIC's commercialization in the U.S. Soon thereafter, Genentech asserted a counterclaim for breach of contract seeking monetary damages and interest related to the cost allocations under the collaboration agreement. On December 29, 2016, Genentech withdrew its counterclaim against us and stated that it would unilaterally change its approach to allocation of promotional expenses arising from commercialization of the COTELLIC plus Zelboraf combination therapy, both retrospectively and prospectively. Notwithstanding Genentech's change of approach, other significant issues remain in dispute between the parties. Genentech's action does not address the claims in our demand for arbitration related to Genentech's clinical development of cobimetinib, or pricing and promotional costs for COTELLIC in the U.S., nor does it fully resolve claims over revenue allocation. And, Genentech has not clarified how it intends to allocate promotional costs incurred with respect to the promotion of other combination therapies that include cobimetinib for other indications that may be developed or are in development and may be approved. As a result, we will continue to press our position before the arbitral panel to obtain a just resolution of these claims. The ultimate outcome and timing of the arbitration is difficult to predict.

We are also completely dependent upon Genentech 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. Subject to contractual diligence obligations, Genentech has complete control over and financial responsibility for cobimetinib's development program and regulatory strategy and execution, and we are not able to control the amount or

timing of resources that Genentech will devote to the product. Of particular significance are Genentech's development efforts with respect to the combination of cobimetinib with immuno-oncology agents, a promising and competitive area of clinical research. Regardless of Genentech's efforts and expenditures for the further development of cobimetinib, the results of such additional clinical investigation may not prove positive and may not produce label expansions or approval in additional indications.

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

Our ability to successfully commercialize cabozantinib, as CABOMETYX tablets for advanced RCC and COMETRIQ capsules for MTC is, and if approved for additional indications, will be, highly dependent upon the extent to which cabozantinib gains market acceptance among physicians, patients, health care payers such as Medicare, Medicaid and commercial plans and the medical community. If cabozantinib does not achieve an adequate level of acceptance, we may not generate significant future product revenues. The degree of market acceptance of CABOMETYX, 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 safety of cabozantinib, including the existence of serious side effects of cabozantinib and their severity in comparison to those of any competing products;
- cabozantinib's relative convenience and ease of administration;
- unexpected results connected with analysis of data from future or ongoing clinical trials;
- the timing of cabozantinib label expansions for additional indications, if any, relative to competitive treatments;
- the price of cabozantinib relative to competitive therapies and any new government initiatives affecting pharmaceutical pricing;
- the strength of CABOMETYX sales efforts, marketing, medical affairs and distribution support;
- the sufficiency of commercial and government insurance coverage and reimbursement; and
- our ability to enforce our intellectual property rights with respect to cabozantinib.

If we are unable to maintain or scale adequate sales, marketing, market access and distribution capabilities or enter into or maintain agreements with third parties to do so, we may be unable to maximize product revenues and our business, financial condition, results of operations and prospects may be adversely affected.*

In connection with the FDA's approval of CABOMETYX for the treatment of patients with advanced RCC, we substantially increased our sales, marketing, market access, medical affairs and product distribution capabilities. Establishing and maintaining these capabilities requires significant resources. Such expenses may be disproportionate compared to the revenues we may be able to generate on sales of cabozantinib, which may have an adverse impact on our results of operations. If we cannot maintain effective sales, marketing, market access, medical affairs and product distribution capabilities, we may be unable to maximize the commercial potential of cabozantinib in its approved indications. Also, to the extent that the commercial opportunities for cabozantinib grow over time, we may not properly judge the requisite size and experience of the commercialization teams or the scale of distribution necessary to market and sell cabozantinib successfully. If we are unable to maintain or scale our organization appropriately, we may not be able to maximize product revenues and our business, financial condition, results of operations and prospects may be adversely affected.

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

Our current and anticipated future dependence upon the activities, support, and legal and regulatory compliance, of third parties, may adversely affect our ability to supply cabozantinib to the marketplace on a timely and competitive basis. These third parties may not provide services in the time required to meet our commercial timelines and objectives or to meet regulatory requirements. We may not be able to maintain or renew our arrangements with third parties, or enter into new arrangements, on acceptable terms, or at all. Third parties could terminate or decline to renew our arrangements based on

their own business priorities. If we are unable to contract for these third party services related to the distribution of cabozantinib on acceptable terms, our commercialization efforts may be delayed or otherwise adversely affected, which could have material adverse impact on our business, financial condition, results of operations and prospects.

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

We are subject to certain healthcare laws and regulations and enforcement by the federal government and the states in which we conduct our business. Should our compliance controls prove ineffective at preventing or mitigating the impact of improper conduct, the laws that may affect our ability to operate include, without limitation:

- the federal Anti-Kickback Statute, or AKS, which governs our business activities, including our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities. The AKS prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. Remuneration is not defined in the AKS and has been broadly interpreted to include anything of value, including for example, gifts, discounts, coupons, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. The AKS has been broadly interpreted to apply to manufacturer arrangements with prescribers, purchasers and formulary managers, among others;
- the Food, Drug, and Cosmetic Act, or FDCA, and its regulations, which prohibit, among other things, the introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;
- the Foreign Corrupt Practices Act, a U.S. law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals);
- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- federal and state government price reporting laws that require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on our marketed drugs (participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our products, increased infrastructure costs, and could potentially affect our ability to offer certain marketplace discounts);
- federal and state financial transparency laws, which generally require certain types of expenditures in the U.S. to be tracked and reported (compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships with healthcare providers and healthcare entities, which could potentially have a negative effect on our business and/or increase enforcement scrutiny of our activities); and
- federal and state healthcare fraud and abuse laws, FDA rules and regulations, as well as false claims laws, including the civil False Claims Act, which govern certain marketing practices, including off-label promotion.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we, or our officers or employees, may be subject to penalties, including administrative civil and criminal penalties, damages, fines, regulatory penalties, the curtailment or restructuring of our operations, exclusion from participation in Medicare, Medicaid and other federal and state healthcare programs, reputational harm, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement, any of which would adversely affect our ability to sell our products and operate our business and also adversely affect our financial results. Of particular concern are suits filed under the civil False Claims Act, known as "*qui tam*" actions, which can be brought by any individual on behalf of the government. Such individuals, commonly known as "whistleblowers," may potentially then share in amounts paid by the entity to the government in fines or settlement. The filing of *qui tam* actions has caused a number of pharmaceutical, medical device and other healthcare companies to have to defend civil False Claims Act actions. When an entity is determined to have violated the civil False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

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 the European Union and between countries in the European Union and countries outside of the European Union, including the U.S. Failure to provide adequate privacy protections and maintain compliance with 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 is, and will be, available from third-party payers, including governmental payers, such as Medicare and Medicaid, and private health insurers. Patients may not be capable of paying for CABOMETYX or COMETRIQ themselves and may rely on third-party payers to pay for, or subsidize, the costs of their medications, among other medical costs. If third-party payers do not provide coverage or reimbursement for CABOMETYX or COMETRIQ, our revenues and prospects for profitability will suffer. In addition, even if third-party payers provide some coverage or reimbursement for CABOMETYX or COMETRIQ, the availability of such coverage or reimbursement for prescription drugs under private health insurance and managed care plans, which often varies based on the type of contract or plan purchased, may not be sufficient for patients to afford cabozantinib. There has been negative publicity regarding, and increasing legislative and enforcement interest in the U.S. with respect to, drug pricing and the use of specialty pharmacies, which may result in physicians being less willing to participate in our patient access programs and thereby limit our ability to increase patient access and adoption of cabozantinib. Specifically, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the price of drugs under Medicare, and reform government program reimbursement methodologies for drugs. If future legislation were to impose direct governmental price controls and access restrictions, it could have a significant adverse impact on our business and financial results.

In addition, in some foreign countries, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, price negotiations with governmental authorities can take six to twelve months or longer after marketing authorization is granted for a product, which has the potential to substantially delay broad availability of the product in some of those countries. To obtain reimbursement and/or pricing approval in some countries, we and our collaboration partner, Ipsen, may be required to conduct a 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 license revenues to us.

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

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

In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, or the PPACA. The Budget Resolution is not a law; however, it is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of PPACA. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with responsibilities under PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider legislation to replace elements of PPACA that are repealed. Moreover, certain politicians, including the President, 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 payers. The implementation of cost containment measures or other healthcare reforms may limit our ability to generate revenue or commercialize our current products and/or those for which we may receive regulatory approval in the future.

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

Pricing for pharmaceutical products has come under increasing scrutiny by governments, legislative bodies and enforcement agencies. These activities may result in actions that have the effect of reducing our revenue or harming our business or reputation.

Many companies in our industry have received a governmental request for documents and information relating to drug pricing and patient support programs. We could receive a similar request, which would require us to incur significant expense and result in distraction for our management team. Additionally, to the extent there are findings, or even allegations, of improper conduct on the part of the company, such findings could further harm our business, reputation and/or prospects. It is possible that such inquiries could result in negative publicity or other negative actions that could harm our reputation; changes in our product pricing and distribution strategies; reduced demand for our approved products and/or reduced reimbursement of approved products, including by federal health care programs such as Medicare and Medicaid and state health care programs.

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

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

The pharmaceutical, biopharmaceutical and biotechnology industries are highly diversified and are characterized by rapid technological change. In particular, the area of novel oncology therapies is a rapidly evolving and competitive field. Specifically, the indication of advanced RCC is highly competitive and several novel therapies and combinations of therapies are in advanced stages of clinical development in this indication, and may compete with or displace cabozantinib. We face, and will continue to face, intense competition from biotechnology, biopharmaceutical and pharmaceutical companies, as well as academic research institutions, clinical reference laboratories and government agencies that are pursuing research activities similar to ours. Some of our competitors have entered into collaborations with leading companies within our target markets, including some of our existing collaborators. Some of our competitors are further along in the development of their products than we are. Delays in the development of cabozantinib or cobimetinib for the treatment of additional tumor types, for example, could allow our competitors to bring products to market before us. Our future success will depend upon our ability to maintain a competitive position with respect to technological advances and the shifting landscape of therapeutic strategy following the advent of immunotherapy. Our products may become less marketable if we are unable to successfully adapt our development strategy to address the likelihood that this new approach to treating cancer with immuno-oncology agents will become prevalent in indications for which our products are approved, most notably advanced RCC, and in additional indications where we may seek regulatory approval. Furthermore, the complexities of such a strategy has and may continue to require collaboration with some of our competitors.

The markets for which we intend to pursue regulatory approval of cabozantinib and for which Roche and Genentech intend to pursue regulatory approval for cobimetinib are highly competitive. Further, our competitors may be more effective at using their technologies to develop commercial products. Many of the organizations competing with us have greater capital resources, larger research and development staff and facilities, more experience in obtaining regulatory approvals and more extensive product manufacturing and commercial capabilities than we do. As a result, our competitors may be able to more easily develop technologies and products that would render our technologies and products, and those of our collaborators, obsolete and noncompetitive. There may also be drug candidates of which we are not aware at an earlier stage of development that may compete with cabozantinib, cobimetinib, and our other product candidates.

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

Under the FDCA, the FDA can approve an Abbreviated New Drug Application, or ANDA, for a generic version of a branded drug without the applicant undertaking the human clinical testing necessary to obtain approval to market a new drug. The FDA can also approve a 505(b)(2) NDA that relies on the agency's findings of safety and/or effectiveness for a previously approved drug. The filing of an ANDA or 505(b)(2) NDA with respect to cabozantinib could have an adverse impact on our stock price. Moreover, if any such ANDAs or 505(b)(2) NDAs were to be approved and the patents covering cabozantinib were not upheld in litigation, or if a generic competitor is found not to infringe these patents, the resulting generic competition would negatively affect our business, financial condition and results of operations. In this regard, generic equivalents, which must meet the same quality standards as the branded drugs, would be significantly less costly than ours to bring to market. Companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, regardless of the regulatory approval pathway, after the introduction of a generic competitor, a significant percentage of the sales of any branded product are typically lost to the generic product.

Clinical testing of product candidates is a lengthy, costly, complex and uncertain process and may fail to demonstrate safety and efficacy.

Clinical trials are inherently risky and may reveal that a product candidate, even if it is approved for other indications, is ineffective or has an unacceptable safety profile that may significantly decrease the likelihood of regulatory approval in a new indication. For example, COMET-1 and COMET-2, our two phase 3 pivotal trials of cabozantinib in metastatic castration-resistant prostate cancer, or mCRPC, failed to meet their respective primary endpoints of 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 our product candidates based on existing knowledge of our compounds in development and industry metrics, we may not be able to meet those timelines.

We may experience numerous unforeseen events, during or as a result of clinical testing, that could delay or prevent commercialization of our product candidates, including:

- lack of efficacy or harmful side effects;
- negative or inconclusive clinical trial results may require us to conduct further testing or to abandon projects that we had expected to be promising;
- our competitors may discover or commercialize other compounds or therapies that show significantly improved safety or efficacy compared to our product candidates;
- our inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs;
- patient registration or enrollment in our clinical testing may be lower than we anticipate, resulting in the delay or cancellation of clinical testing;
- failure of our third-party contract research organization or investigators to satisfy their contractual obligations, including deviating from trial protocol; and
- regulators or institutional review boards may withhold authorization to commence or conduct clinical trials of a product candidate, or delay, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or their determination that participating patients are being exposed to unacceptable health risks.

If we were to have significant delays in or termination of our clinical testing of our product candidates as a result of any of the events described above or otherwise, our expenses could increase and our ability to generate revenues could be impaired, either of which could adversely impact our financial results.

We may not be able to rapidly or effectively continue the further development of our product candidates or meet current or future requirements of the FDA or regulatory authorities in other jurisdictions, including those identified based on our discussions with the FDA or such other regulatory authorities. Our planned clinical trials may not begin on time, or at all, may not be completed on schedule, or at all, may not be sufficient for registration of our product candidates or may not result in an approvable product.

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

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

Any delay could limit our ability to generate revenues, cause us to incur additional expense and cause the market price of our common stock to decline significantly. Our partners under our collaboration agreements may experience similar risks with respect to the compounds we have out-licensed to them. If any of the events described above were to occur with such programs or compounds, the likelihood of receipt of milestones and royalties under such collaboration agreements could decrease.

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

The activities associated with the research, development and commercialization of our products and product candidates, are subject to extensive regulation by the FDA and other regulatory agencies in the U.S. and by comparable authorities in other countries. We have only limited experience in preparing and filing the applications necessary to gain regulatory approvals. The process of obtaining regulatory approvals in the U.S. and other foreign jurisdictions is expensive, and often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidates involved. For example, before an NDA or sNDA can be submitted to the FDA, or a marketing authorization application to the European Medicines Agency or any application or submission to regulatory authorities in other jurisdictions, the product candidate must undergo extensive clinical trials, which can take many years and require substantial expenditures.

Any clinical trial may fail to produce results satisfactory to the FDA or regulatory authorities in other jurisdictions. For example, the FDA could determine that the design of a clinical trial is inadequate to produce reliable results. The regulatory process also requires preclinical testing, and data obtained from preclinical and clinical activities are susceptible to varying interpretations. The FDA has substantial discretion in the approval process and may refuse to approve any NDA or decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. For example, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of cabozantinib for any individual, additional indications.

In addition, delays or rejections may be encountered based upon changes in regulatory policy for product approval during the period of product development and regulatory agency review, which may cause delays in the approval or rejection of an application for our product candidates.

Even if the FDA or a comparable authority in another jurisdiction approves cabozantinib for one or more indications beyond advanced RCC and MTC, or one of our other product candidates, the approval may be limited, imposing significant restrictions on the indicated uses, conditions for use, labeling, distribution, advertising, promotion, marketing and/or production of the product and could impose ongoing requirements for post-approval studies, including additional research and development and clinical trials. For example, in connection with the FDA's approval of COMETRIQ for the treatment of progressive, metastatic MTC, we are subject to post-marketing requirement to conduct a clinical study comparing a lower dose of cabozantinib to the approved dose of 140 mg daily cabozantinib in progressive, metastatic MTC. Failure to complete any post-marketing requirements in accordance with the timelines and conditions set forth by the FDA could significantly increase costs or delay, limit or eliminate the commercialization of cabozantinib. Further, these agencies may also impose various administrative, civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval.

We may be unable to expand our development pipeline, which could limit our growth and revenue potential.

We are committed to the discovery, development and promotion of new medicines with the potential to improve care and outcomes for people with cancer. In this regard, we have resumed internal drug discovery efforts with the goal of identifying new product candidates to advance into clinical trials. Internal discovery efforts to identify new product candidates require substantial technical, financial and human resources. These internal discovery efforts may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including the research methodology used may not be successful in identifying potential product candidates, or potential product candidates may, on further study, be shown to have inadequate efficacy, harmful side effects, suboptimal pharmaceutical profile or other characteristics suggesting that they are unlikely to be effective products. Apart from our internal discovery efforts, our strategy to expand our development pipeline is also dependent on our ability to successfully identify and acquire or in-license relevant product candidates. However, the in-licensing and acquisition of product candidates is a competitive area, and many other companies are pursuing the same or similar product candidates to those that we may consider attractive. Established companies, in particular, may have a competitive advantage over us due to their size, financial resources and more extensive clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We may also be unable to in-license or acquire a relevant product candidate on acceptable terms that would allow us to realize an appropriate return on our investment. If we are unable to develop suitable product candidates through internal discovery effort or if we are unable to successfully obtain rights to suitable product candidates, our business, financial condition and prospects for growth could suffer. Even if we succeed in our efforts to obtain rights to suitable product candidates, the competitive business environment may result in higher acquisition or licensing costs.

With respect to acquisitions, we may not be able to integrate the target company successfully into our existing business, maintain the key business relationships of the target, or retain key personnel of an acquired business. Furthermore, we could assume unknown or contingent liabilities or incur unanticipated expenses. Any acquisitions or investments made by us also could result in our spending significant amounts, issuing dilutive securities, assuming or incurring significant debt obligations and contingent liabilities, incurring large one-time expenses and acquiring intangible assets that could result in significant future amortization expense and significant write-offs, any of which could harm our operating results.

Risks Related to Our Capital Requirements and Financial Results

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

As of March 31, 2017, we had $475.8 million in cash and investments, which included $471.6 million available for operations and $4.2 million of long-term restricted investments. Our business operations grew substantially during 2016 and experienced further development during the three months ended March 31, 2017. In order to maintain business growth and maximize the clinical and commercial opportunities for cabozantinib and cobimetinib, we plan to continue to execute on the U.S. launch of CABOMETYX, while reinvesting in our product pipeline through the continued development of cabozantinib, continued research and development activities, as well as through in-licensing and acquisition efforts. Our ability to execute on these business objectives will depend on many factors including but not limited to:

- the commercial success of both CABOMETYX and COMETRIQ and the revenues we generate from those approved products;
- costs associated with maintaining our expanded sales, marketing, medical affairs and distribution capabilities for CABOMETYX in advanced RCC and COMETRIQ in the approved MTC indications;
- the achievement of stated regulatory and commercial milestones under 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 against Genentech in which we have asserted claims related to Genentech's clinical development, pricing and commercialization of COTELLIC, and cost and revenue allocations arising from COTELLIC's commercialization in the U.S.;
- the potential regulatory approval of cabozantinib as a treatment for previously untreated advanced RCC and in other indications, both in the U.S. and abroad;
- future clinical trial results, notably the results from CELESTIAL, our phase 3 pivotal trial in patients with advanced HCC;
- our future investments in the expansion of our pipeline through drug discovery and corporate development activities;
- 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 U.S. and abroad, especially in the European Union;
- scientific developments in the market for oncologic therapeutics and the timing of regulatory approvals for competing oncologic therapies; and
- the filing, maintenance, prosecution, defense and enforcement of patent claims and other intellectual property rights.

Our commitment of cash resources to CABOMETYX and the reinvestment in our product pipeline through the continued development of cabozantinib, continued research and development activities as well as through in-licensing and acquisition efforts, could require us to obtain additional capital. In addition, we intend to prepay the Deerfield Notes in full on or about July 1, 2017, which will require the use of a substantial portion of our cash resources. Our commitment of cash resources to the prepayment of the Deerfield Notes could limit our ability to fund our current and future operating plans, which in turn could require us to raise additional funds. We may seek additional capital through some or all of the following methods: corporate collaborations, licensing arrangements, and public or private debt or equity financings. We do not know whether additional capital will be available when needed, or that, if available, we will obtain additional capital on terms favorable to us or our stockholders. If we are unable to raise additional funds when we need them, we may be required to limit the expansion of our product development programs or commercialization efforts, which could have a material adverse affect on our business and growth prospects.

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

We have incurred net losses in every fiscal year since our inception, with the exception of the 2011 fiscal year, and as of March 31, 2017, we had an accumulated deficit of $2.0 billion. Although we reported net income of $16.7 million for the three months ended March 31, 2017, we may not be able to maintain or increase profitability on a quarterly or annual basis and we are otherwise unable to accurately predict the extent of long-range future profits or losses. Excluding fiscal 2011 and the three months ended March 31, 2017, 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 during 2017. In addition, we intend to expand our product pipeline through the measured resumption of drug discovery and the evaluation of in-licensing and acquisition opportunities that align with our oncology drug expertise, which efforts could involve substantial costs. As a result, we are unable to predict the extent of any future profits or losses because we expect to continue to incur substantial operating expenses and, consequently, we will need to generate substantial revenues to maintain or increase profitability.

Since the launch of our first commercial product in January 2013, through March 31, 2017, we have generated an aggregate of $278.5 million in net product revenues, including $68.9 million for the three months ended March 31, 2017. Other than sales of CABOMETYX and COMETRIQ, we have derived substantially all of our revenues since inception from collaborative arrangements, including upfront and milestone payments and research funding we earn from any products developed from the collaborative research. The amount of our net profits or losses will depend, in part, on: the level of sales of CABOMETYX and COMETRIQ in the U.S.; achievement of clinical, regulatory and commercial milestones and the amount of royalties, if any, from sales of CABOMETYX and COMETRIQ under our collaboration agreements with Ipsen and Takeda; our share of the net profits and losses for the commercialization of COTELLIC in the U.S. under our collaboration with Genentech; the amount of royalties from COTELLIC sales outside the U.S. under our collaboration with Genentech; other license and contract revenues; and the level of our expenses, including commercialization activities for cabozantinib and any pipeline expansion efforts.

Our current and any potential future 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.*

As of March 31, 2017, our total indebtedness was $113.9 million, which consisted of the Deerfield Notes which we intend to prepay in full on or about July 1, 2017. 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 current and any potential future indebtedness could have significant negative consequences for our business, results of operations and financial condition, including:

- increasing our vulnerability to adverse economic and industry conditions;
- 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; and
- placing us at a possible competitive disadvantage with less leveraged competitors and competitors that may have better access to capital resources.

The prepayment of the Deerfield Notes will require the use of a substantial portion of our cash resources and while we intend to prepay the Deerfield Notes on or about July 1, 2017, 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 complete such planned early repayment 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 planned early repayments, or if we fail to comply with the various covenants imposed under the terms of the Deerfield Notes, or any indebtedness which we may incur in the future, we would be in default, which would permit the holders of the Deerfield Notes or other future indebtedness to accelerate the maturity of such indebtedness. Any default under the Deerfield Notes, or any indebtedness that we may incur in the future could have a material adverse effect on our business, results of operations and financial condition.

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 March 31, 2017, no assurance can be given that a deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or investments or our ability to meet our financing objectives.

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

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

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

In addition, future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our financial position or results of operations. New pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future and as a result we may be required to make changes in our accounting policies. Those changes could adversely affect our reported revenues and expenses, prospects for profitability or financial position. For example, in May 2014, the Financial Accounting Standards Board issued an Accounting Standards Update entitled Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, or ASU 2014-09, which will replace existing revenue recognition guidance in U.S. generally accepted accounting pronouncements when it becomes effective for us in the first quarter of fiscal year 2018. We do not expect that ASU 2014-09 will have a material impact on the recognition of revenue from product sales. However, we are still in the process of evaluating the effect that this guidance will have on revenue recognition from our collaboration and license agreements, such as our arrangements with Ipsen, Takeda and Genentech. In any event, we will continue to evaluate the impact of the new standard on all of our revenues, including those mentioned above, and our preliminary assessments may change in the future based on our continuing evaluation. The application of existing or future financial accounting standards, particularly those relating to the way we account for revenues and costs, could have a significant impact on our reported results.

Risks Related to Our Relationships with Third Parties

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

We have established collaborations with leading pharmaceutical and biotechnology companies, including, Ipsen, Takeda, Genentech, Daiichi Sankyo, Merck (known as MSD outside of the U.S. and Canada), BMS and Sanofi for the development and ultimate commercialization of certain compounds generated from our research and development efforts. Our dependence on our relationships with existing collaborators for the development and commercialization of compounds under the collaborations subjects us to, and our dependence on future collaborators for development and commercialization of additional compounds will subject us to, a number of risks, including:

- we are not able to control the amount and timing of resources that our collaborators or potential future collaborators will devote to the development or commercialization of drug candidates or to their marketing and distribution;
- we are not able to control the U.S. commercial resourcing decisions made and resulting costs incurred by Genentech for cobimetinib, which costs we are obligated to share, in part, under our collaboration agreement with Genentech;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a drug candidate, repeat or conduct new clinical trials or require a new formulation of a drug candidate for clinical testing;
- disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization of our drug candidates, or that diminish or delay receipt of the economic benefits we are entitled to receive under the collaboration, or that result in costly litigation or arbitration that diverts management's attention and resources;
- collaborators may experience financial difficulties;
- collaborators may not be successful in their efforts to obtain regulatory approvals in a timely manner, or at all;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- collaborators may not comply with applicable healthcare regulatory laws;
- business combinations or significant changes in a collaborator's business strategy may adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- a collaborator could independently move forward with a competing drug candidate developed either independently or in collaboration with others, including our competitors;
- we may be precluded from entering into additional collaboration arrangements with other parties in an area or field of exclusivity;
- future collaborators may require us to relinquish some important rights, such as marketing and distribution rights; and
- collaborations may be terminated or allowed to expire, which would delay, and may increase the cost of development of our drug candidates.

If any of these risks materialize, we may not receive collaboration revenue or otherwise realize anticipated benefits from such collaborations, our product development efforts could be delayed and our business, operating results and financial condition could be adversely affected.

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

We do not have the ability to conduct clinical trials for cabozantinib independently, including our post-marketing commitments in connection with the approvals of CABOMETYX in advanced RCC and COMETRIQ in progressive, metastatic MTC, so we rely on independent third parties for the performance of these trials, such as the U.S. federal government (including NCI-CTEP, a department of the National Institutes of Health, with whom we have our CRADA), third-party contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties must be replaced or if the quality or accuracy of the data they generate or provide is

compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for or commercialize cabozantinib for additional indications beyond the advanced RCC and MTC.

We lack the manufacturing capabilities necessary for us to produce cabozantinib for clinical development or for commercial sale and rely on third parties to do so, which subjects us to various risks.

We do not own or operate manufacturing or distribution facilities for clinical or commercial production and distribution of CABOMETYX and COMETRIQ. Instead, we have multiple contractual agreements in place with third party contract manufacturing organizations who, on our behalf, manufacture clinical and commercial supplies of CABOMETYX and COMETRIQ, and will continue to do so for the foreseeable future. To establish and manage this supply chain requires a significant financial commitment, the creation of numerous third-party contractual relationships and continued oversight of these third parties. Although we maintain significant resources to directly oversee the activities and relationships with companies in our supply chain effectively, we do not have direct control over their operations. Our third party manufacturers may not be able to produce material on a timely basis or manufacture material with the required quality standards, or in the quantity required to meet our development and commercial needs and applicable regulatory requirements. Additionally, as part of our collaboration with Ipsen, we are responsible for the manufacturing and supply of finished, labeled cabozantinib products to Ipsen and Takeda. Failure to meet our supply obligations under the collaboration could impair Ipsen's ability to successfully commercialize cabozantinib and reduce revenues to which we are entitled under the collaboration.

If our third party contract manufacturers and suppliers do not continue to supply us with our products or product candidates in a timely fashion and in compliance with applicable quality and regulatory requirements, or otherwise fail or refuse to comply with their obligations to us under our supply and manufacturing arrangements, we may not have adequate remedies for any breach, and their failure to supply us could impair or preclude our ability to meet our and/or Ipsen's commercial needs, or our supply needs for clinical trials.

Risks Related to Our Intellectual Property

Data breaches and cyber-attacks could compromise our intellectual property or other sensitive information and cause significant damage to our business and reputation.

In the ordinary course of our business, we collect, maintain and transmit sensitive data on our networks and systems, including our intellectual property and proprietary or confidential business information (such as research data and personal information) and confidential information with respect to our customers, clinical trial patients and our business partners. We have also outsourced significant elements of our information technology infrastructure and, as a result, third parties may or could have access to our confidential information. The secure maintenance of this information is critical to our business and reputation. We believe that companies have been increasingly subject to a wide variety of security incidents, cyber-attacks and other attempts to gain unauthorized access. These threats can come from a variety of sources, ranging in sophistication from an individual hacker to a state-sponsored attack and motive (including corporate espionage). Cyber threats may be generic, or they may be custom-crafted against our information systems. Cyber-attacks continue to become more prevalent and much harder to detect and defend against. Our network and storage applications and those of our vendors may be subject to unauthorized access by hackers or breached due to operator error, malfeasance or other system disruptions. It is often difficult to anticipate or immediately detect such incidents and the damage caused by such incidents. These data breaches and any unauthorized access or disclosure of our information or intellectual property could compromise our intellectual property and expose sensitive business information. A data security breach could also lead to public exposure of personal information of our clinical trial patients, customers and others. Cyber-attacks could cause us to incur significant remediation costs, result in product development delays, disrupt key business operations and divert attention of management and key information technology resources. Our network security and data recovery measures and those of our vendors may not be adequate to protect against such security breaches and disruptions. These incidents could also subject us to liability, expose us to significant expense and cause significant harm to our reputation and business.

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

Our success will depend in part upon our ability to obtain patents and maintain adequate protection of the intellectual property related to our technologies and products. The patent positions of biopharmaceutical companies, including our patent position, are generally uncertain and involve complex legal and factual questions. We will be able to protect our intellectual property rights from unauthorized use by third parties only to the extent that our technologies are

covered by valid and enforceable patents or are effectively maintained as trade secrets. We will continue to apply for patents covering our technologies and products as, where and when we deem appropriate. However, these applications may be challenged or may fail to result in issued patents. Our issued patents have been and may in the future be challenged by third parties as invalid or unenforceable under U.S. or foreign laws, or they may be infringed by third parties. As a result, we are from time to time involved in the defense and enforcement of our patents or other intellectual property rights in a court of law, U.S. Patent and Trademark Office inter partes review or reexamination proceeding, foreign opposition proceeding or related legal and administrative proceeding in the U.S. and elsewhere. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings and litigation may be substantial and the outcome can be uncertain. An adverse outcome may allow third parties to use our intellectual property without a license and negatively impact our business.

In addition, because patent applications can take many years to issue, third parties may have pending applications, unknown to us, which may later result in issued patents that cover the production, manufacture, commercialization or use of our product candidates. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Furthermore, others may independently develop similar or alternative technologies or design around our patents. In addition, our patents may be challenged or invalidated or may fail to provide us with any competitive advantages, if, for example, others were the first to invent or to file patent applications for closely related inventions.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the U.S., and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, the patent owner has failed to “work” the invention in that country or the third party has patented improvements). In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. Compulsory licensing of life-saving drugs is also becoming increasingly popular in developing countries either through direct legislation or international initiatives. Such compulsory licenses could be extended to include our products or product candidates, which could limit our potential revenue opportunities. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patent and other intellectual property protection, which makes it difficult to stop infringement. We rely on trade secret protection for some of our confidential and proprietary information. We have taken security measures to protect our proprietary information and trade secrets, but these measures may not provide adequate protection. While we seek to protect our proprietary information by entering into confidentiality agreements with employees, collaborators and consultants, we cannot assure you that our proprietary information will not be disclosed, or that we can meaningfully protect our trade secrets. In addition, our competitors may independently develop substantially equivalent proprietary information or may otherwise gain access to our trade secrets.

Litigation or third-party claims of intellectual property infringement could require us to spend substantial time and money and adversely affect our ability to develop and commercialize products.

Our commercial success depends in part upon our ability to avoid infringing patents and proprietary rights of third parties and not to breach any licenses that we have entered into with regard to our technologies and the technologies of third parties. Other parties have filed, and in the future are likely to file, patent applications covering products and technologies that we have developed or intend to develop. If patents covering technologies required by our operations are issued to others, we may have to obtain licenses from third parties, which may not be available on commercially reasonable terms, or at all, and may require us to pay substantial royalties, grant a cross-license to some of our patents to another patent holder or redesign the formulation of a product candidate so that we do not infringe third-party patents, which may be impossible to obtain or could require substantial time and expense. Third parties may accuse us of employing their proprietary technology without authorization. In addition, third parties may obtain patents that relate to our technologies and claim that use of such technologies infringes on their patents. Regardless of their merit, such claims could require us to incur substantial costs, including the diversion of management and technical personnel, in defending ourselves against any such claims or enforcing our patents. In the event that a successful claim of infringement is brought against us, we may be required to pay damages and obtain one or more licenses from third parties. We may not be able to obtain these licenses at a reasonable cost, or at all. Defense of any lawsuit or failure to obtain any of these licenses could adversely affect our ability to develop and commercialize products.

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

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

Risks Related to Employees and Location

If we are unable to manage our growth, our business, financial condition, results of operations and prospects may be adversely affected.

We have experienced and expect to continue to experience growth in the number of our employees and in the scope of our operations. This growth places significant demands on our management, operational and financial resources, and our current and planned personnel, systems, procedures and controls may not be adequate to support our growth. To effectively manage our growth, we must continue to improve existing, and implement new, operational and financial systems, procedures and controls and must expand, train and manage our growing employee base, and there can be no assurance that we will effectively manage our growth without experiencing operating inefficiencies or control deficiencies. We expect that we may need to increase our management personnel to oversee our expanding operations, and recruiting and retaining qualified individuals is difficult. In addition, the physical expansion of our operations may lead to significant costs and may divert our management and capital resources. If we are unable to manage our growth effectively, or are unsuccessful in recruiting qualified management personnel, our business, financial condition, results of operations and prospects may be adversely affected.

The loss of key personnel or the inability to retain and, where necessary, attract additional personnel could impair our ability to operate and expand our operations.

We are highly dependent upon the principal members of our management, as well as clinical, commercial and scientific staff, the loss of whose services might adversely impact the achievement of our objectives. Also, we may not have sufficient personnel to execute our business plan. Retaining and, where necessary, recruiting qualified clinical, commercial and scientific personnel will be critical to support activities related to advancing the development program for cabozantinib and our other compounds, successfully executing upon our commercialization plan for cabozantinib and our internal proprietary research and development efforts. Competition is intense for experienced clinical, commercial and scientific personnel, and we may be unable to retain or recruit such personnel with the expertise or experience necessary to allow us to successfully develop and commercialize our products. Further, all of our employees are employed "at will" and, therefore, may leave our employment at any time.

Our collaborations with outside scientists may be subject to restriction and change.

We work with scientific and clinical advisors and collaborators at academic and other institutions that assist us in our research and development efforts. These advisors and collaborators are not our employees and may have other commitments that limit their availability to us. Although these advisors and collaborators generally agree not to do competing work, if a conflict of interest between their work for us and their work for another entity arises, we may lose their services. In such a circumstance, we may lose work performed by them, and our development efforts with respect to the matters on which they were working may be significantly delayed or otherwise adversely affected. In addition, although our advisors and collaborators sign agreements not to disclose our confidential information, it is possible that valuable proprietary knowledge may become publicly known through them.

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

Our headquarters are located in 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

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 sales, marketing, medical affairs and distribution capabilities for CABOMETYX, COMETRIQ and COTELLIC;
- our ability to obtain regulatory approval for cabozantinib as a treatment of first-line advanced RCC;
- the achievement of stated regulatory and commercial milestones, under our collaboration with Ipsen;
- the outcome of our arbitration against Genentech in which we have asserted claims related to Genentech's clinical development, pricing and commercialization of COTELLIC, and cost and revenue allocations arising from COTELLIC's commercialization in the U.S.;
- 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;
- our future investments in the expansion of our pipeline through drug discovery and corporate development activities;
- the inability to obtain adequate product supply for any approved drug product or inability to do so at acceptable prices;
- recognition of upfront licensing or other fees or revenues;
- payments of non-refundable upfront or licensing fees, or payment for cost-sharing expenses, to third parties;
- the introduction of new technologies or products by our competitors;
- the timing and willingness of collaborators to further develop or, if approved, commercialize our product candidates out-licensed to them;
- the termination or non-renewal of existing collaborations or third party vendor relationships;
- regulatory actions with respect to our product candidates and any approved products or our competitors' products;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- the timing and amount of expenses incurred for clinical development and manufacturing of cabozantinib;
- adjustments to expenses accrued in prior periods based on management's estimates after the actual level of activity relating to such expenses becomes more certain;
- the impairment of acquired goodwill and other assets;
- additions and departures of key personnel;
- general and industry-specific economic conditions that may affect our or our collaborators' research and development expenditures; and
- other factors described in this "Risk Factors" section.

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

Our stock price may be extremely volatile.

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

- adverse results or delays in our or our collaborators' clinical trials;
- the announcement of FDA approval or non-approval, or delays in the FDA review process, of cabozantinib or our collaborators' product candidates or those of our competitors or actions taken by regulatory agencies with respect to our, our collaborators' or our competitors' clinical trials;
- the commercial success of both CABOMETYX and COMETRIQ and the revenues we generate from those approved products;

- the timing of achievement of our clinical, regulatory, partnering and other milestones, such as the commencement of clinical development, the completion of a clinical trial, the filing for regulatory approval or the establishment of collaborative arrangements for cabozantinib or any of our other programs or compounds;
- actions taken by regulatory agencies with respect to cabozantinib or our clinical trials for cabozantinib;
- the announcement of new products by our competitors;
- quarterly variations in our or our competitors' results of operations;
- developments in our relationships with our collaborators, including the termination or modification of our agreements;
- the announcement of an in-licensed product candidate or strategic acquisition;
- 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;
- the satisfaction of outstanding debt obligations or entry into new financing arrangements;
- developments in the biotechnology, biopharmaceutical or pharmaceutical industry;
- sales of large blocks of our common stock or sales of our common stock by our executive officers, directors and significant stockholders;
- departures of key personnel or board members;
- FDA or international regulatory actions;
- third-party coverage and reimbursement policies;
- disposition of any of our technologies or compounds; and
- general market, economic and political conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

These factors, as well as general economic, political and market conditions, may materially adversely affect the market price of our common stock. In addition, the stock markets in general, and the markets for biotechnology and pharmaceutical stocks in particular, have historically experienced significant volatility that has often been unrelated or disproportionate to the operating performance of particular companies. For example, negative publicity regarding drug pricing and price increases by pharmaceutical companies has negatively impacted, and may continue to negatively impact, the markets for biotechnology and pharmaceutical stocks. Likewise, as a result of the United Kingdom's pending withdrawal from the European Union and/or significant changes in U.S. social, political, regulatory and economic conditions or in laws and policies governing foreign trade and health care spending and delivery, including the potential repeal and/or replacement of all or portions of PPACA or greater restrictions on free trade stemming from Trump Administration policies, the financial markets could experience significant volatility that could also negatively impact the markets for biotechnology and pharmaceutical stocks. These broad market fluctuations have adversely affected and may in the future adversely affect the trading price of our common stock. Excessive volatility may continue for an extended period of time following the date of this report.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. A securities class action suit against us could result in substantial costs and divert management's attention and resources, which could have a material and adverse effect on our business.

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

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

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

While we intend to prepay the Deerfield Notes on or about July 1, 2017, to the extent the Deerfield Notes remain outstanding, certain provisions applicable to 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 Major Transaction under the note purchase agreement governing the Deerfield Notes, holders of the Deerfield Notes will have the right to require us to purchase their notes in cash. In this case, and in other cases, our obligations under 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, 2016, that an ownership change, as defined under Section 382, had not occurred. However, if there is an ownership change under Section 382 of the Code in the future, we may not be able to utilize a material portion of our net operating losses, or NOLs. Furthermore, our ability to utilize our NOLs, other than the NOLs expected to be utilized to offset income in 2017, is conditioned upon our attaining profitability and generating U.S. federal taxable income. We have incurred significant cumulative operating losses since our inception; thus, we do not know whether or when we will generate the U.S. federal taxable income necessary to utilize our remaining NOLs. A full valuation allowance has been provided for the entire amount of our remaining NOLs.

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

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.

May 1, 2017	/s/ CHRISTOPHER J. SENNER
Date	**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	
10.1*	Collaboration and License Agreement dated January 30, 2017, between Exelixis, Inc. and Takeda Pharmaceutical Company Limited					X
10.2*	Clinical Trial Collaboration Agreement dated February 24, 2017, by and between Exelixis, Inc. and Bristol-Myers Squibb Company					X
10.3*	Supplement to the Clinical Trial Collaboration Agreement dated February 24, 2017, by and between Exelixis, Inc., Bristol-Myers Squibb Company and Ipsen Pharma SAS					X
10.4	Non-Employee Director Equity Compensation Policy under the Exelixis, Inc. 2014 Equity Incentive Plan	10-K	000-30235	10.17	2/27/2017	
10.5	Compensation Information for Non-Employee Directors	10-K	000-30235	10.29	2/27/2017	

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

* Confidential treatment requested for certain portions of this exhibit.

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

Exhibit 10.1

COLLABORATION AND LICENSE AGREEMENT

THIS COLLABORATION AND LICENSE AGREEMENT (the "**Agreement**") is entered into as of January 30, 2017 (the "**Effective Date**"), by and between **EXELIXIS, INC.**, a Delaware company having an address at 210 East Grand Avenue, South San Francisco, CA 94080, USA ("**Exelixis**") and Takeda Pharmaceutical Company Limited, a Japanese corporation with principal offices located at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, JAPAN ("**Collaborator**"). Exelixis and Collaborator may be referred to herein individually as a "**Party**" or collectively as the "**Parties**".

RECITALS

WHEREAS, Exelixis, a biopharmaceutical company, is developing its proprietary compound known as cabozantinib for the treatment of cancer, and owns or controls certain patents, know-how, and other intellectual property relating to such compound;

WHEREAS, Collaborator, a pharmaceutical company, possesses substantial resources and expertise in the development and commercialization of pharmaceutical products;

WHEREAS, Collaborator and Exelixis desire to form a collaboration for the continued development and commercialization of cabozantinib, under which Exelixis will continue to have primary responsibility for the conduct of the global development program for cabozantinib, with Collaborator providing input and support; and Exelixis desires to obtain Collaborator's specific Japanese clinical development expertise in order for Exelixis and Collaborator to collaborate and pursue such development in Japan as the Parties agree;

WHEREAS, Collaborator desires to obtain the exclusive rights to develop and commercialize cabozantinib in Japan and to have primary responsibility for the commercialization of cabozantinib in Japan; and, Exelixis desires to manufacture and supply cabozantinib for Collaborator's development and commercialization activities in Japan;

WHEREAS, the Parties wish to establish such collaboration, all on the terms and conditions set forth below.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Exelixis and Collaborator hereby agree as follows:

1. DEFINITIONS

1.1 "**Affiliate**" means, subject to the final sentence of this paragraph, with respect to any party, any entity that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with such party, but for only so long as such control exists. As used in this Section 1.1, "control" means (a) to possess, directly or indirectly, the power to direct the management or policies of an entity, whether through ownership of voting securities, by contract relating to voting rights or corporate governance; or (b) direct or indirect beneficial ownership of more than fifty percent (50%) (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting share capital or other equity interest in such entity. For the avoidance of any doubt, neither [*] nor [*] shall constitute an Affiliate of Collaborator.

1.2 "**API**" means cabozantinib, having the chemical structure set forth in **Exhibit 1.2**.

1.3 "**Applicable Laws**" means the applicable provisions of any and all national, supranational, regional, state, and local laws, treaties, statutes, rules, regulations, administrative codes, guidance (including cGCP, cGLP and cGMP), ordinances, judgments, decrees, directives, orders, permits (including MAAs) of or from any court, Regulatory Authority, or governmental agency or authority having competent jurisdiction over or related to the subject item.

1.4 "**Business Day**" means Monday through Friday of each week, except that a legal holiday recognized as such by the federal government of the United States and/or a national holiday in Japan shall not be regarded as a Business Day.

1.5 "**Calendar Quarter**" means each respective period of three (3) consecutive months ending on March 31, June 30, September 30, and December 31.

1.6 "**Calendar Year**" means each respective period of twelve (12) consecutive months ending on December 31.

1.7 "**Clinical Trial**" or "**Clinical Trials**" means Phase 1 Clinical Trial, Phase 2 Clinical Trial, Phase 3 Clinical Trial, Phase 4 Clinical Trial or Expanded Access Program as the context dictates.

1.8 "**cGCP**" means the current clinical practice as set out in (i) ICH Harmonized Guidance on current Good Clinical Practice (CPMP/ICH/135/95), (ii) US Code of Federal Regulations, Title 21, Chapters 50, 54, 56, 58, 210, 211 and 312, as may be amended from time to time, or (iii) the equivalent law or regulation in any other applicable jurisdiction in the Collaborator Territory.

1.9 "**cGLP**" means the current good laboratory practice standards promulgated or endorsed by the FDA, as defined in U.S. 21 C.F.R. Part 58 (or such other

comparable regulatory standards in jurisdictions outside the U.S.), as they may be updated from time to time.

1.10 "**cGMP**" means the current standards for systems to assure the proper design, monitoring, and control of processes and facilities to be used for the manufacture, processing, packing, or holding of a drug as specified by applicable laws of the relevant countries at the time of manufacturing conducted in accordance with this Agreement, defined under (i) 21 C.F.R. Part 210 and 211 or (ii) equivalent law or regulations in the Collaborator Territory.

1.11 "**Collaborator Know-How**" means all Know-How that Collaborator or its Affiliate Controls as of the Effective Date or during the Term, including any Joint Inventions, that is used in the research, Development, manufacture, use, importation, offer for sale, sale or Commercialization of any Compound or Product in the Field. The Collaborator Know-How includes the Collaborator Data.

1.12 "**Collaborator Patents**" means all Patents that Collaborator or its Affiliate Controls as of the Effective Date or during the Term (including any Joint Patents) that would be infringed, absent a license or other right to practice granted under such Patents, by the research, Development, manufacture, use, importation, offer for sale, sale or Commercialization of any Compound or Product in the Field (considering patent applications to be issued with the then-pending claims and considering Joint Patents as if owned solely by Collaborator or its Affiliate).

1.13 "**Collaborator Technology**" means the Collaborator Know-How and the Collaborator Patents, including Collaborator's interest in the Joint Inventions and Joint Patents.

1.14 "**Collaborator Territory**" means Japan.

1.15 "**Commercialization**" means the conduct of all activities undertaken before and after Regulatory Approval relating to the promotion, sales, marketing, medical support, and distribution (including importing, exporting, transporting, customs clearance, warehousing, invoicing, handling, and delivering Products to customers) of Products in the Field in or outside of the Collaborator Territory, including sales force efforts, detailing, advertising, market research, market access (including list price and reimbursement activities), medical education and information services, publication, scientific and Medical Affairs; advisory and collaborative activities with opinion leaders and professional societies including symposia, marketing, sales force training, and sales (including receiving, accepting, and filling Product orders) and distribution. "**Commercialize**" and "**Commercializing**" have correlative meanings.

1.16 "**Commercially Reasonable Efforts**" means, with respect to a Party and its obligations under this Agreement, those commercially reasonable efforts and resources consistent with the usual practices of a similarly situated company for the development

and commercialization of a pharmaceutical product originating from its own research and development department, which is at a similar stage of research, development, or commercialization, taking into account that product's profile of efficacy and safety; proprietary position, including patent and regulatory exclusivity; regulatory status, including anticipated or approved labeling and anticipated or approved post-approval requirements; present and future market and commercial potential, including competitive market conditions, and all other relevant factors, including technical, legal, business, scientific, and/or medical factors. Commercially Reasonable Efforts requires that a Party: (i) promptly assign responsibility for each contractual obligation to specific employee(s) who are held accountable for progress and monitor such progress on an ongoing basis, (ii) set and seek to achieve specific and meaningful objectives for carrying out such obligation, and (iii) make and implement decisions and allocate resources designed to advance progress with respect to such objectives.

1.17 "**Committee**" means the JEC, JDC, JCC or any subcommittee established by the JEC, as applicable.

1.18 "**Competing Product**" means any product or compound, other than the Compound and Products: (a) for which the mechanism of action includes modulation of the kinase activities of cMET and/or VEGFR2, **and** (b) which directly binds and modulates the activity of: (i) VEGFR2 and/or (ii) cMET, [*].

1.19 "**Competitive Field**" means the diagnosis, treatment, or prevention of cancer indications other than:

(a) [*]; and

(b) [*]; provided, however, that (i) if and when [*], and [*]; and (ii) if [*].

1.20 "**Compound**" means API in a form approved by the applicable Regulatory Authority in a particular jurisdiction for use in connection with the Development or Commercialization of the Product in such jurisdiction.

1.21 "**Confidentiality Agreement**" means that certain Confidential Disclosure Agreement between Exelixis and Collaborator dated as of [*].

1.22 "**Confidential Information**" means all Know-How and other proprietary scientific, marketing, financial, or commercial information or data that is generated by or on behalf of a Party or its Affiliates or which one Party or any of its Affiliates has supplied or otherwise made available to the other Party or its Affiliates, whether made available orally, in writing, or in electronic form, including information comprising or relating to concepts, discoveries, inventions, data, designs, or formulae in relation to this Agreement; provided that all Exelixis Technology will be deemed Exelixis' Confidential Information, all Collaborator Technology will be deemed Collaborator's Confidential

Information, and all Joint Inventions and Joint Patents will be deemed both Parties' Confidential Information. Confidential Information shall include: (a) the terms and conditions of this Agreement, and (b) Confidential Information disclosed by either Party pursuant to the Confidentiality Agreement.

1.23 "**Control**" or "**Controlled**" means, with respect to any Know-How, Patents, or other intellectual property rights, the legal authority or right (whether by ownership, license, or otherwise but without taking into account any rights granted by one Party to the other Party pursuant to this Agreement) of a Party to grant access, a license, or a sublicense of or under such Know-How, Patents, or other intellectual property rights to another Party, or to otherwise disclose proprietary or trade secret information to such other Party, without breaching the terms of any agreement with a Third Party, or misappropriating the proprietary or trade secret information of a Third Party.

1.24 "**Cost of Goods**" means the fully burdened cost to manufacture Compound or Drug Product, as applicable, (the "**Supplied Product**") which means: (a) [*]; and (b) in the case of [*]. Actual unit costs shall consist of [*].

1.25 "**Data**" means any and all scientific, technical, test, marketing, or sales data pertaining to any API, Compound and/or Product that is generated by or on behalf of Exelixis, Collaborator, their respective Affiliates, and, to the extent Controlled by a Party, Exelixis' other licensee(s) and Collaborator's Sublicensees, including research data, clinical pharmacology data, pre-clinical data, CMC data, clinical data, clinical study reports, or submissions made in association with an IND or MAA with respect to any API, Compound and/or Product.

1.26 "**Development**" means all development activities for the Compound and Product (whether alone or for use together, or in combination, with another active agent or pharmaceutical product as a combination product or combination therapy) that are directed to obtaining Regulatory Approval(s) of the Product and/or lifecycle management of the Product in any country in the world, including all non-clinical, preclinical, and clinical testing and studies of the Product; toxicology, pharmacokinetic, and pharmacological studies; statistical analyses; assay development; protocol design and development; the preparation, filing, and prosecution of any MAA for the Product; development activities directed to label expansion and/or obtaining Regulatory Approval for one or more additional indications following initial Regulatory Approval; development activities conducted after receipt of Regulatory Approval, including Phase 4 Clinical Trials and Expanded Access Program; and all regulatory affairs related to any of the foregoing. "**Develop**" and "**Developing**" have correlative meanings.

1.27 "**Development Costs**" means the costs incurred by a Party or for its account, during the Term and pursuant to this Agreement, that are specifically directed (or reasonably allocable) to the Development of a Product. The Development Costs shall

include amounts that a Party pays to Third Parties involved in the Development of a Product (at cost, and excluding any Third Party Royalties), and all internal costs (calculated on an FTE basis at the then-current FTE Rate) and reasonable out-of-pocket costs incurred by or on account of a Party in performing Development work in accordance with the GDP. Development Costs shall also include [*]. For clarity, [*].

1.28 "**Drug Product**" means, for a given Product, packaged and unlabeled product comprising the Compound in its final dosage form for such Product.

1.29 "**Executive Officers**" the Chief Executive Officer of Exelixis and the Chief Executive Officer of Collaborator (or his/her designated person).

1.30 "**Exelixis Know-How**" means all Know-How that Exelixis or its Affiliate Controls as of the Effective Date or during the Term, including any Joint Inventions, that is necessary or reasonably useful for the Development, use, importation, offer for sale, or sale of any Compound or Product in the Field in or for the Collaborator Territory. The Exelixis Know-How includes the Exelixis Data.

1.31 "**Exelixis Patents**" means all Patents in the Collaborator Territory that Exelixis or its Affiliate Controls as of the Effective Date or during the Term (including any Joint Patents) that would be infringed, absent a license or other right to practice granted under such Patents, by the Development, use, importation, offer for sale, sale or Commercialization of any Compound or Product in the Field in the Collaborator Territory (considering patent applications to be issued with the then-pending claims and considering Joint Patents as if owned solely by Exelixis). The Exelixis Patents existing as of the Effective Date are set forth in **Exhibit 1.31** which shall be periodically, at least annually, updated by Exelixis or its counsel).

1.32 "**Exelixis Technology**" means the Exelixis Know-How and the Exelixis Patents, including Exelixis' interest in the Joint Inventions and Joint Patents.

1.33 "**Exelixis Territory**" means worldwide, excluding the Collaborator Territory (i.e., Japan).

1.34 "**Expanded Access Program**" means the administration of the Product to named individuals who do not meet the clinical trial enrollment criteria either outside of a clinical trial or after the completion of a clinical trial. Expanded Access Programs are also known as named patient programs, named patient supply, and temporary authorization for use (including patient request treatment pursuant to Article 63-2(4) of Japanese Act on Health Insurance).

1.35 "**Export Control Laws**" means all applicable U.S. laws and regulations relating to (a) sanctions and embargoes imposed by the Office of Foreign Assets Control of the U.S. Department of Treasury or (b) the export or re-export of commodities, technologies, or services, including the Export Administration Act of 1979, 24 U.S.C. §§

2401-2420, the International Emergency Economic Powers Act, 50 U.S.C. §§ 1701-1706, the Trading with the Enemy Act, 50 U.S.C. §§ 1 et. seq., the Arms Export Control Act, 22 U.S.C. §§ 2778 and 2779, and the International Boycott Provisions of Section 999 of the U.S. Internal Revenue Code of 1986 (as amended).

1.36 "**FCPA**" means the U.S. Foreign Corrupt Practices Act (15 U.S.C. Section 78dd-1, et. seq.), as amended.

1.37 "**FDA**" means the U.S. Food and Drug Administration or its successor.

1.38 "**Field**" means all indications and uses in humans and animals, including, but not limited to, RCC and HCC.

1.39 "**Finished Manufacture**" means the manufacture of Finished Product from Compound or Drug Product, as the case may be.

1.40 "**Finished Product**" means, with respect to a given Product, (i) the applicable Compound or Drug Product, as the case may be, packaged and labeled for Development or Commercialization purposes, as applicable, in accordance with the applicable Specifications and legal requirements in the Collaborator Territory, or (ii) the Compound or Drug Product, as the case may be, along with its appropriate packaging and labeling in such other configuration as may be agreed upon by the Parties and set forth in the applicable Supply Agreement.

1.41 "**First Commercial Sale**" means, on a Product-by-Product basis, the first commercial sale by Collaborator or any of its Affiliates or Sublicensees to a Third Party for end use of such Product in the Collaborator Territory after Regulatory Approval has been granted with respect to such Product in the Collaborator Territory.

1.42 "**FTE**" means the equivalent of a full-time individual's work for a twelve (12) month period (consisting of a total of [*] hours per year of dedicated effort). Any person who devotes more or less than [*] hours per year on the applicable activities shall be treated as an FTE on a pro-rata basis, based upon the actual number of hours worked by such person on such activities, divided by [*]. For the avoidance of any doubt, the hours spent by Exelixis temporary workers and contractors on applicable activities and the hours allocated to the work of general corporate or administrative personnel shall not be incorporated into FTE.

1.43 "**FTE Rate**" means, with respect to Exelixis' personnel, an initial rate of [*] U.S. Dollars ($[*]) per FTE per year, which rate shall apply through December 31, 2017. Thereafter, the FTE Rate for Exelixis' personnel shall be changed annually on a Calendar Year basis to reflect any year-to-year percentage increase or decrease (as the case may be) in the Consumer Price Index for All Urban Consumers for the U.S., as published by the U.S. Department of Labor, Bureau of Labor Statistics ("**CPI**"). With respect to Collaborator's personnel, "FTE Rate" means a reasonable rate in Japanese yen

reasonably determined by Collaborator based on Collaborator's actual, fully-burdened costs for Collaborative Work on a case-by-case basis, provided that Collaborator shall provide Exelixis with supporting documentation for each such determination.

1.44 "**Generic Product**" means, with respect to a Product, any pharmaceutical product that (a) contains the same API as such Product; and (b) is approved by the Regulatory Authority in such regulatory jurisdiction as a substitutable generic for such Product (for an indication for which such Product obtained Regulatory Approval from the applicable Regulatory Authority in such jurisdiction) on an expedited or abbreviated basis based on bioequivalence or interchangeability with the Product under Article 14-4.1 of Pharmaceuticals and Medical Device Act or equivalent laws or regulations in any other jurisdiction in the Exelixis Territory.

1.45 "**Governmental Authority**" means any national, international, federal, state, provincial, or local government, or political subdivision thereof, or any multinational organization or any authority, agency, or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory, or taxing authority or power, any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).

1.46 "**HCC**" means hepatocellular carcinoma.

1.47 "**ICH**" means the International Conference on Harmonization (of Technical Requirements for Registration of Pharmaceuticals for Human Use).

1.48 "**IND**" means an investigational new drug application or equivalent application filed with the applicable Regulatory Authority, which application is required to commence human clinical trials in the applicable country.

1.49 "**Initiation**" means, with respect to a Clinical Trial, the first dosing of the first human subject in such Clinical Trial.

1.50 "**Inventions**" means all inventions, whether or not patentable, discovered, made, conceived, or reduced to practice, in the course of activities contemplated by this Agreement.

1.51 "**Know-How**" means all technical information, know-how, and data, including inventions, discoveries, trade secrets, specifications, instructions, processes, formulae, compositions of matter, cells, cell lines, assays, animal models and other physical, biological, or chemical materials, expertise and other technology applicable to, development, registration, use, or marketing or to methods of assaying or testing them, and including all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical, and analytical, safety, nonclinical, and clinical data, regulatory documents, data and filings, instructions, processes, formulae, expertise and information, relevant to the research, development, use, importation, offering for sale or sale of, or

which may be useful in studying, testing, or developing Products in the Field. Know-How excludes Patents and manufacturing know-how of the Compound or Product.

1.52 "**MAA**" means a marketing authorization application or equivalent application, and all amendments and supplements thereto, filed with the applicable Regulatory Authority in the Collaborator Territory. For clarity, MAA does not include any application for Pricing and Reimbursement Approval.

1.53 "**MAA Approval**" means approval of an MAA by the applicable Regulatory Authority for marketing and sale of a Product in the Collaborator Territory, but excluding any Pricing and Reimbursement Approval.

1.54 "**Medical Affairs**" or "**Medical Affairs Activities**" means activities designed to ensure or improve appropriate medical use of, conduct medical education of, or further research regarding, the Product, including by way of example: (a) activities of medical scientific liaisons who, among their other functions, may: (i) conduct service-based medical activities including providing input and assistance with consultancy meetings, proposing investigators for clinical trials sponsored or co-sponsored by a Party or Affiliate, and providing input in the design of such trials and other research related activities; and/or (ii) deliver non-promotional communications and conduct non-promotional activities; (b) grants to support continuing medical education, symposia, or Third Party research related to the Product; (c) development, publication, and dissemination of publications relating to the Products; (d) medical information services provided in response to inquiries communicated via sales representatives or received by letter, phone call, or email; (e) conducting advisory board meetings, international advisory board activities or other consultant programs, including the engagement of key opinion leaders and health care professional in individual or group advisory and consulting arrangements; and (f) conducting company-sponsored studies (CSS) and post-marketing surveillance trials or the evaluation of area of permissible scientific and medical inquiry (including, the evaluation of applications submitted to Collaborator for support of off-label or on-label investigator-initiated trials or studies).

1.55 "**MHLW**" means Japan's Ministry of Health, Labour and Welfare, or any successor agency thereto.

1.56 "**Net Sales**" means, with respect to any Product, the gross amounts invoiced for sales or other dispositions of such Product by or on behalf of Collaborator and its Affiliates and Sublicensees to Third Parties in the Collaborator Territory, less the following deductions to the extent included in the gross invoiced sales price for such Product or otherwise directly paid or incurred by Collaborator or its Affiliates or Sublicensees, as applicable, with respect to the sale or other disposition of such Product:

(a) normal and customary trade and quantity discounts actually allowed and properly taken directly with respect to sales of such Product (provided that

such discounts are not applied disproportionately to such Product when compared to the other products of Collaborator or its Affiliate or Sublicensee, as applicable);

(b) credits or allowances given or made for rejection or return of previously sold Products or for retroactive price reductions and billing errors;

(c) rebates and chargeback payments granted to managed health care organizations, pharmacy benefit managers (or equivalents thereof), national, state/provincial, local, and other governments, their agencies and purchasers and reimbursers, or to trade customers;

(d) costs of freight, carrier insurance, and other transportation charges directly related to the distribution of such Product; and/or

(e) taxes, duties or other governmental charges (including any tax such as a value added or similar tax, other than any taxes based on income, and annual contributions paid pursuant to the Japanese Act on Pharmaceuticals and Medical Devises Agency) directly levied on or measured by the billing amount for such Product, as adjusted for rebates and refunds.

Upon any sale or other disposition of any Product that should be included within Net Sales for any consideration other than exclusively monetary consideration on bona fide arms'-length terms, then for purposes of calculating Net Sales under this Agreement, such Product shall be deemed to be sold exclusively for money at the average sales price of the relevant Product in arm's-length transactions during the applicable reporting period generally achieved for such Product in the Collaborator Territory when such Product is sold alone and not with other products (average sales price to be measured as the aggregate Product Net Sales divided by the aggregate number of units sold in the Collaborator Territory).

In no event will any particular amount identified above be deducted more than once in calculating Net Sales. Sales of a Product between Collaborator and its Affiliates or Sublicensees for resale shall be excluded from the computation of Net Sales, but the subsequent resale of such Product to a Third Party shall be included within the computation of Net Sales.

The supply of Product as samples, for use in non-clinical or clinical trials/studies, or for use in any test or studies reasonably necessary to comply with any applicable laws, rules, or regulations or as is otherwise normal and customary in the industry (including for use in Phase 4 Clinical Trial, Expanded Access Program or any other Medical Affairs Activities) shall not be included in the computation of Net Sales, so long as Collaborator, its Affiliates, and Sublicensees do not receive payment for such Product in excess of the Cost of Goods of such Product.

1.57 "**Patents**" means (a) all patents, certificates of invention, applications for certificates of invention, priority patent filings, and patent applications, and (b) any renewals, divisions, continuations (in whole or in part), or requests for continued examination of any of such patents, certificates of invention and patent applications, and any all patents or certificates of invention issuing thereon, and any and all reissues, reexaminations, extensions, supplementary protection certificates, divisions, renewals, substitutions, confirmations, registrations, revalidations, revisions, and additions of or to any of the foregoing.

1.58 "**Phase 1 Clinical Trial**" means a clinical trial in any country conducted in a small number of human volunteers designed or intended to establish an initial safety profile, pharmacodynamics, or pharmacokinetics of a Product. For clarity, a Phase 1 Clinical Trial may include studies conducted in oncology patients.

1.59 "**Phase 2 Clinical Trial**" means a clinical trial of a Product in human patients in any country to determine initial efficacy and safety and dose range finding. A Phase 2 Clinical Trial is typically conducted before embarking on a Phase 3 Clinical Trial, but may be registrational.

1.60 "**Phase 3 Clinical Trial**" means a pivotal clinical trial of a Product in human patients in any country with a defined dose or a set of defined doses of a Product designed to ascertain efficacy and safety of such Product for the purpose of submitting a MAA to the competent Regulatory Authorities.

1.61 "**Phase 4 Clinical Trial**" means a product support clinical trial of a Product that is commenced after receipt of MAA Approval in the country where such trial is conducted. Phase 4 Clinical Trial may include epidemiological studies, modeling and pharmacoeconomic studies and post-marketing surveillance trials.

1.62 "**PMDA**" means Japan's Pharmaceuticals and Medical Devices Agency, or any successor agency thereto.

1.63 "**Pricing and Reimbursement Approval**" means, with respect to a Product, the approval, agreement, determination, or decision of any Governmental Authority establishing the list price or level of reimbursement for such Product, as required in a given country or jurisdiction prior to sale of such Product in such jurisdiction.

1.64 "**Product**" means any pharmaceutical product containing the Compound as an active ingredient, in any form, presentations, dosage, or formulation. For purposes of this Agreement, all formulations of single-agent Product containing the Compound shall be considered the same Product, and all formulations of combination products, if any, containing the same set of active agents shall be considered the same Product.

1.65 "**Public Official or Entity**" means (a) any officer, employee (including physicians, hospital administrators, or other healthcare professionals), agent, representative, department, agency, de facto official, representative, corporate entity, instrumentality or subdivision of any government, military or international organization, including any ministry or department of health or any state-owned or affiliated company or hospital, or (b) any candidate for political office, any political party or any official of a political party.

1.66 "**RCC**" means renal cell carcinoma.

1.67 "**Regulatory Approval**" means any and all approvals (including MAA Approval, and Pricing and Reimbursement Approval), licenses, registrations, permits, notifications, and authorizations (or waivers) of any Regulatory Authority that are necessary for the manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale, or other commercialization of a Product in any country or jurisdiction.

1.68 "**Regulatory Authority**" means any Governmental Authority that has responsibility in its applicable jurisdiction over the testing, development, manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale or other commercialization of pharmaceutical products in a given jurisdiction, including the FDA and MHLW, or any successor agency of the foregoing having regulatory jurisdiction over the manufacture, distribution, and sale of drugs in the Collaborator Territory, and any Governmental Authority whose review or approval of pricing or reimbursement of such product is required.

1.69 "**Regulatory Exclusivity**" means any exclusive marketing rights or data exclusivity rights conferred by any Regulatory Authority with respect to a Product other than patents, including, without limitation, rights conferred in the U.S. under the Hatch-Waxman Act or the FDA Modernization Act of 1997 (including pediatric exclusivity), or rights similar thereto in the Collaborator Territory.

1.70 "**Regulatory Filing**" means all applications, filings, submissions, approvals, licenses, registrations, permits, notifications, and authorizations (or waivers) with respect to the testing, Development, manufacture, or Commercialization of any Product made to or received from any Regulatory Authority in a given country, including any INDs and MAAs.

1.71 "**Safety Data**" means Data related solely to any adverse drug experiences and serious adverse drug experience as such information is reportable to Regulatory Authorities. Safety Data also includes "adverse events", "adverse drug reactions", and "unexpected adverse drug reactions" as defined in the ICH Harmonised Tripartite Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.

1.72 "**Supplied Product**" has the meaning set forth in Section 1.24.

1.73 "**SEC**" means the U.S. Securities and Exchange Commission, or any successor entity or its foreign equivalent in the Collaborator Territory, as applicable.

1.74 "**Specifications**" means all the attributes, acceptance criteria, tests, analytical methods, and/or limits, and the results thereof, as applicable, for which the raw materials, bulk active, intermediates, or process of making the Drug Product must conform to in order for the Drug Product or Finished Product, as the case may be, to be acceptable for clinical use or commercial use, as applicable, as may be modified as set forth in this Agreement or the applicable Supply Agreement.

1.75 "**Sponsor**" means the Party that takes the ultimate responsibility for the initiation, performance and management of, including financing or arranging the financing for, the appropriate Clinical Trial.

1.76 "**Sublicensee**" means a Third Party to whom Collaborator grants a sublicense to Develop, use, import, promote, offer for sale, sell or otherwise Commercialize any Product in the Field in the Collaborator Territory, beyond the mere right to purchase Products from Collaborator and its Affiliates, and excluding wholesalers, full-service distributors that do not promote the sale of the Product, and other similar physical distributors. In no event shall Exelixis or any of its Affiliates be deemed a Sublicensee.

1.77 "**Third Party**" means any entity other than Exelixis or Collaborator or an Affiliate of Exelixis or Collaborator.

1.78 "**Tier 1 Indication**" means [*].

1.79 "**Tier 2 Indication**" means [*].

1.80 "**U.S.**" means the United States of America, including its territories and possessions (including Puerto Rico).

1.81 "**Valid Claim**" means (a) a claim of an issued and unexpired patent that has not been revoked or held unenforceable, unpatentable, or invalid by a decision of a court or other governmental agency of competent jurisdiction that is not appealable or has not been appealed within the time allowed for appeal, and that has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise, or (b) a claim of a pending patent application that has not been cancelled, withdrawn or abandoned or finally rejected by an administrative agency action from which no appeal can be taken and that has not been pending for more than [*].

1.82 Additional Definitions. The following table identifies the location of definitions set forth in various Sections of the Agreement:

Defined Terms	**Section**
Acquisition Transaction	16.8(b)
Alliance Manager	3.7
Allowable Increases	4.5(a)
Auditor	9.4
Beneficial Party	8.2(d)
Budget Cap	4.5(a)
Claim	12.3
Collaborative Work	4.5(a)
Collaborator Data	10.1(a)
Collaborator Indemnitee	12.1
Collaborator Local Development Work	4.5(c)
Commercialization Plan	6.2
Competing Program	2.8(a)
Compound Invention	10.1(b)(i)
Development Budget	4.2(b)
Developing Party	4.3
Disputed Matter	15.2
Divest	2.8(b)
Exelixis Data	10.1(a)
Exelixis Entity	16.8(a)(i)(1)
Exelixis Indemnitee	12.2
Exelixis Local Development Work	4.5(c)
First Full Calendar Year	6.3(b)
First Generic Entry	2.8(a)
Global Development Plan or GDP	4.2(a)
Indemnitee	12.3
Indemnitor	12.3
Independent Work	4.3
Independent Work Cost	8.2(b)
Injunctive Relief	15.3(b)
Joint Commercialization Committee or JCC	3.3
Joint Development Committee or JDC	3.2
Joint Executive Committee or JEC	3.1
Joint Inventions	10.1(b)(ii)
Joint Patents	10.1(b)(ii)
Local Regulatory Requirement	3.5(b)(i)(2)
Losses	12.1

Defined Terms	Section
Materials	4.14
Minimum Commercial Performance	6.3(b)
Minimum Commercial Performance Period	6.3(b)
Newly-Proposed Development	4.3
Non-Developing Party	4.3
PV Costs	5.5(c)
Pharmacovigilance Agreement	5.5(a)
Previously Achieved Sales Milestone	8.4(a)
Product Infringement	10.4(a)
Product Marks	10.8(a)
Promotional Materials	6.4(c)
Proposal	4.3
Quality Agreement	7.1
Recall	5.9
Regulatory Meeting	5.3
Remaining Royalty Term	8.5(d)
Responding Party	13.4(a)
Royalty Term	8.5(c)
Rules	15.3(a)
Sole Inventions	10.1(b)(ii)
Standstill Period	16.8(a)
Submitting Party	13.4(a)
Sunshine Reporting Laws	5.10
Supply Agreement	7.1
Supply Contacts	3.8
Term	14.1(a)
Unaffiliated Third Party	2.8(a)
Withholding Tax Action	9.3(c)

2. GRANT OF LICENSES

2.1 Licenses Granted to Collaborator. Subject to the terms and conditions of this Agreement, Exelixis hereby grants to Collaborator, during the Term:

(a) an exclusive (even as to Exelixis, except as expressly set forth in Section 2.3), royalty-bearing license, with the right to grant sublicenses solely as provided in Section 2.2, under the Exelixis Technology to use, sell, offer for sale, import, and otherwise Commercialize (but not to make or have made) the Products in the Field and in the Collaborator Territory;

(b) to the extent Exelixis supplies to Collaborator Compound or Drug Product and not Finished Product, an exclusive (even as to Exelixis), royalty-bearing license, with the right to grant sublicenses as provided in Section 2.2, under the Exelixis Technology to conduct or have conducted Finished Manufacture in the Collaborator Territory for use in the Development and Commercialization of the Products in the Field in the Collaborator Territory; and

(c) a co-exclusive license, together solely with Exelixis and its other licensee(s) of the Product, with the right to grant sublicenses solely as provided in Section 2.2, under the Exelixis Technology to Develop (but not to make or have made) the Products in the Collaborator Territory under the GDP, and to use the Products for that purpose.

2.2 Sublicensees/Contractors. Collaborator shall not have the right to grant sublicenses under the licenses granted in Section 2.1 without Exelixis' express prior written consent. All sublicenses granted under the licenses granted in Section 2.1 with Exelixis' consent shall be expressed in writing and shall be subject to, and consistent with, the terms and conditions of this Agreement and shall provide that any such Sublicensee (for clarity, excluding any wholesale distributor) shall not further sublicense except with the consent of Collaborator and Exelixis. Collaborator shall ensure that each agreement with a Sublicensee grants Exelixis all rights with respect to Data, Inventions, and Regulatory Filings made or generated by such Sublicensee as if such Data, Inventions, and Regulatory Filings were made or generated by Collaborator. Collaborator shall be responsible for the compliance of its Affiliates involved in the Development or Commercialization of the Compound and Products and Sublicensees (for clarity, excluding any wholesale distributor) and subcontractors with the terms and conditions of this Agreement. Within [*] after execution, Collaborator shall provide Exelixis with a copy of each agreement granting a sublicense under the license granted in Section 2.1. Unless otherwise set forth in this Agreement, Collaborator may contract with any of its Affiliates or Third Party contractors (e.g., contract research organization, contract sales organization, contract manufacturing organization, or regulatory agent) to conduct any of its activities contemplated hereunder without the prior written consent of Exelixis; provided, however, that Collaborator shall impose on each such contractor the same obligations that Collaborator undertakes hereunder and Collaborator shall remain responsible to Exelixis for the performance of such obligations by each such contractor.

2.3 Reserved Rights. Subject to the terms and conditions of this Agreement, Exelixis hereby expressly reserves:

(a) the right under the Exelixis Technology to exercise its rights and perform its obligations under this Agreement, whether directly or through one or more licensees or subcontractors, including the right to Develop the Compound and Products in the Collaborator Territory under the GDP; and

(b) subject to Section 2.8, all rights to practice, and to grant licenses under, the Exelixis Technology outside of the scope of the licenses granted in Section 2.1, including the exclusive right to make and have made the Compound and Products anywhere in the world, and the exclusive rights to practice the Exelixis Patents and Exelixis Know-How with respect to compounds and products other than Compound and Products.

2.4 Licenses Granted to Exelixis. Subject to the terms and conditions of this Agreement, Collaborator hereby grants to Exelixis, during the Term:

(a) an exclusive (even as to Collaborator), royalty-free, fully-paid, and irrevocable license, with the right to sublicense through multiple tiers, under the Collaborator Technology to use, sell, offer for sale, import, and otherwise Commercialize the Products in the Field in the Exelixis Territory as long as such Collaborator Technology is those actually applied and/or used in the Product Developed or Commercialized by Collaborator;

(b) a co-exclusive (with Collaborator), royalty-free, fully-paid, and irrevocable license, with the right to grant sublicenses through multiple tiers, under the Collaborator Technology to Develop the Compound and Products on a worldwide basis under the GDP as long as such Collaborator Technology is those actually applied and/or used in the Product Developed or Commercialized by Collaborator; and

(c) an exclusive (even as to Collaborator), royalty-free, fully-paid, and irrevocable license, with the right to sublicense through multiple tiers, under the Collaborator Technology to make and have made the Compound and Products anywhere in the world as long as such Collaborator Technology is those actually applied and/or used in the Product Developed or Commercialized by Collaborator.

For the avoidance of any doubt, a scope of the license under the Collaborator Technology granted to Exelixis under this Section 2.4 shall be limited only to each purpose of license explicitly provided in the above (a) through (c), and Collaborator may reserve the rights to use or grant a license under the Collaborator Technology freely for outside of such scope of Exelixis' exclusive license set forth above. For the avoidance of any doubt, any such use by Collaborator of the Collaborator Technology outside of the scope of Exelixis' exclusive license set forth above shall be subject to the conditions under Section 2.8 (Exclusivity).

2.5 No Implied Licenses; Negative Covenant. Except as set forth in this Agreement, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, under or to any Patents, Know-How, or other intellectual property owned or controlled by the other Party. Neither Party shall, nor shall it permit any of its Affiliates or sublicensees to, practice any Patents or Know-How licensed to it by the other Party outside the scope of the licenses granted to it under this Agreement.

Without limitation of the foregoing, each Party acknowledges the restrictions on its activities set forth in Section 4.13 and Collaborator agrees that such activities are outside the scope of the licenses granted to it herein.

2.6 Disclosure of Know-How. For as long as the Parties are conducting Development activities under the GDP, Exelixis shall, without additional compensation, disclose and make available to Collaborator, in electronic form where possible, all Exelixis Know-How that comes into existence after the Effective Date and that was not previously provided to Collaborator, promptly after the development, making, conception, or reduction to practice of such Exelixis Know-How. For as long as the Parties are conducting Development activities under the GDP, Collaborator shall and shall cause its Affiliates to, without additional compensation, disclose and make available to Exelixis, in electronic form where possible, any Collaborator Know-How not previously provided to Exelixis, and promptly after the earlier of the development, making, conception, or reduction to practice of such Collaborator Know-How. The JDC and JCC shall each establish a mechanism for the reciprocal disclosure of Know-How within its respective area of responsibility.

2.7 Third Party Licenses.

(a) If Exelixis enters into any agreement with a Third Party after the Effective Date that includes a license from such Third Party to Exelixis under any Patents that would be infringed, absent a license or other right to practice granted under such Patents, by the Development, use, Manufacture, sales, offer for sale, import, or Commercialization of the Product in the Field and in the Collaborator Territory (including as contemplated in Section 10.5), then Exelixis shall notify Collaborator and identify for Collaborator the relevant Patents. Such Patents, to the extent falling within the definition of Exelixis Patents, will be sublicensed to Collaborator if Collaborator provides Exelixis with written notice in which (i) Collaborator consents to adding such Patents to the definition of Exelixis Patents, (ii) Exelixis and Collaborator shall [*] of the payments that would be owed by Exelixis under such Third Party license agreement as a result of Exelixis granting a sublicense to Collaborator or Collaborator's practice thereunder, including Collaborator's and its Affiliates' and Sublicensees' Development, use, Manufacture, sale, offer for sale, importation, and Commercialization of the Compound and Products in the Field in the Collaborator Territory, and such payments would be reasonably allocated proportionately to Collaborator Territory in the case such Third Party license agreement covers multiple countries including the Collaborator Territory, and to make all payments when due and provide all reports required under such license agreement; and (iii) Collaborator acknowledges in writing that its sublicense under such license agreement is subject to the terms and conditions of such license agreement.

(b) Collaborator shall promptly notify Exelixis if it becomes aware of any Third Party's Patents that are necessary or reasonably useful to Develop, make, have

made, use, sell, offer for sale, import or Commercialize the Compound and Products in the Field in the Collaborator Territory, and shall give Exelixis the first right to negotiate and obtain a license from such Third Party under such Patents. Except with the prior written consent of Exelixis, Collaborator shall not obtain a license to Third Party's Patents that is necessary or reasonably useful to Develop, make, have made, use, sell, offer for sale, import or Commercialize the Products in either Party's territory, unless it obtains the right to sublicense such rights to Exelixis.

2.8 Exclusivity.

(a) Subject to Section 2.8(b) below, (i) for the period starting from the Effective Date until the earlier of either of (1) eight (8) years after the First Commercial Sale of any Product in the Collaborator Territory or (2) the first commercial sale in the Collaborator Territory by an Unaffiliated Third Party of a Generic Product for which such Third Party has obtained National Health Insurance pricing from the MHLW ("**First Generic Entry**"), neither Party (nor any of its Affiliates) shall, directly or indirectly (including through a Third Party), develop [*] any Competing Product for any use in the Competitive Field in the Collaborator Territory (a "**Competing Program**"), and (ii) for the period starting from the Effective Date and continuing until two (2) years following the First Generic Entry, neither Party (nor any of its Affiliates) shall, directly or indirectly (including through a Third Party), commercialize any Competing Product for any use in the Competitive Field in the Collaborator Territory. For purposes of this Section 2.8, "**Unaffiliated Third Party**" means a Third Party that is not a Sublicensee and did not purchase the applicable Generic Product in a chain of distribution that included any of Exelixis, Collaborator, or their respective Affiliates, licensees, or sublicensees.

(b) In the event that a Third Party becomes an assignee of this Agreement, or an Affiliate of a Party after the Effective Date through merger, acquisition, consolidation, or other similar transaction, and such Third Party, as of the closing date of such transaction, is engaged in the development [*] or commercialization of a Competing Program:

(i) if such transaction arises with respect to [*], then such assignee or new Affiliate (as the case may be) shall have the right to continue the Competing Program and such continuation shall not constitute a breach of [*] exclusivity obligations set forth above; provided that such assignee or new Affiliate (as the case may be) conducts the Competing Program independently of the activities of this Agreement and does not use any [*] in the conduct of the Competing Program and provided further that [*] shall continue to Develop [*] the Product for the Collaborator Territory in accordance with the terms of this Agreement [*] as if the Competing Program was not acquired;

(ii) if such transaction arises with respect to [*], then such assignee or new Affiliate (as the case may be; in either case, referred to as [*] for the

remainder of this Section 2.8(b)(ii)) shall continue to Develop and Commercialize the Product [*] that assumes as if the Competing Program was not acquired, provided that, within [*] after the closing of such transaction, [*] shall either: (a) Divest the Competing Program to a Third Party, or (b) discontinue the Competing Program. For clarity, if the closing of such transaction occurs after the earlier of 2.8(a)(i)(1) or 2.8(a)(i)(2), [*] may continue the development of such Competing Program [*], but shall in no event be permitted to commercialize such Competing Program in the Competitive Field in the Collaborator Territory until two (2) years after the First Generic Entry, as set forth in Section 2.8(a)(ii). For the avoidance of any doubt, during such [*] period, [*] shall continue to fulfill its obligations under this Agreement in all respects, shall conduct Competing Program activities independently of the activities pursuant to this Agreement, shall not use any [*] in the conduct of the Competing Program, and shall not initiate or launch any new Competing Program activities. Notwithstanding the foregoing, in the event that [*] reasonably anticipates that it will require more than [*] to complete any then-ongoing clinical trials or studies with respect to the Competing Program, then [*] shall notify Exelixis via the JEC and the JEC shall discuss and determine in good faith any necessary extension to such [*] period to permit [*] solely to complete and not to interrupt such ongoing clinical trials and studies with respect to the Competing Program, and [*] shall not withhold its consent to any such necessary extension. For clarity, if [*] completely winds down the Competing Program within such [*] time period plus the period of time of the extension, if any, [*] shall be allowed to Divest the Competing Program later, provided that it does not restart any Competing Program activities. For the purpose of this Section 2.8(b)(ii), an "ongoing clinical trial or study" shall be any clinical trial or study for which [*] as of the closing of such transaction.

As used in this Section 2.8(b), "**Divest**" means the sale or transfer of all rights to the Competing Program to a Third Party without receiving any contractual mechanism for Collaborator to provide involvement in or support of any diligence or performance obligations of such Third Party with respect to the Competing Program, or to perform or be involved in any development or commercial activities with respect to such Competing Program ("**Divesture**" has a correlative meaning). For the avoidance of any doubt, "Divest" does not mean the renouncement nor waiver of any right to receive payment from the Third Party involved in the development and commercial activities with respect to the Competing Program and to the extent that [*].

(c) During the Term of this Agreement, to the extent permitted by Applicable Law, for the legitimate and proportionate purpose and means for the protection of Confidential Information and Know-How and for the lifecycle management of the Product, neither Party (nor any of its Affiliates) shall, directly or indirectly (including through a Third Party), commercialize any Generic Product of any Product in the other Party's territory; provided, however, that the foregoing restriction shall apply to [*] only until [*].

2.9 Authorized Generics and Off Patent Products.

(a) Authorized Generics. The Parties acknowledge that it may become in the Parties' mutual interest to create an authorized generic of the Product either during or after the Royalty Term for such Product in the Collaborator Territory. If and when [*] believes that creating such an authorized generic for commercialization in the Collaborator Territory would be mutually beneficial to the Parties, [*] shall notify [*] and the Parties shall discuss whether to create such an authorized generic for commercialization in the Collaborator Territory. In the event that the Parties determine to create an authorized generic version of the Product, the Parties shall negotiate the commercially reasonable terms and conditions of manufacturing and commercializing such authorized generic in the Collaborator Territory and either amend this Agreement or enter into a separate agreement with respect thereto, as appropriate.

(b) Off Patent Products. The Parties acknowledge that it may be in the Parties' mutual interest and wishes to continue to commercialize the Product for patients in the Collaborator Territory by using Exelixis supplied API, Compound, or Product even after the [*] for such Product. If Collaborator desires to purchase the API, Compound, and/or Product of the Collaborator Territory after the [*] for such Product, Collaborator shall notify Exelixis up to [*] prior to the expiration of the [*] and the Parties shall discuss in good faith with the intent to determine commercially reasonable terms and conditions for the continued supply of the API, Compound, and/or Product (in the form then-currently supplied to Collaborator by Exelixis and which supply price shall include a reasonable margin) and a license under the Product Marks for use in connection with the Commercialization of the Product.

3. GOVERNANCE

3.1 Joint Executive Committee. As of the Effective Date, the Parties have established a joint executive committee (the "**Joint Executive Committee**" or the "**JEC**"), composed of an equal number of up to [*] senior officers/representatives of each Party, to oversee and guide the strategic direction of the collaboration of the Parties under this Agreement. The JEC shall act as a joint consultative body and to the extent expressly provided herein, a joint decision-making body. The JEC in particular shall:

(a) review the overall status of the Development and Commercialization of the Compound and Products in the Exelixis Territory and the Collaborator Territory, as presented by the JDC and JCC;

(b) review and approve any proposed amendments to the GDP, including corresponding budgets, following recommendation by the JDC;

(c) review and approve the Commercialization Plans for the Collaborator Territory, including proposed amendments, following recommendation by the JCC;

(d) review and approve Minimum Commercial Performance thresholds pursuant to Section 6.3(b), following recommendation by the JCC;

(e) review the status and strategy of manufacturing and supply, following recommendation by the JDC or JCC;

(f) resolve any disputed matter submitted to it by the JDC or JCC;

(g) establish additional Committees as it deems necessary or advisable to further the purpose of this Agreement; and

(h) perform such other functions as appropriate to further the purposes of this Agreement, as expressly set forth in this Agreement or allocated to it by the Parties' written agreement, including providing financial oversight of the activities conducted pursuant to this Agreement.

For clarity, any information sharing of Commercialization matters regarding the Exelixis Territory shall be solely for purposes of the coordination of the Parties' activities, and Exelixis shall retain all decision making authority with respect to such matters without requiring any approvals except as expressly provided in Sections 13.4 and 13.5.

3.2 Joint Development Committee. As of the Effective Date, the Parties have established a joint Development, Medical Affairs, and regulatory committee (the "**Joint Development Committee**" or the "**JDC**"), composed of up to [*] representatives of each Party, to monitor and coordinate the Development of, and Medical Affairs Activities connected with, the Compound and Products at the operational level. Each JDC representative shall have knowledge and expertise in the clinical development of products similar to the Products. The JDC shall in particular:

(a) coordinate and monitor the Development activities of the Parties under the GDP and oversee implementation of the GDP, and report to the JEC on all significant Development activities in the Collaborator Territory;

(b) provide a forum for and facilitate communications between the Parties with respect to the Development of Products in the Collaborator Territory and the Exelixis Territory, including sharing of Development information and Data in accordance with Section 4.7;

(c) review and approve for the Collaborator Territory Clinical Trial protocols, including investigator-initiated and cooperative group clinical trial plans and protocols, and statistical analysis plans for Clinical Trials (and any amendments thereto);

(d) define areas of permissible scientific and medical inquiry and parameters for Phase 4 Clinical Trials in the Collaborator Territory;

(e) review Data resulting from Clinical Trials to determine if progression to additional Clinical Trials or submission of Regulatory Filings in the Collaborator Territory is warranted in terms of regulatory and scientific point of view;

(f) review and recommend amendments to the GDP (including the Development Budget) and propose the recommendation to JEC;

(g) provide a forum for Exelixis to provide Collaborator with a status report, at each regularly-scheduled meeting of the JDC, of any significant potential or proposed change(s) in any of Exelixis' or its other Product licensee's Development plans and activities that may result in or require an amendment to the GDP, including any global clinical trial or study of the Product in which Collaborator may wish to participate;

(h) review the status of Product manufacturing and supply activities and strategies associated with Development;

(i) provide a forum for evaluation of Japanese regulatory actions, communications and submissions for the Compound and Products under the GDP, and pharmacovigilance and safety matters worldwide;

(j) establish joint working groups (such as clinical, regulatory and safety working groups) as it deems necessary or appropriate to oversee the day-to-day management of different aspects of the Development work under the GDP;

(k) oversee and coordinate the material Medical Affairs Activities for the Product in all indications, which shall be subject to a Medical Affairs portion of the GDP and may be coordinated through a Medical Affairs working group established and overseen by the JDC;

(l) review and coordinate decisions related to research or Development of Products for new indications, characterization, and Development of [*] (if any); and

(m) perform such other functions as may be appropriate to further the purposes of this Agreement with respect to the Development of Products, including endeavoring to resolve any disputes between the Parties arising from the deliberations of the JDC, or as otherwise directed by the JEC.

3.3 Joint Commercialization Committee. As of the Effective Date, the Parties have established a joint commercialization committee (the "**Joint Commercialization Committee**" or the "**JCC**"), composed of up to [*] representatives of each Party, to monitor and discuss the Commercialization of Products at the operational level. Each JCC representative shall have knowledge and expertise in the commercialization of products similar to Products. The JCC shall in particular:

(a) review and recommend the Commercialization Plans and related activities with respect to the Commercialization of Products in the Collaborator Territory, and report to the JEC on all significant Commercialization activities in the Collaborator Territory;

(b) provide a forum for and facilitate communications and coordination between the Parties with respect to the Commercialization of Products in the Collaborator Territory and the Exelixis Territory;

(c) on an annual basis, discuss and establish Collaborator's Minimum Commercial Performance thresholds pursuant to Section 6.3(b) and propose recommendation to JEC;

(d) review the status of material Product manufacturing and supply activities and strategies associated with Commercialization;

(e) review and discuss the major findings of Collaborator's market research with respect to any Product in the Collaborator Territory, if any;

(f) review and oversee the branding and product positioning strategy for Products in the Collaborator Territory and evaluate Collaborator's brand strategy for the Product in the Collaborator Territory for consistency with the then-current global brand strategy for the Product;

(g) discuss Product list price and status of reimbursement in the Collaborator Territory; and

(h) perform such other functions as may be appropriate to further the purposes of this Agreement with respect to the Commercialization of Products, including endeavoring to resolve any disputes between the Parties arising from the deliberations of the JCC, or as otherwise directed by the JEC.

3.4 Committee Membership and Meetings.

(a) Committee Members. Each Committee representative shall have appropriate knowledge and expertise and sufficient seniority within the applicable Party to make decisions arising within the scope of the applicable Committee's responsibilities. Each Party may replace its representatives on any Committee on written notice to the other Party, but each Party shall strive to maintain continuity in the representation of its Committee members. The [*]. [*]. The chairperson shall have Alliance Manager prepare and circulate agendas and any background materials to be discussed at the Committee to Committee members at least [*] before each Committee meeting and shall direct the preparation of reasonably detailed minutes for each Committee meeting, which shall be approved by the chairperson and circulated to Committee members within [*] of such meeting. The initial members of each of the

JEC, JCC, and JDC shall be determined by the Parties promptly following the Effective Date.

(b) Meetings. Each Committee shall hold meetings at such times as it elects to do so, but in no event shall meetings of the JDC be held less frequently than once every [*] during the first [*] following the Effective Date; meetings of the JCC be held less frequently than once every [*] during the [*] in the Collaborator Territory and [*]; and meetings of the JEC once every [*] during the first [*] following the Effective Date and once every [*] during the [*] in the Collaborator Territory; provided, the Parties may decide to reduce the frequency of the Committee meetings. The first JEC meeting, first JDC meeting, and first JCC meeting shall be held within [*] after the Effective Date, at which meetings the dates for the first Calendar Year shall be set. Meetings of any Committee may be held in person, or by audio or video teleconference; provided that unless otherwise agreed, at least one (1) meeting per year of each Committee shall be held in person. In-person Committees shall be held at locations alternately selected by the Parties and Collaborator shall select the location of the first meeting. Each Party shall be responsible for all of its own expenses of participating in any Committee meetings. No action taken at any meeting of a Committee shall be effective unless at least [*] of each Party is participating. In addition, upon written notice to the other Party, either Party may request that a special *ad hoc* meeting of the (i) JEC be convened for the purpose of resolving disputes or for the purpose of reviewing or making decisions pertaining to material subject-matter, the review or resolution of which cannot be reasonably postponed until the following scheduled JEC meeting, and (ii) JDC be convened for the purpose of addressing or resolving (on an expedited basis) any dispute with respect to any Local Regulatory Requirement. Such *ad hoc* meeting shall be convened at such time as may be mutually agreed by the Parties, but no later than [*] following the notification date of request that such meeting be held.

(c) Non-Member Attendance. Each Party may from time to time invite a reasonable number of participants, in addition to its representatives, to attend the Committee meetings in a non-voting capacity; provided that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Party shall provide reasonable prior written notice to the other Party and obtain the other Party's approval for such Third Party to attend such meeting, which approval shall not be unreasonably withheld, delayed, or conditioned. Such Party shall ensure that such Third Party is bound by written confidentiality and non-use obligations consistent with the terms of this Agreement.

3.5 Decision-Making.

(a) All decisions of each Committee shall be made by unanimous vote, with each Party's representatives collectively having one (1) vote. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before

a Committee, the representatives of the Parties cannot reach an agreement as to such matter within [*] after such matter was brought to such Committee for resolution, then, except as provided in Section 3.5(c), if such disagreement arose within the JDC or JCC, it shall be referred to the JEC for resolution. If the JEC cannot resolve such matter within [*], or if the disagreement first arose within the JEC, then either Party at any time may refer such issue to the Executive Officers for resolution.

(b) If the Executive Officers cannot resolve such matter within [*] after such matter has been referred to them, then:

(i) Exelixis shall have the final decision making authority, which shall be exercised in its reasonable discretion, with respect to Development and regulatory matters that may be reasonably expected to affect the Exelixis Territory, except for:

(1) the [*], the costs of which would be [*];

(2) any material modification to a [*]. For clarity, the foregoing shall include any material modification to [*]. As used in this clause, "material modification" means any material changes to the agreed upon [*];

(3) any modification to the Development Budget, the costs of which would be [*]; and/or

(4) the addition or inclusion of [*], whether the Parties [*] or not.

(ii) Notwithstanding Section 3.5(b)(i), Collaborator shall have the final decision making authority, which shall be exercised in its reasonable discretion, with respect to (1) Commercialization in the Collaborator Territory (except for [*]), (2) regulatory matters in the Collaborator Territory that are reasonably expected not to directly affect the Exelixis Territory (including, [*]), and (3) immediate treatment that is reasonably necessary to protect patient safety in any Development activities held in the Collaborator Territory; in each case provided that Collaborator's decision shall be consistent with the terms and conditions of this Agreement.

(iii) Neither Party shall have the final decision making authority with respect to the matters in Sections 3.5(b)(i)(1), 3.5(b)(i)(2), 3.5(b)(i)(3), and 3.5(b)(i)(4) and the status quo shall persist with respect to such matter unless and until the Parties mutually agree; provided, however, that with respect to any material modification in order to fulfill a [*] in Section 3.5(b)(i)(2), Exelixis' consent through the JDC shall not be unreasonably withheld, delayed, or conditioned.

(c) Notwithstanding Section 3.5(a) and (b), [*] representative shall have the deciding vote on all tactical or strategic [*] matters for the Products in

Collaborator Territory ([*]), and such matter shall not be subject to escalation to [*]; provided that such decision is reasonably expected not to directly affect [*] and such decision shall be consistent with the terms and conditions of this Agreement.

3.6 Limitations on Authority. Each Committee shall have only such powers as are expressly assigned to it in this Agreement, and such powers shall be subject to the terms and conditions of this Agreement. Without limiting the generality of the foregoing, no Committee will have the power to amend this Agreement, and no decision of a Committee may be in contravention of any terms and conditions of this Agreement.

3.7 Alliance Managers. Promptly after the Effective Date, each Party shall appoint an individual who shall be an employee of such Party having appropriate qualification and experience to act as the alliance manager for such Party (the "**Alliance Manager**"). Each Alliance Manager shall be responsible for coordinating and managing processes and interfacing between the Parties on a day-to-day basis throughout the Term. The Alliance Manager will ensure communication to the JEC of all relevant matters raised at the JDC, the JCC, and at any joint subcommittees and project teams (if any). Each Alliance Manager shall be permitted to attend meetings of the JEC and other Committees as appropriate as non-voting participants. The Alliance Managers shall be the primary contact for the Parties regarding the activities contemplated by this Agreement and shall facilitate all such activities hereunder. Each Party may replace its Alliance Manager with an alternative representative at any time with prior written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager. Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment within the JEC and its subcommittees. Each Party shall bear its own costs of its Alliance Manager, which costs shall be excluded from the Parties' respective Development and manufacturing costs (i.e., Development Costs and Cost of Goods).

3.8 Supply Contacts. Each Party shall designate one (1) qualified and experienced supply chain professional to serve as that Party's primary supply contact regarding the supply of Compound and Products within this Agreement ("**Supply Contacts**") and under the direction of the JCC. Each Party may replace its Supply Contact with an alternative representative at any time with prior written notice to the other Party. Supply Contacts shall be responsible for facilitating information exchange and discussion between the Parties regarding the supply of Compound and Products under this Agreement. [*]. Each Party shall bear its own costs of its Supply Contact, which costs shall be excluded from the Parties' respective Development and Cost of Goods.

4. DEVELOPMENT

4.1 Overview. Subject to the terms and conditions of this Agreement, the Parties will collaborate with respect to the Development of the Compound and Products and share the Data resulting from such collaboration to facilitate the Development of the Compound and Products throughout the Collaborator Territory and the Exelixis Territory.

4.2 Development Plan.

(a) The Development of the Compound and Products under this Agreement (including the development of the Compound and any Product as a combination product or combination therapy with another product and/or therapy), including Independent Work and Local Development Work, shall be conducted only pursuant to a comprehensive written global Development plan which shall be updated at least [*] through the JDC subject to the JEC's approval during the Term (the "**Global Development Plan**" or "**GDP**"). The GDP shall be incorporated by reference as part of this Agreement. As of the Effective Date, the Parties have agreed upon an initial GDP, including an initial Development Budget, attached to this Agreement as **Exhibit 4.2**. If the terms of the then-current GDP contradicts, or creates inconsistencies or ambiguities with, the terms of this Agreement, then the terms of this Agreement shall govern.

(b) The GDP shall set forth the timeline and details (including line of therapy, tumor type, primary endpoints, approximate patient size, combination agents, and comparator agents) of all preclinical and clinical Development activities to be conducted by the Parties as necessary to generate Data sufficient to meet the common requirements of both the FDA and PMDA for MAA Approval of the Compound and Products for RCC (1st line and 2nd line), HCC (2nd line), and other indications agreed upon by the Parties. The GDP shall also include (i) any other Development activities approved by the JDC, including parameters for permissible scientific inquiry in Phase 4 Clinical Trials or Expanded Access Program; (ii) Clinical Trials that the Parties are committed to conducting; (iii) any modification to the Clinical Trials set forth in GDP that will be decided by the JDC based on requirement from a Regulatory Authority or any local or regional IRB (Institutional Review Board)/ethics committee or reasonably necessary to protect patient safety; and (iv) Clinical Trials that will be decided by the JDC based on Data and results obtained after the Effective Date and the Parties' review of the future competitive landscape. The GDP shall include a coordinated Development and regulatory strategy, including the Parties' respective roles in the Development of the registration dossier and Regulatory Filings for the Products and the countries in which Development of the Products will occur. The GDP shall also set forth the detailed budget of the anticipated costs for such Development activities (the "**Development Budget**") on a study-by-study or Clinical Trial-by-Clinical Trial basis. For clarity, the Development Budget shall not include any Development Costs associated with Collaborator Local Development Work or Exelixis Local Development Work.

(c) If upon the determination by the JDC, any modification to the then-current GDP, including any non-clinical or Clinical Trials not included in the GDP,

(i) is required in order to obtain and/or maintain MAA Approval for a Product in the Collaborator Territory or in one or more of the countries of the Exelixis Territory, (ii) is otherwise recommended or suggested by the PMDA in the Collaborator Territory or the FDA or other Regulatory Authority in the Exelixis Territory, (iii) is required by any local or regional IRB/ethics committee or (iv) is reasonably deemed necessary to protect patient safety, then the JDC shall prepare an amendment to the GDP reflecting such required, recommended or suggested modification, including associated Development Budget. The costs of such additional studies shall be borne by the Parties as provided in Section 4.5(a).

4.3 Independent Work. If either Party is interested in pursuing additional Development work on a Product (the "**Developing Party**") for the benefit of the Exelixis Territory (in the case of Exelixis) or the Collaborator Territory (in the case of Collaborator) beyond what is set forth in the then-current GDP, then such Party shall provide the other Party with a written detailed plan and budget for such additional work (the "**Proposal**"). Within [*] of receipt of the Proposal, the JDC or delegated team shall meet to review the Proposal and to permit the other Party (the "**Non-Developing Party**") an opportunity to ask questions and request additional information from the Developing Party related to the Proposal, including whether such Proposal is reasonably likely to have a material and adverse effect on the Product in the Non-Developing Party's territory. No additional Development work shall proceed without the approval of the JDC, and following each such approval such additional Development work and corresponding budget shall be incorporated into the GDP by the JDC (the "**Newly-Proposed Development)**. For any Newly-Proposed Development work, the Non-Developing Party that did not propose such work originally may elect, at its discretion, to share the Development Costs with respect to such Development work under Section 8.2(b). For clarity, for any Newly-Proposed Development by Exelixis, if Collaborator elects to share the Development Costs with respect to such Development work in accordance with Section 8.2(b), Collaborator shall have the option to [*]. If the Non-Developing Party does not decide to pursue the Newly-Proposed Development work jointly with the Developing Party or does not share the Development Costs with respect to such Newly-Proposed Development work, in which event such Development work shall be deemed "**Independent Work**" and the Developing Party may pursue such work in the Field in its respective territory and the Development Costs with respect thereto shall be deemed Independent Work Costs and subject to Sections 4.5(b) and 8.2(b). Notwithstanding the foregoing, following the approval of the Independent Work by the JDC, the Party proposing the Independent Work may conduct such Independent Work, provided that: (A) it shall do so in accordance with the amended GDP; (B) such Independent Work shall be conducted under the oversight of the JDC; and (C) neither Party shall conduct Independent Work in a manner that would have a material adverse effect on any Product(s) in either Party's territory. For the purpose of clarification, the Development activities conducted by Exelixis for RCC (1st line and 2nd line) and HCC (2nd line) before the Effective Date shall not be treated as Independent Work.

4.4 Annual Update to Development Budget. The JDC shall discuss and agree, without a casting vote by either Party with respect to costs that would be shared by the Parties, upon the subsequent year's Development Budget on an annual basis no later than [*] of each year. The JDC shall report any significant changes in the annual budgets to the JEC at the next regularly-scheduled JEC meeting.

4.5 Development Cost.

(a) Collaborative Work Cost. Exelixis shall be responsible for eighty percent (80%) and Collaborator shall be responsible for twenty percent (20%) of all Development Costs for any Development activities (including Clinical Trials) set forth in the GDP other than Independent Work, Collaborator Local Development Work and/or Exelixis Local Development Work (the "**Collaborative Work**"). For the avoidance of any doubt, such Development Costs with respect to the Collaborative Work shall include work performed by temporary workers and contractors on applicable activities and all Allowable Increases. For the purpose of this Section 4.5(a), "**Allowable Increases**" are defined as increased Development Costs in connection with the Collaborative Work resulting from (i) changes in study design after the Effective Date that are approved by the JDC [*] (up to the amount of a mutually-agreed budget increase), (ii) changes in regulatory requirements arising after the Effective Date (including changes required or recommended by Regulatory Authorities, but excluding changes required or recommended specifically by a Regulatory Authority of the Exelixis Territory solely for the benefit of the Exelixis Territory), or (iii) extensions in the duration of Clinical Trials resulting from a lower than anticipated patient accrual rate, rate of clinical events, or higher rates of survival. The Parties' foregoing Development Cost obligations with respect to the Collaborative Work (including Allowable Increases, if any) are subject to a maximum payment obligation of [*] of the amount specified in the Development Budget (the "**Budget Cap**"). For clarification, notwithstanding Section 3.2(f), in the event that the Collaborative Work is conducted in accordance with the GDP and within the Budget Cap, no amendment of the Development Budget shall be required. In the event that Development Costs are expected or anticipated to exceed the Budget Cap, the Party conducting the applicable Clinical Trial shall notify the other Party and the JDC shall meet to discuss amending the Development Budget.

(b) Independent Work Cost. Notwithstanding Section 4.5(a), the Party conducting the Independent Work approved by the JDC under Section 4.3 shall be solely responsible for the Development Costs with respect to such Independent Work, subject to Section 8.2(b).

(c) Local Development Work. Notwithstanding Section 4.5(a), each Party shall be solely responsible for all Development Costs with respect to Development activities that are exclusively for the benefit of the country(ies) within such Party's territory, including: (i) any and all country-specific activities (e.g., a Canada only trial for Exelixis, a Japan only trial for Collaborator, or an Expanded Access Program); (ii) all

Phase 4 Clinical Trials solely benefiting such Party's territory; (iii) any and all Development activities required for any pricing and/or reimbursement approvals in such Party's territory (but are not required for the MAA Approval in such territory); and (iv) any and all indirect manufacturing overhead costs solely benefiting such Party's territory. The Development work set forth in this Section 4.5(c) pertaining to Collaborator shall be deemed the "**Collaborator Local Development Work**" and the Development work set forth in this Section 4.5(c) pertaining to Exelixis shall be deemed the "**Exelixis Local Development Work**". For clarity, only studies that are exclusively for the benefit of the Collaborator Territory shall be deemed local Development activities which constitute Collaborator Local Development Work; all other studies under the GDP, including studies with portions conducted in the Collaborator Territory, shall constitute global Development activities subject to Section 4.5(a). All planned and in-process Collaborator Local Development Work and Exelixis Local Development Work shall be included in and conducted in accordance with the GDP, to be performed reasonably and subject to the oversight of the JDC.

4.6 Development Responsibilities. The JDC shall reasonably allocate Development responsibilities of the Compound and Products under the GDP between the Parties and such allocation shall be set forth in the GDP, provided that: (a) Exelixis or its designee shall be the Sponsor and have the operational responsibility for all Development work under the GDP that is ongoing as of the Effective Date; (b) each Party shall have the operational responsibility for its own Independent Work in its Territory; and (c) Collaborator shall be the Sponsor and have the operational responsibility for the Collaborator Local Development Work and Exelixis or its designee shall be the Sponsor and have the operational responsibility for the Exelixis Local Development Work.

4.7 Data Exchange and Use.

(a) General. In addition to its adverse event and Safety Data reporting obligations pursuant to Section 5.5, each Party shall promptly provide the other Party with (i) [*] status reports on trial recruitment and other metrics consistent with the performing Party's internal reporting for clinical studies and Development activities, provided however that in case of unexpected events that may have any impact on safety, (such case will be elaborated and defined in Pharmacovigilance Agreement), each Party shall inform the other Party within [*] from knowledge of the occurrence of such event; (ii) supporting documentation (e.g. protocols, case report forms, analysis plans, etc.); (iii) preliminary and final Data, and interim, preliminary, and final results and reports; and (iv) output from advisory committees and investigator meetings, any and all such documentation generated by each Party (including by any Sublicensee or licensee) from its Development activities under this Agreement as such documentation could reasonably be deemed to affect the Development or Commercialization activities of the Product in each Party's territory. As time may be of the essence, each Party shall collaborate in good faith in the exchange of any such Data set forth in this Section within [*] of receipt. The Parties shall cooperate on a secure website to facilitate the sharing of reports, Data, and

other information on a routine basis. Except as set forth in Section 4.7(b) below, each Party shall have the right to use and reference, without additional consideration, any and all Data generated by or on behalf of the other Party (including by any Sublicensee or other licensee) under this Agreement for obtaining and maintaining Regulatory Approval for the Products and otherwise Commercializing the Products in its territory in accordance with the terms of this Agreement. For clarity, this Section 4.7(a) shall apply to any and all Data generated in the Development under the GDP, including Independent Work (but subject to Section 4.7(b) below), Exelixis Local Development Work, and Collaborator Local Development Work. Notwithstanding the foregoing, should either Party fail to obtain such use and reference rights entirely from any Sublicensee or other licensee, such Party shall not have the right to grant use and access or rights to such Sublicensee or other licensee to any corresponding documentation for which such Party failed to obtain such right listed in this Section 4.7(a) generated by or on behalf of the other Party.

(b) Independent Work. Notwithstanding the foregoing, the Party receiving Data resulting from the other Party's Independent Work shall have the right to use such Data only to the extent reasonably necessary for the receiving Party to comply with its regulatory reporting and compliance obligations, including safety reporting obligations, but shall not have the right to use such Data to support its own Development, Regulatory Approval, or Commercialization except pursuant to Section 8.2(b).

4.8 Diligence. Each Party shall use Commercially Reasonable Efforts to perform the Development activities assigned to such Party under and in accordance with the GDP. In addition, consistent with the GDP, Collaborator shall use Commercially Reasonable Efforts to perform Collaborator Local Development Work and any Collaborator Independent Work, file MAAs and seek and maintain Regulatory Approval (including Pricing and Reimbursement Approval, as applicable) for the Products in the Collaborator Territory.

4.9 Compliance. Each Party shall Develop the Compound and Products in compliance with all Applicable Laws, including good scientific and clinical practices under the Applicable Laws of the country in which such activities are conducted.

4.10 Development Records. Each Party shall maintain complete, current, and accurate records of all Development activities conducted by it hereunder, and all Data and other information resulting from such activities. Such records shall fully and properly reflect all work done and results achieved in the performance of the Development activities in good scientific manner appropriate for regulatory and patent purposes. Each Party shall document all non-clinical studies and Clinical Trials in formal written study reports according to Applicable Laws and national and international guidelines (e.g., ICH, cGCP, cGLP, and cGMP).

4.11 Development Reports. At [*] JDC meeting, each Party shall provide the JDC with regular reports detailing its Development activities for the Products under this Agreement, and the results of such activities. In addition, after the completion of any Clinical Trial or other study of the Products, the Party responsible for the conduct of such Clinical Trial or study shall provide the other Party with a data package consisting of, at a minimum, tables, lists, and figures, as well as any other Data specified in the GDP or otherwise agreed by the Parties, within [*] following the completion of such data package. The Parties shall discuss the status, progress, and results of each Party's Development activities under this Agreement at such JDC meetings.

4.12 Use of Subcontractors. Each Party may perform its Development activities under this Agreement through one or more subcontractors, provided that (a) such Party will remain responsible for the work allocated to, and payment to, such subcontractors to the same extent it would if it had done such work itself; (b) each subcontractor undertakes in writing obligations of confidentiality and non-use regarding Confidential Information that are substantially the same as those undertaken by the Parties pursuant to Article 13, and (c) each subcontractor agrees in writing to assign all intellectual property developed in the course of performing any such work to such Party (or, in the event such assignment is not feasible, a license to such intellectual property with the right to sublicense to such other Party). The Parties may also subcontract work on terms other than those set forth in this Section 4.12 with the prior written approval of the JDC.

4.13 Restrictions. After the Effective Date and during the Term, neither Party nor any of its Affiliates or (sub)licensees shall, directly or through any Third Party, sponsor, conduct, or cause to be conducted, otherwise assist in, supply any Product for use in connection with, or otherwise fund: (a) any Development of any Product outside the scope of the GDP; or (b) comparative studies of its product versus the Product outside the scope of the GDP. For clarity and without limiting the foregoing, except as expressly approved by the JDC and included in the GDP, Collaborator shall not perform or sponsor any study or test on the Compound or Products, including any pre-clinical or non-clinical study, toxicology study, or CMC-related study, or seek to modify or create the Compound or any analog thereof.

4.14 Materials Transfer. In order to facilitate the Development activities contemplated by this Agreement, either Party may provide to the other Party certain biological materials or chemical compounds Controlled by the supplying Party (collectively, "**Materials**") for use by the other Party in furtherance of such Development activities. Except as otherwise provided for under this Agreement, all such Materials delivered to the other Party will remain the sole property of the supplying Party, will be used only in furtherance of the Development activities conducted in accordance with this Agreement, will not be used or delivered to or for the benefit of any Third Party, except to subcontractors permitted in Section 4.12, without the prior written consent of the supplying Party, and will be used in compliance with all Applicable Laws. The Materials

supplied under this Agreement must be used with prudence and appropriate caution in any experimental work because not all of their characteristics may be known. Except as expressly set forth in this Agreement, THE MATERIALS ARE PROVIDED "AS IS" AND WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE OF THE MATERIALS WILL NOT INFRINGE OR VIOLATE ANY PATENT OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY.

5. REGULATORY ACTIVITIES

5.1 Regulatory Responsibilities.

(a) General.

(i) The GDP shall set forth the regulatory strategy for seeking Regulatory Approval for the Compound and Products by the appropriate Regulatory Authorities in the Collaborator Territory and Exelixis Territory. Unless otherwise necessary for global registration requirements, Collaborator shall apply for and hold Regulatory Filings in the Collaborator Territory with respect to the conduct of Development activities. Subject to the direction and oversight of the JDC, each Party shall be responsible for implementing such regulatory strategy in its territory. Except as otherwise provided herein or required by Applicable Law, each Party shall be responsible for the preparation and submission of any and all Product registrations and marketing approvals in its territory and shall own and hold all such Regulatory Filings (including Regulatory Approvals), and neither Party shall submit any application for Product registration or marketing approval in the other Party's territory.

(ii) Each Party shall be responsible for the cost and expense of all regulatory activities in connection with obtaining or maintaining Regulatory Approval of Products in its territory.

(iii) Collaborator acknowledges that Exelixis may be required to communicate with Regulatory Authorities in the Collaborator Territory as a result of manufacturing activities for the Collaborator Territory. Exelixis shall notify Collaborator as soon as reasonably possible of such communication with Regulatory Authorities and seek to incorporate input from Collaborator in preparation for such communication. Exelixis shall then keep Collaborator informed of any such communications.

(b) Transfer of Regulatory Filings. Exelixis shall provide, promptly after the execution of this Agreement, to Collaborator a copy of all the IND for the Product for the Collaborator Territory submitted to the PMDA, which IND the Parties acknowledge is, as of the Effective Date, closed and inactive in the Collaborator

Territory. Collaborator shall have a right to use and/or reference such IND in connection with Collaborator's Development and regulatory activities under this Agreement.

5.2 Regulatory Information Sharing. To the extent that such Regulatory Filings that relate to the activities in the requesting Party's territory, each Party shall, upon the other Party's reasonable request, promptly provide the other Party (but in no event more than [*]) with copies of Regulatory Filings prepared (including any drafts and supporting information), submitted or received by such Party in the Exelixis Territory including the U.S. and the Collaborator Territory pertaining to the Compound and Products, and such other Party shall have the right to review and comment on drafts of such Regulatory Filings, provided that such review and comment shall not delay the submission of any Regulatory Filings. The sharing of Regulatory Filings shall include any communications/correspondence with the Regulatory Authority regarding label changes, IND annual reports and cover letters, and documents related to regulatory milestones and dates (e.g., submissions and validations). If any Regulatory Filing to be provided under this Section 5.2 was originally created in a language other than the English language, then at the receiving Party's request and to the extent already existing and readily available, the providing Party shall provide an English translation along with the original document to the receiving Party. The Parties acknowledge that it is their intent to collaborate in good faith in the exchange of such Regulatory communications including with any Sublicensee or other Exelixis licensee. Each of Collaborator and Exelixis shall reasonably endeavor to grant access and rights for the other Party to use any such communications with any Regulatory Authority generated by or on behalf of any Sublicensee or other Exelixis licensee, respectively. For clarity, a Party's provision to the other Party of copies of Regulatory Filings prepared, submitted, or received in each Party's territory is expressly conditioned upon the receiving Party granting to the providing Party the right to share with the providing Party's own licensee for its territory copies of any and all Regulatory Filings prepared, submitted, or received by the receiving Party in its territory. Should either Party fail to obtain such access and rights from any Sublicensee or Exelixis licensee, such Party shall not have the right to grant access or rights to such Sublicensee or other Exelixis licensee to any such communications with any Regulatory Authority generated by or on behalf of the other Party.

5.3 Meetings with Regulatory Authorities. On a current and ongoing basis, each Party shall provide the other Party with a list and schedule of any significant in-person meeting or teleconference with the Regulatory Authorities (or related advisory committees) in the Collaborator Territory planned for the next [*] that relates to the Development of the Compound and Products under the GDP in the Collaborator Territory (each, a "**Regulatory Meeting**"). In addition, each Party shall notify the other Party as soon as reasonably practicable if such Party becomes aware of any additional Regulatory Meetings that become scheduled for such [*] and will keep the other Party informed of any significant interface or communication with any Regulatory Authority which is reasonably expected to affect efforts to obtain Regulatory Approval for the Product in its respective territory. Collaborator shall be solely responsible for any communications

with the Regulatory Authorities occurring or required in connection with performing its regulatory responsibilities set forth in this Article 5 with respect to the Product in the Collaborator Territory, and Exelixis shall have the right to provide input in preparation for all Regulatory Meetings and the right, but not the obligation, to have its representatives attend (but, unless otherwise requested by Collaborator, not participate in) the Regulatory Meetings. Collaborator shall have these same rights with respect to any such Regulatory Meetings in the Collaborator Territory before such Regulatory Filings are transferred to Collaborator under Section 5.1(b).

5.4 Regulatory Inspections. Collaborator shall permit the Regulatory Authority(ies) in the Exelixis Territory to conduct inspections of Collaborator, its Affiliates, Sublicensees, or subcontractors (including Clinical Trial sites) relating to Product Development under the GDP or the Finished Manufacture of the Finished Product, and shall ensure that such Affiliates, Sublicensees, and subcontractors permit such inspections. In addition, Collaborator shall promptly notify Exelixis of any such inspection and shall supply Exelixis with all information pertinent thereto. Exelixis shall have the right, but not the obligation, to attend any such inspection with the presence of Collaborator. Exelixis shall permit the Regulatory Authority(ies) in the Collaborator Territory to conduct inspections of Exelixis, its Affiliates, and its sublicensees or subcontractors (including Clinical Trial sites) relating to Product Development under the GDP for the Collaborator Territory, and shall ensure that such Affiliates, sublicensees, and subcontractors permit such inspections. In addition, Exelixis shall promptly notify Collaborator of any such inspection and shall supply Collaborator with all information pertinent thereto. Collaborator shall have the right, but not the obligation, to attend any such inspection with the presence of Exelixis.

5.5 Pharmacovigilance and Adverse Event Reporting.

(a) Pharmacovigilance Agreement. Within [*] after the Effective Date, but in any case prior to the Initiation of a Clinical Trial for the Product in the Collaborator Territory, the Parties shall enter into a pharmacovigilance agreement setting forth the worldwide pharmacovigilance procedures for and responsibilities of the Parties with respect to the Products, such as Safety Data sharing, adverse events reporting, and safety signal and risk management (the "**Pharmacovigilance Agreement**"), which agreement shall be amended by the Parties [*] to comply with any changes in Applicable Laws or any guidance received from Regulatory Authorities. Such procedures shall be in accordance with, and enable the Parties to fulfill, local and national regulatory reporting obligations under Applicable Laws.

(b) Global Safety Database. Exelixis has established and shall continue to hold, at its expense, the Product global safety database, and shall maintain such global safety database for so long as such Product is under Development and/or Commercialization hereunder. Exelixis will ensure that each Party is able to access the Safety Data, if necessary indirectly, from the global safety database in order to meet legal

and regulatory obligations. For the Collaborator Territory, the Parties will agree on data cut points for periodic aggregate safety reports, Exelixis will author such reports, including the integrated data sets, the Parties will jointly review and approve such reports, and Collaborator will generate final versions of the reports for submission in accordance with regulatory requirements in the Collaborator Territory. If the PMDA requires any additional reports, Collaborator shall prepare such reports for submission to the PMDA, consulting with Exelixis as practicable and appropriate and, upon Exelixis' reasonable request, providing to Exelixis a copy (in English) of any such report.

(c) PV Costs. As between the Parties, Exelixis shall be responsible for the cost and expense incurred by Exelixis for establishing and maintaining such global safety database and the preparation of periodic aggregate safety reports that are specifically directed (or reasonably allocable) to the Product (the "**PV Costs**") prior to [*]. For the period of time commencing upon [*] until [*], Exelixis shall be responsible for [*] of PV Costs and Collaborator shall be responsible for [*] of PV Costs. Thereafter, Exelixis shall be responsible for [*] of PV Costs and Collaborator shall be responsible for [*] of PV Costs.

(d) PV Governance. The JDC shall establish a safety subcommittee and all Safety Data, including adverse event reports, shall be submitted to such safety subcommittee and Exelixis concurrently so that Exelixis may update the global safety database accordingly. Such safety subcommittee shall coordinate with respect to any Safety Data reporting for the Product to Regulatory Authorities in the Collaborator Territory, but Collaborator shall be primarily responsible for (i) reporting quality complaints, adverse events, and Safety Data related to the Products, and all case processing of adverse events, to applicable Regulatory Authorities in the Collaborator Territory, and (ii) responding to safety issues and to all requests of Regulatory Authorities in the Collaborator Territory related to the Products, in each case at its own expense. Collaborator shall have the right to use, at its own expense, a safety database owned by Collaborator for the purpose of tracking and reporting quality complaints, adverse events, and Safety Data related to the Products in the Collaborator Territory; provided, however, that such right shall not relieve Collaborator of its obligation to communicate all such information directly to the safety subcommittee and Exelixis. Each Party agrees to comply with its respective obligations under the Pharmacovigilance Agreement and to cause its Affiliates, licensees, and sublicensees to comply with such obligations.

5.6 No Harmful Actions. If a Party believes that the other Party is taking or intends to take any action with respect to a Product that could reasonably be expected to have a material adverse impact upon the regulatory status of such Product in the first Party's territory, then such Party may bring the matter to the attention of the JDC and the Parties shall discuss in good faith to resolve such concern.

5.7 Notification of Threatened Action. Each Party shall notify the other Party within [*] of any information it receives regarding any threatened or pending

action, inspection, or communication by any Regulatory Authority, which may affect the safety or efficacy claims of any Product or the continued Development or Commercialization of any Product. Upon receipt of such information, the Parties shall promptly consult with each other in an effort to arrive at a mutually acceptable procedure for taking appropriate action.

5.8 Right of Reference to Regulatory Materials. Each Party hereby grants to the other Party the right of reference to all Regulatory Filings pertaining to the Compound and Products submitted by or on behalf of such Party. The receiving Party may use such right of reference solely for the purpose of seeking, obtaining, and maintaining Regulatory Approval of the Products for use in its territory in accordance with this Agreement. Notwithstanding the foregoing, the receiving Party has such right of reference to any Regulatory Filings based on Data resulting from the other Party's Independent Work only to comply with its safety reporting obligations, unless the receiving Party pays the other Party for such work as set forth in Section 8.2(b).

5.9 Recalls. In the event that a recall, withdrawal, or correction (including the dissemination of relevant information) of any Product in a Party's territory is required by a Regulatory Authority of competent jurisdiction, or if any Regulatory Authority requires or advises either Party or such Party's Affiliates or sublicensees to distribute a "Dear Doctor" letter or its equivalent regarding use of such Product in a Party's territory, or if a recall, withdraw, or correction of a Product in its territory is deemed advisable by such Party in its sole discretion, such Party shall so notify the other Party no later than [*] in advance of the earlier of (i) initiation of a recall, withdrawal, or correction; or (ii) the submission of plans for such an action to a Regulatory Authority. Any such recall, withdrawal, correction, or dissemination of information (e.g., "Dear Doctor" letter) shall be referred to herein as a "**Recall**". Promptly after being notified of a Recall, each Party shall provide the other Party with such assistance in connection with such Recall as may be reasonably requested by such other Party. All costs and expenses in connection with a Recall in a Party's territory shall be paid by such Party, including without limitation the costs and expenses related to the dissemination of relevant information. Each Party shall handle exclusively the organization and implementation of all Recalls of Products in its territory. Notwithstanding the foregoing, any Recall related to the manufacture and supply of the Product by Exelixis to Collaborator shall be governed by the terms and conditions of the Parties' applicable Supply Agreement and the Quality Agreement.

5.10 Sunshine Reporting Laws. Each Party acknowledges that the other Party may be subject to federal, state, local, international, industrial and internal laws, regulations, rules and guidelines related to the tracking and reporting of payments and transfers of value provided to health care professionals, health care organizations, and other relevant individuals and entities (collectively, "**Sunshine Reporting Laws**"), and agrees to provide the other Party with all information regarding such payments or transfers of value by such Party as necessary for such other Party to comply in a timely manner with its reporting obligations under the Sunshine Reporting Law.

6. COMMERCIALIZATION

6.1 General. Subject to the terms and conditions of this Article 6, Collaborator shall have the sole and exclusive responsibility, at its own expense, for all aspects of the Commercialization of the Products in the Collaborator Territory, including: (a) developing and executing a commercial launch and pre-launch plan, (b) negotiating with applicable Governmental Authorities and other payors regarding the price and reimbursement status of the Products; (c) marketing and promotion; (d) booking sales and distribution and performance of related services; (e) handling all aspects of order processing, invoicing, and collection, inventory and receivables; (f) providing customer support, including handling medical queries, and performing other related functions; and (g) conforming its practices and procedures to Applicable Laws relating to the promotion, sales and marketing, access, and distribution of the Products.

6.2 Commercialization Plan. No later than [*], Collaborator shall prepare and present to the JCC a Commercialization plan for Products in the Collaborator Territory, including a reasonably detailed description and an anticipated timeline for Collaborator's significant Commercialization activities for the Products for the next [*] the plan will include, at a minimum, a reasonably detailed description of the activities contemplated by Sections 6.4 through 6.7 (the "**Commercialization Plan**"). Collaborator shall update and amend the Commercialization Plan periodically ([*]) and shall present such updates and amendments to the JCC for review and discussion. Without limiting the provisions of this Section 6.2, through the JCC, Collaborator shall consult with and provide updates to Exelixis regarding strategy and tactics for Commercialization of Products in the Collaborator Territory. Subject to the provisions of this Agreement and compliance with the Commercialization Plan, Collaborator shall have full control and authority with respect to the day-to-day Commercialization of the Products and implementation of the Commercialization Plan.

6.3 Diligence.

(a) General. During the Term, Collaborator shall use Commercially Reasonable Efforts to Commercialize the Products for all indications that have received or will receive Regulatory Approval throughout the Collaborator Territory. In addition, and without limitation of the foregoing, Collaborator shall, as soon as possible following each MAA Approval(s), launch the Product for such indication and obtain all necessary Price and Reimbursement Approvals. Thereafter, Collaborator shall utilize Commercially Reasonable Efforts in the ongoing support for the Product in the Collaborator Territory.

(b) Minimum Commercial Performance. In addition to the foregoing general commitments, Collaborator shall also achieve for the first six (6) full Calendar Years following the First Commercial Sale of the Product in the Collaborator Territory (the "**Minimum Commercial Performance Period**") (i) a minimum annual sale volume based on the aggregate sales forecast for the Collaborator Territory, and (ii)

minimum annual promotional and sales force requirements for the Collaborator Territory, for each Calendar Year as set forth in the table below ((i) and (ii) collectively, the "**Minimum Commercial Performance**"). The Minimum Commercial Performance for the First Full Calendar Year shall be determined by [*], and set forth in the first Commercialization Plan. Thereafter during the Minimum Commercial Performance Period, the Minimum Commercial Performance will be updated [*], to reflect any changes in the timing of Regulatory Approvals and the First Commercial Sale of a Product for each approved indication in the Collaborator Territory as well as actual experience and competitive conditions then prevailing.

Full Calendar Year	**Sales Volume Minimum**	**Promotional Efforts Minimum**
1	[*]	[*]
2	[*]	[*]
3	[*]	[*]
4	[*]	[*]
5	[*]	[*]
6	[*]	[*]

For clarity, for the [*], the sales volume and promotional effort minimums set forth in the table above will be non-binding and solely for planning purposes and of no effect under this Agreement. For the [*], Collaborator shall be required to achieve either the sales volume minimum or the promotional efforts minimum, but not both. For the [*], Collaborator shall be required to achieve the sales volume minimum only. Collaborator's failure to achieve Minimum Commercial Performance for any [*] Calendar Years during the Minimum Commercial Performance Period (excluding the [*]) shall be considered a material breach of this Agreement, giving rise to Exelixis' right to terminate the Agreement pursuant to Section 14.2(a) as a sole and exclusive remedy for Exelixis regarding such material breach of Collaborator. For the purpose of this Section 6.3(b), "**First Full Calendar Year**" means the period commencing on the January 1st following the date of the First Commercial Sale of the Product in the Collaborator Territory and ending on December 31st of such Calendar Year. For example, if the First Commercial Sale of the Product occurs in August 2021, the First Full Calendar Year begins on January 1, 2022 and ends on December 31, 2022.

(c) Commercial Updates. Collaborator shall update the JCC on a [*] basis regarding its Commercialization activities with respect to the Products in the Collaborator Territory. Each such update shall be in a form to be agreed by the JCC and shall summarize Collaborator's, its Affiliates', and Sublicensees' significant Commercialization activities with respect to the Products in the Collaborator Territory, and shall contain at least such information at such level of detail reasonably required by Exelixis to determine Collaborator's compliance with its diligence obligations set forth herein. Such updates shall include Collaborator's sales activities, marketing activities, and Medical Affairs Activities.

6.4 Coordination of Commercialization Activities.

(a) Generally. The Parties recognize that their collaboration may benefit from the coordination of certain activities in support of the Commercialization of Products in both the Collaborator Territory and the Exelixis Territory. As such, the JCC shall review Collaborator's Commercialization strategies for the Product in the Collaborator Territory (e.g., branding and messaging, international congresses, national- or global-level advisory boards) in order to provide input and drive consistency with those Commercialization strategies for the Product in the Exelixis Territory that have proven successful. For clarity, (i) the foregoing sentence shall not be construed as limiting Collaborator's rights under Section 3.5, and (ii) Exelixis shall not be obligated to seek Collaborator's consent in connection with the establishment and/or implementation of any sales, marketing, or medical affairs practices in the Exelixis Territory.

(b) List Price and Pricing for Combination Products. Collaborator shall keep Exelixis timely informed on the status of any application for Pricing and Reimbursement Approval or material updates to an existing Pricing and Reimbursement Approval in the Collaborator Territory, including any discussion with a Regulatory Authority with respect thereto, via the JCC. Collaborator and its Affiliates and Sublicensees shall not sell any Product [*], as part of [*], or as [*], or offer [*] to customers that include a Product, in such a manner as to disproportionately discount the selling price of the Product [*]. For clarification, should Collaborator derive direct economic benefit from the sale of another pharmaceutical product that is approved to be used in combination with the Product, [*].

(c) Sharing of Promotional Materials. Collaborator shall, at its own expense, prepare, develop, produce, or otherwise obtain and utilize sales, promotional, advertising, marketing, website, educational, and training materials (the "**Promotional Materials**") to support its Commercialization activities in the Collaborator Territory. The Parties shall share samples of Promotional Materials (including English translation, if such materials are not in the English language) with respect to and for use in the Commercialization of the Products with one another. Additional materials, including medical education and medical information, sales force and sales force training materials, will be made available to the other Party upon reasonable request.

(d) Commercialization in Exelixis Territory. Subject to the terms and conditions of this Agreement, Exelixis shall have the exclusive right to Commercialize the Product in the Exelixis Territory at its own cost and expense, with or without Third Party(ies).

6.5 Detailing and Promotion.

(a) Collaborator shall have the right to engage Third Party contract sales representatives to help with the promotion of the Product in the Collaborator Territory without prior written JCC approval, provided that in no event shall the total number of such contract sales representatives exceed [*] of the total sales representatives provided in support of the Product in the Collaborator Territory at any given [*] during the Royalty Term without prior written JCC approval. If Collaborator elects to engage Third Party contract sales representatives in accordance with this Section 6.5(a), it shall inform the JCC in reasonable detail of the number of contract sales representatives to be provided. All Third Party contract sales representatives engaged by Collaborator shall have at least, but in no event less than, the same or similar level of experience, capabilities, and training as Collaborator's in-house sales representatives for the Product.

(b) Collaborator shall not use the same sales force to promote or detail the Product and a separate product that is [*] (except in the case [*]). If Collaborator desires to use the same sales force to promote or detail the Product and a separate product that is [*], Collaborator shall indicate such desire to Exelixis and Exelixis shall, in its sole discretion, determine whether to permit such sales force to promote or detail both the Product and such other product.

6.6 Medical Affairs Activities.

(a) Collaborator shall lead and conduct all Medical Affairs Activities for the Product in the Collaborator Territory in accordance with the medical affairs portion of the GDP, provided, however, that medical affairs publications and medical information activities shall be subject to Section 13.4. Exelixis will not undertake any Medical Affairs Activities in the Collaborator Territory without prior coordination with and consent of Collaborator, such consent not to be unreasonably withheld.

(b) To the extent practicable, Collaborator shall provide Exelixis with written notice at least [*] in advance of any national-level advisory panel meetings with key opinion leaders regarding the Development or Commercialization of the Products in the Collaborator Territory. If requested by Exelixis, Collaborator shall provide Exelixis with a written summary (in English) of such meetings.

6.7 Diversion. Each Party hereby covenants and agrees that it and its Affiliates shall not, and it shall contractually obligate (and use Commercially Reasonable Efforts to enforce such contractual obligation) its sublicensees not to, directly or

indirectly, promote, market, distribute, import, sell, or have sold any Product, including via the Internet or mail order, to any Third Party or to any address or Internet Protocol address or the like in the other Party's territory. Neither Party shall engage, nor permit its Affiliates and sublicensees to engage, in any advertising or promotional activities relating to any Product for use directed primarily to customers or other buyers or users of such Product located in any country or jurisdiction in the other Party's territory, or solicit orders from any prospective purchaser located in any country or jurisdiction in the other Party's territory. If a Party or its Affiliates or sublicensees receives any order for a Product for use from a prospective purchaser located in a country or jurisdiction in the other Party's territory, such Party shall immediately refer that order to such other Party and shall not accept any such orders. Neither Party shall, nor permit its Affiliates and sublicensees to, deliver or tender (or cause to be delivered or tendered) any Product for use in the other Party's territory.

7. MANUFACTURE AND SUPPLY.

7.1 Manufacture and Supply. Exelixis, through one or more Third Party contract manufacturers, will provide all Supplied Product for use in the Development and Commercialization of the Products under this Agreement. All Supplied Product supplied by Exelixis to Collaborator shall be at a price equal to [*]. During the Term, Exelixis shall use Commercially Reasonable Efforts to [*]. If [*] for particular Supplied Product is reasonably expected to exceed [*] per tablet of any dose strength, Exelixis shall inform Collaborator promptly, and discuss with Collaborator in good faith a reasonable mitigation plan to reduce [*]. Exelixis (through one or more Third Party contract manufacturers) shall be exclusively responsible for the supply of Supplied Product to Collaborator and Collaborator shall be exclusively responsible, at its expense, for the Finished Manufacture of the Finished Product. [*] of the Supplied Product used in the Development work under the GDP shall be included in the Development Cost and shared by the Parties in accordance with Section 4.5. Exelixis shall source such Supplied Product supply for both Parties either from a facility owned by Exelixis or from a reputable, qualified, and certified Third Party and, in the event that Collaborator is responsible for conducting any Clinical Studies pursuant to Section 4.2 or 4.3, Exelixis shall provide such supply to Collaborator for such Clinical Studies in accordance with the GDP. As soon as reasonably practicable after the Effective Date, but in any event prior to the initial supply of the Supplied Product to Collaborator for use in Development work, the Parties shall enter into supply agreements for the manufacture and supply of the Supplied Product to Collaborator for use in Development or Commercialization activities (each, a "**Supply Agreement**"), and a Quality Agreement setting forth in detail the quality assurance arrangements and procedures for Exelixis' manufacture of Supplied Product (the "**Quality Agreement**"). Exelixis shall, upon Collaborator's reasonable request, allow Collaborator to access Exelixis and/or its manufacturing facility of the Supplied Product, as applicable, for the purpose of regulatory and Collaborator's reasonable in-house auditing.

8. FINANCIAL PROVISIONS

8.1 Upfront Payment. Collaborator shall make a one-time, non-refundable, non-creditable upfront payment to Exelixis of fifty million U.S. dollars ($50,000,000) within five (5) Business Days after the Effective Date.

8.2 Sharing/Reimbursements of Development Costs and PV Costs.

(a) Future Development Costs. No later than [*] after the beginning of each Calendar Quarter during which a Party will perform any Collaborative Work in such Calendar Quarter pursuant to the GDP, such Party shall submit to the other Party a statement setting forth the Development Costs incurred, including the other Party's share (calculated in accordance with Section 4.5) of (i) estimated Development Costs for the then current quarter; (ii) variances from prior invoiced estimates and actual Development Costs; and (iii) Development Costs incurred by or on account of such Party in the past quarter not previously invoiced. Such invoice shall include a reasonably detailed report for such Development Costs, including supporting documents. To the extent provided in Section 4.5, the other Party shall pay the amount invoiced within [*] after the receipt of the invoice. For clarity, making such a payment does not preempt the paying Party's audit rights under Section 9.4, which remain in full force and effect. If both Parties will perform Development activities under the GDP in such Calendar Quarter, the Parties shall consolidate the payments for such Calendar Quarter into a single payment from one Party to the other Party.

(b) Independent Work. Subject to Section 4.7(b), and except as set forth below in this Section 8.2(b), each Party shall bear all the internal (calculated on an FTE basis using the then current FTE Rate) and reasonable out-of-pocket expenses incurred by or on account of such Party in performing its own Independent Work (the "**Independent Work Costs**"). After the completion of such Independent Work, such Party shall provide the other Party with a report of such Independent Work Costs. If a Party desires to submit any portion of the Data resulting from any Independent Work conducted by the other Party and related Regulatory Filings generated by the other Party to support Regulatory Approval in its territory, then such Party shall notify the other Party in writing at any time upon the completion of such Independent Work. Within [*] after its receipt of such notice, the Party conducting or having conducted such Independent Work shall submit to the other Party a reasonably detailed invoice setting forth [*] of the Independent Work Costs that would have been incurred by or on account of such other Party in connection with the generation of such Data under Section 8.2(b) as if such Independent Work Costs were Development Costs with respect to Collaborative Work. If the Party seeking to use such Data decides to use such Data to support Regulatory Approval in its territory, then such Party shall notify the other Party in writing and pay the amount invoiced (i.e., if Collaborator seeks to use the Data resulting from Exelixis' Independent Work, twenty percent (20%) of [*] of the Independent Work Costs) within [*] after the receipt of such invoice. For clarity, making such a payment does not

preempt the paying Party's audit rights under Section 9.4, which remain in full force and effect.

(c) Internal Development Cost. Each Party shall record and calculate its internal Development Costs with respect to Collaborative Work and/or its Independent Work on an FTE basis at the FTE Rate.

(d) Development Cost for Products in Combination. If the Parties agree to Develop a Product under this Agreement in combination with [*] (the "**Beneficial Party**"), either as a combination product or combination therapy, then such Development work shall be conducted in accordance with the GDP and the Development Costs with respect to such Development shall be included in the Development Budget, provided that only [*] of the Development Cost with respect to such Development shall be subject to the Parties' cost sharing under Section 8.2(b) and the Beneficial Party shall be solely responsible for the other [*] of the Development Costs.

(e) PV Costs Following Initiation of Clinical Trials. Following the Initiation of the first Clinical Trial in the Collaborator Territory, no later than [*] after the beginning of each Calendar Quarter, Exelixis shall submit to Collaborator a statement setting forth the PV Costs incurred, including Collaborator's share (calculated in accordance with Section 5.5) of (i) estimated PV Costs for the then current quarter; (ii) variances from prior invoiced estimates and actual PV Costs; and (iii) PV Costs incurred by or on account of Exelixis in the past quarter not previously invoiced. Such invoice shall include a reasonably detailed report for such PV Costs, including supporting documents. To the extent provided in Section 5.5, Collaborator shall pay the amount invoiced within [*] after the receipt of the invoice. For clarity, making such a payment does not preempt Collaborator's audit rights under Section 9.4, which remain in full force and effect.

8.3 Development Milestone Payments.

(a) Development Milestones. Subject to the remainder of this Section 8.3, Collaborator shall pay to Exelixis the non-refundable, non-creditable payment set forth in the table below upon the achievement of the applicable milestone event (whether by or on behalf of Collaborator, Exelixis, or their Affiliates, licensee(s) of Exelixis, or Sublicensees):

Milestone Event	Milestone Payments				
	For RCC (2nd line)	For RCC (1st line)	For HCC (2nd line)	Tier 1 Indications	Tier 2 Indications
Milestone #1: Upon [*] the first Phase 3 Clinical Trial for the Product in the Collaborator Territory	[*]	$[*]	[*]	$[*]	$[*]
Milestone #2: Upon [*] the first MAA for the Product in the Collaborator Territory	$[*]	$[*]	$[*]	$[*]	$[*]
Milestone #3: Upon First Commercial Sales for the Product in the relevant indication in the Collaborator Territory	$[*]	$[*]	$[*]	$[*]	$[*]

(i) For RCC (2nd line), RCC (1st line), and HCC (2nd line), each milestone payment shall be paid only once for the first applicable events described above for each different applicable Product.

(ii) Milestone #1 shall be deemed achieved and payable, if not already achieved, upon achievement of any of Milestone #2 and/or Milestone #3 for the same indication. Milestone #2 shall be deemed achieved and payable, if not already achieved, upon achievement of Milestone #3 for the same indication.

(iii) Without limiting the foregoing, with respect to RCC (1st line) and RCC (2nd line), if Milestone #3 is achieved for RCC (1st line) prior to being achieved for RCC (2nd line), then Milestone #3 for RCC (2nd line) shall be deemed achieved and payable upon achievement of Milestone #3 for RCC (1st line), except if Collaborator is, at the time of such achievement, diligently engaged in the performance of Development or regulatory activities with respect to Products for the express purpose of achieving Milestone #3 for both RCC (1st line) and RCC (2nd line), in which case Milestone #3 for RCC (2nd line) shall not be deemed achieved and payable unless and until achieved by a Product for RCC (2nd line).

(b) Notice and Payment. Each Party shall notify the other Party in writing within [*] after the achievement of any milestone set forth in this Section 8.3 by such Party, its Affiliates, licensee(s) of Exelixis, or Sublicensees. Collaborator shall pay to Exelixis the applicable development milestone payments within [*] after the delivery or receipt of such notice.

8.4 Sales-Based Milestones Payments.

(a) Sales Milestones. Collaborator shall pay to Exelixis the one-time, non-refundable, non-creditable payments set forth in the table below when the aggregated Net Sales of all Products in the Collaborator Territory in any period of four (4) consecutive Calendar Quarters first reach the values indicated in the table below. Once one of the values indicated in the table below is first reached and the corresponding Milestone Payment is paid by Collaborator under this Section 8.4 (the "**Previously Achieved Sales Milestone**"), the period of four (4) consecutive Calendar Quarters to be applied to determine the reaching of a subsequent Net Sales amount in the table below shall only start at the Calendar Quarter immediately following the fourth (4th) Calendar Quarter which served as the period to determine the reaching of the Net Sales amount triggering the Previously Achieved Sales Milestone. For the avoidance of any doubt, each payment in this Section 8.4(a) shall be payable once only, regardless of the number of times such milestone is achieved.

Aggregate Net Sales of all Products in the Collaborator Territory in any 4 consecutive Calendar Quarters	**Sales Milestone Payments**
Equal or exceed $[*]	$[*]
Equal or exceed $[*]	$[*]
Equal or exceed $[*]	$[*]
Equal or exceed $[*]	$[*]

(b) Notice and Payment. As part of the report in Section 9.1, Collaborator shall provide written notice to Exelixis upon the aggregated Net Sales of all Products in the Collaborator Territory in any four (4) consecutive Calendar Quarters first reaching the values set forth in Section 8.4(a) above, and Collaborator shall pay to Exelixis the corresponding sales milestone payment within [*] after the end of the Calendar Quarter.

(c) Cumulative Net Sales Milestones. Collaborator shall pay to Exelixis the one-time, non-refundable, non-creditable payments set forth in the table below when the cumulative Net Sales of all Products in the Collaborator Territory first reach the values indicated in the table below.

Cumulative Net Sales of all Products in the Collaborator Territory	Cumulative Net Sales Milestone Payments
Exceed $[*]	$[*]
Exceed $[*]	$[*]

(d) Notice and Payment. As part of the report in Section 9.1, Collaborator shall provide written notice to Exelixis upon the cumulative Net Sales of all Products in the Collaborator Territory first reaching the values set forth in Section 8.4(c) above, and Collaborator shall pay to Exelixis the corresponding cumulative Net Sales milestone payment within [*] after the end of the Calendar Quarter.

8.5 Royalty Payments.

(a) Royalty Rate. Subject to the other terms of this Section 8.5, during the Royalty Term, Collaborator shall make quarterly, non-refundable, non-creditable royalty payments to Exelixis on the annual Net Sales of all Products sold in the Collaborator Territory at the applicable rate set forth in the table below. For clarity, if the threshold in Section 8.5(b) is achieved in any Calendar Year, then the Net Sales for purposes of this Section 8.5(a) will commence on the date after which such threshold is achieved.

Annual Net Sales of all Products in the Collaborator Territory	Royalty Rate
Tier 1: Portion less than or equal to $[*]	20%
Tier 2: Portion greater than $[*] and less than or equal to $[*]	[*]%
Tier 3: Portion greater than $[*] and less than or equal to $[*]	[*]%
Tier 4: Portion greater than $[*] and less than or equal to $[*]	[*]%
Tier 5: Portion greater than $[*]	30%

(b) Initial Royalty Rate Adjustment Period. Notwithstanding Section 8.5(a), for the first three hundred million dollars ($300,000,000) of cumulative Net Sales of all Products sold in the Collaborator Territory, Collaborator shall make quarterly, non-refundable, non-creditable royalty payments to Exelixis on the Net Sales of all Products sold in the Collaborator Territory at the rates set forth in the table below. Thereafter, the royalty rate for all Net Sales shall be at the applicable rate set forth in Section 8.5(a).

Cumulative Net Sales of all Products in the Collaborator Territory	Royalty Rate
Tier 1: Portion less than or equal to $[*]	15%
Tier 2: Portion greater than $[*] and less than or equal to $[*]	[*]%
Tier 3: Portion greater than $[*] and less than or equal to $[*]	[*]%
Tier 4: Portion greater than $[*] and less than or equal to $[*]	24%

(c) Royalty Term. Royalties shall be paid on a Product-by-Product basis in the Collaborator Territory from the First Commercial Sale of such Product by or on behalf of Collaborator, its Affiliates, or Sublicensees, until the earlier of (i) two (2) years after the First Generic Entry with respect to such Product, and (ii) the later of (A) expiration of the last-to-expire Valid Claim of the Exelixis Patents, Joint Patents, and Collaborator Patents and (B) expiration of any Regulatory Exclusivity covering such Product in the Collaborator Territory (the "**Royalty Term**").

(d) Royalty Rate Adjustment for Collaborator Patents. If the Royalty Term extends beyond the expiration of the last-to-expire Valid Claim of the [*] Patents, and any Regulatory Exclusivity [*] (the "**Remaining Royalty Term**"), the

royalty rates to be paid by Collaborator to Exelixis during the Remaining Royalty Term shall be reduced by [*] of the amounts otherwise applicable under Section 8.5(a).

(e) Basis of Payment. This Section 8.5 is intended to provide for royalty payments to Exelixis equal to the percentages of Net Sales set forth in this Section 8.5 for the entire duration of the Royalty Term. In establishing this payment structure, Collaborator recognizes and acknowledges the substantial value of the various actions and investments that Exelixis has taken and will undertake under this Agreement, as well as the fact that the value of the license granted hereunder resides substantially in the Know-How. Therefore, Collaborator agrees that the royalty payments set forth above are appropriate for the entire duration of such payment obligation. The Parties have agreed to the payment structure set forth herein as a convenient and fair mechanism for both Parties to be compensated for the value of their actions and investments under this Agreement.

8.6 Exelixis Payments to Third Party. Exelixis shall be solely responsible for all payments, including royalties and milestone payments, due with respect to Compound and Products pursuant to any Third Party agreement that Exelixis entered into prior to or as of the Effective Date, including any obligations [*].

8.7 Supply Payments. Collaborator shall pay Exelixis for Compound, Drug Product, or Finished Product, as the case may be, Exelixis supplies to Collaborator an amount equal to [*], as applicable, all as provided in the applicable Supply Agreement.

9. PAYMENT; RECORDS; AUDITS

9.1 Payment; Reports. Royalty payments due by Collaborator to Exelixis under Section 8.5 shall be calculated and reported for each Calendar Quarter during the Royalty Term. Within [*] after the end of each month during the Royalty Term, Collaborator shall provide to Exelixis a preliminary report setting forth the gross amount of sales of the Products by Collaborator and its Affiliates and Sublicensees in the Collaborator Territory during such month. Within [*] after the end of each Calendar Quarter during the Royalty Term, Collaborator shall provide to Exelixis a preliminary report setting forth the estimated Net Sales of the Products by Collaborator and its Affiliates and Sublicensees in the Collaborator Territory during such Calendar Quarter. Within [*] after the end of each Calendar Quarter, Collaborator shall deliver to Exelixis all royalty payments due under Section 8.5. Each such payment shall be accompanied by a final report setting forth the Net Sales of the Products by Collaborator and its Affiliates and Sublicensees in the Collaborator Territory in such Calendar Quarter in sufficient detail to permit confirmation of the accuracy of the royalty payment made, including the number of Products sold, the gross sales and Net Sales of Products, including the deductions from gross sales to arrive at Net Sales, the royalties payable, the method used to calculate the royalties, the exchange rates used, and whether any commercial milestone under Section 8.4 has been achieved. Collaborator shall submit a single report for all Net

Sales during the Calendar Quarter, including all of Collaborator's and its Affiliates' and Sublicensees' Net Sales, but shall separately identify the Net Sales and other information applicable to each entity.

9.2 Exchange Rate; Manner and Place of Payment. All references to dollars and "$" herein shall refer to U.S. dollars. All payments hereunder shall be payable in U.S. dollars. With respect to conversion of Net Sales in Japanese yen to U.S. dollars, such conversion shall be at the exchange rate equal to the U.S. dollar conversion rate for the Japanese yen as published by [*]. All payments owed under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by Exelixis, unless otherwise specified in writing by Exelixis.

9.3 Taxes.

(a) Taxes on Income. Except as otherwise provided in this Section 9.3, each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the activities of the Parties under this Agreement.

(b) Tax Cooperation. The Parties agree to cooperate with one another and use reasonable efforts to avoid or reduce tax withholding, transfer taxes, or similar obligations with respect to milestone payments, royalty payments, and other payments made by Collaborator to Exelixis under this Agreement. To the extent Collaborator is required by Applicable Laws to deduct and withhold taxes on any payment to Exelixis, Collaborator shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to Exelixis an official tax certificate or other evidence of such payment sufficient to enable Exelixis to claim such payment of taxes. Exelixis shall provide Collaborator any tax forms that may be reasonably necessary in order for Collaborator to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty, to the extent legally able to do so. Exelixis shall use reasonable efforts to provide any such tax forms to Collaborator in advance of the due date provided that Exelixis may direct Collaborator to temporarily hold a payment otherwise payable in order to avoid withholding taxes if Exelixis is waiting for a required tax form to be issued by a Governmental Authority. Collaborator shall provide Exelixis with reasonable assistance to enable the recovery, as permitted by Applicable Laws, of withholding taxes, transfer taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of Exelixis. Each Party agrees to assist the other Party in claiming exemption from such deductions or withholdings under double taxation or similar agreement or treaty from time to time in force and in minimizing the amount required to be so withheld or deducted.

(c) Taxes Resulting From Collaborator's Action. Collaborator represents and warrants that, as of the Effective Date, (i) Collaborator is not required by Applicable Law to deduct or withhold taxes on the upfront payment, milestone payments,

royalty payments, and other payments payable to Exelixis under this Agreement and (ii) no transfer taxes will be imposed on the foregoing payments under the laws of Japan. If a Party takes any action of its own discretion (i.e., not required by a Regulatory Authority), including any assignment, sublicense, change of place of incorporation, or failure to comply with Applicable Laws or filing or record retention requirements, which results in a withholding or deduction obligation or a transfer tax (the "**Withholding Tax Action**"), then such Party shall pay the sum associated with such Withholding Tax Action. For clarity, if Collaborator undertakes a Withholding Tax Action, then the sum payable by Collaborator (in respect of which such deduction or withholding is required to be made) shall be increased to the extent necessary to ensure that Exelixis receives a sum equal to the sum that it would have received had no such Withholding Tax Action occurred. Otherwise, the sum payable by Collaborator (in respect of which such deduction or withholding is required to be made) shall be made to Exelixis after deduction of the amount required to be so withheld or deducted. If a change in Applicable Laws results in a withholding or deduction obligation absent either Party taking a Withholding Tax Action, then the amount of such withholding or deduction obligation shall be paid by Collaborator to the applicable Governmental Authority on behalf of Exelixis in accordance with the provisions of Section 9.3(b). The Parties shall use commercially reasonable efforts to invoke the application of any applicable bilateral income tax treaty that would reduce or eliminate otherwise applicable taxes with respect to payments payable pursuant to this Agreement.

9.4 Records; Audit. Each Party shall maintain complete and accurate records in sufficient detail in relation to this Agreement to permit the other Party to confirm the accuracy of the amount of Development Costs and the Cost of Goods to be reimbursed or shared, achievement of commercial milestones, and the amount of royalty and other payments under this Agreement. Each Party will keep such books and records for [*] following the Calendar Year to which they pertain, or such longer period of time as may be required by Applicable Laws. Upon reasonable prior notice, such records shall be inspected during regular business hours at such place or places where such records are customarily kept by an independent certified public accountant (the "**Auditor**") selected by the auditing Party and reasonably acceptable to the audited Party for the sole purpose of verifying for the auditing Party the accuracy of the financial reports furnished by the audited Party pursuant to this Agreement or of any payments made, or required to be made, by or to the audited Party pursuant to this Agreement. Before beginning its audit, the Auditor shall execute an undertaking acceptable to each Party by which the Auditor agrees to keep confidential all information reviewed during the audit. Such audits shall be limited to once each Calendar Year and once with respect to records covering any specific period of time. Such auditor shall not disclose the audited Party's Confidential Information to the auditing Party, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by the audited Party or the amount of payments to or by the audited Party under this Agreement. In the event that the final result of the inspection reveals an undisputed underpayment or overpayment, the underpaid or overpaid amount shall be settled within [*] after the Auditor's report. The

auditing Party shall bear the full cost of such audit unless such audit reveals an underpayment of more than [*] by the audited Party, in which case the audited Party shall reimburse the auditing Party for the costs of such audit.

9.5 Late Payments. In the event that any payment due under this Agreement is not paid when due in accordance with the applicable provisions of this Agreement, the payment shall accrue interest from the date due at [*]; provided, however, that in no event shall such rate exceed the maximum legal annual interest rate. The payment of such interest shall not limit the Party entitled to receive payment from exercising any other rights it may have as a consequence of the lateness of any payment.

10. INTELLECTUAL PROPERTY

10.1 Ownership.

(a) Data. All Data generated in connection with any Development or Commercial activities with respect to any Product conducted by or on behalf of Exelixis and its Affiliates and licensees (other than Collaborator) (the "**Exelixis Data**") shall be the sole and exclusive property of Exelixis or its Affiliates or licensees, as applicable. All Data generated in connection with any Development or Commercial activities with respect to any Product conducted by or on behalf of Collaborator or its Affiliates or Sublicensees (the "**Collaborator Data**") shall be the sole and exclusive property of Collaborator or of its Affiliates or Sublicensees, as applicable. For clarity, each Party shall have access to and the right to use and reference the other Party's Data as and to the extent set forth in this Agreement.

(b) Inventions. Inventorship of any Inventions will be determined in accordance with the standards of inventorship and conception under U.S. patent laws. The Parties will work together to resolve any issues regarding inventorship or ownership of Inventions. Ownership of Inventions will be allocated as follows:

(i) Exelixis will solely own all data, Inventions, and Patents claiming such Inventions that relate to the composition, manufacture, or use of any Compound, or any improvement of any such composition, manufacture, or use, or are necessary for use in any combination therapy with the Compound produced by either Party or jointly during the Term and in the course of Development or Commercialization of the Product (each, a "**Compound Invention**"). All Compound Inventions will be included in the Exelixis Know-How, and Patents in the Collaborator Territory claiming such Inventions will be included in the Exelixis Patents. To the extent any Compound Invention is made by or on behalf of Collaborator, whether solely or jointly with Exelixis, Collaborator shall, and hereby does, transfer and assign to Exelixis, without additional consideration, all of its interest in such Compound Invention. To effectuate the foregoing assignment by Collaborator to Exelixis, Collaborator shall ensure that its Affiliates and Sublicensees are obligated to assign all such Compound Inventions to Collaborator. In

addition, Exelixis hereby grants to Collaborator a non-exclusive, fully-paid, perpetual, and irrevocable license under such Compound Inventions in the Collaborator Territory for any purpose other than to Develop, use, manufacture, sell, offer for sale, import, or otherwise Commercialize the Compound or Product.

(ii) Except for Compound Inventions, each Party shall solely own any Inventions made solely by its and its Affiliates' employees, agents, or independent contractors (the "**Sole Inventions**"), and the Parties shall jointly own any Inventions that are made jointly by employees, agents, or independent contractors of one Party or its Affiliates together with employees, agents, or independent contractors of the other Party or its Affiliates (the "**Joint Inventions**"). All Patents claiming patentable Joint Inventions shall be referred to herein as "**Joint Patents.**" Except to the extent either Party is restricted by the licenses granted to the other Party under this Agreement, each Party shall be entitled to practice, license, assign, and otherwise exploit its interest under the Joint Inventions and Joint Patents without the duty of accounting or seeking consent from the other Party.

10.2 Patent Prosecution and Maintenance.

(a) Exelixis Patents.

(i) Subject to this Section 10.2(a), Exelixis shall have the sole right, but not the obligation, to control the preparation, filing, prosecution, and maintenance (including any interferences, reissue proceedings, reexaminations, inter partes review, patent term extensions, applications for supplementary protection certificates, oppositions, invalidation proceedings, and defense of validity or enforceability challenges) of the Exelixis Patents (other than Joint Patents) worldwide, using counsel of its own choice in the Exelixis Territory and counsel mutually agreed to by the Parties in the Collaborator Territory. Collaborator shall reimburse Exelixis for all costs and expenses incurred with respect to the preparation, filing, prosecution, and maintenance of Exelixis Patents in the Collaborator Territory after the Effective Date and until the expiration or termination of this Agreement as provided in Section 14.1(a), within [*] from the date of invoice for such costs and expenses provided by Exelixis. In the event that Collaborator does not reimburse Exelixis for such costs and expenses for any Exelixis Patent or notifies Exelixis in writing that it elects to cease reimbursing Exelixis for such costs and expenses for any Exelixis Patent, such Patent shall cease to be an Exelixis Patent and shall no longer be subject to the licenses and other rights granted by Exelixis to Collaborator under this Agreement. Exelixis shall keep Collaborator informed of material progress with regard to the preparation, filing, prosecution, and maintenance of Exelixis Patents in the Collaborator Territory, sufficiently in advance for Collaborator to be able to review any material documents, including content, timing, and jurisdiction of the filing of such Exelixis Patents in the Collaborator Territory, and Exelixis shall consult with, and consider in good faith the requests and suggestions of,

Collaborator with respect to strategies for filing, prosecuting, and defending, if any, Exelixis Patents in the Collaborator Territory.

(ii) In the event that Exelixis desires to abandon or cease prosecution or maintenance of any Exelixis Patent in the Collaborator Territory during the Term, Exelixis shall provide reasonable prior written notice to Collaborator of such intention to abandon (which notice shall, to the extent possible, be given no later than [*] prior to the next deadline for any action that must be taken with respect to any such Exelixis Patent in the relevant patent office). In such case, upon Collaborator's written election provided no later than [*] after such notice from Exelixis, Exelixis shall continue prosecution and maintenance of such Exelixis Patent at Collaborator's direction and expense. If Collaborator does not provide such election within [*] after such notice from Exelixis, Exelixis may, in its sole discretion, continue prosecution and maintenance of such Exelixis Patent or discontinue prosecution and maintenance of such Exelixis Patent.

(b) Collaborator Patents.

(i) Subject to this Section 10.2(b), Collaborator shall have the first right, but not the obligation, to control the preparation, filing, prosecution, and maintenance (including any interferences, reissue proceedings, reexaminations, patent term extensions, applications for supplementary protection certificates, oppositions, invalidation proceedings and defense of validity or enforceability challenges) of all Collaborator Patents (other than Joint Patents) worldwide, at its sole cost and expense and by counsel of its own choice in the Collaborator Territory and by counsel mutually agreed to by the Parties in the Exelixis Territory. Collaborator shall keep Exelixis informed of the status of filing, prosecution, maintenance and defense, if any, of the Collaborator Patents, and Collaborator shall consult with, and consider in good faith the requests and suggestions of, Exelixis with respect to strategies for filing, prosecuting and defending, if any, Collaborator Patents.

(ii) In the event that Collaborator desires to abandon or cease prosecution or maintenance of any Collaborator Patent during the Term, Collaborator shall provide reasonable prior written notice to Exelixis of such intention to abandon (which notice shall, to the extent possible, be given no later than [*] prior to the next deadline for any action that must be taken with respect to any such Collaborator Patent in the relevant patent office). In such case, upon Exelixis' written election provided no later than [*] after such notice from Collaborator, Exelixis shall have the right to assume prosecution and maintenance of such Collaborator Patent at Exelixis' expense and Collaborator shall assign to Exelixis all of its rights, title, and interest in and to such Collaborator Patent. If Exelixis does not provide such election within [*] after such notice from Collaborator, Collaborator may, in its sole discretion, continue prosecution and maintenance of such Collaborator Patent or discontinue prosecution and maintenance of such Collaborator Patent.

(c) Joint Patents.

(i) Subject to this Section 10.2(c), Exelixis shall have the first right, but not the obligation, to prepare, file, prosecute, and maintain (including any interferences, reissue proceedings, reexaminations, patent term extensions, applications for supplementary protection certificates, oppositions, invalidation proceedings and defense of validity or enforceability challenges) Joint Patents using a patent counsel selected by Exelixis in the Exelixis Territory and counsel mutually agreed to by the Parties in the Collaborator Territory. Collaborator shall reimburse Exelixis for all costs and expenses incurred with respect to the preparation, filing, prosecution, and maintenance of Joint Patents in the Collaborator Territory, within [*] from the date of invoice for such costs and expenses provided by Exelixis. In the event that Collaborator does not reimburse Exelixis for such costs and expense for any Joint Patent or notifies Exelixis in writing that it elects to cease reimbursing Exelixis for such costs and expense for any Joint Patent, Collaborator shall execute such documents and perform such acts, at Collaborator's expense, as may be reasonably necessary to effect an assignment of Collaborator's entire right, title, and interest in and to such Joint Patent to Exelixis, and such Patent shall cease to be either a Joint Patent or an Exelixis Patent and shall no longer be subject to the licenses and other rights granted by Exelixis to Collaborator under this Agreement. Exelixis shall keep Collaborator informed of material progress with regard to the preparation, filing, prosecution, maintenance, and defense, if any, of Joint Patents, including content, timing, and jurisdiction of the filing of such Joint Patents, and Exelixis shall consult with, and consider in good faith the requests and suggestions of, Collaborator with respect to filing, prosecuting and defending, if any, Joint Patents in the Collaborator Territory.

(ii) In the event that Exelixis desires to abandon or cease prosecution or maintenance of any Joint Patent in the Collaborator Territory, Exelixis shall provide reasonable prior written notice to Collaborator of such intention to abandon (which notice shall, to the extent possible, be given no later than [*] prior to the next deadline for any action that must be taken with respect to any such Joint Patent in the relevant patent office). In such case, at Collaborator's sole discretion, upon written notice from Collaborator to Exelixis, Collaborator may elect to continue prosecution or maintenance of any such Joint Patent at its own expense, and Exelixis shall execute such documents and perform such acts, at Collaborator's expense, as may be reasonably necessary to allow Collaborator to continue the prosecution and maintenance of such Joint Patent in the Collaborator Territory. Any such assignment shall be completed in a timely manner to allow Collaborator to continue prosecution and maintenance of any such Joint Patent and any such Patent so assigned shall cease to be either a Joint Patent or a Collaborator Patent and shall no longer be subject to the licenses and other rights granted by Collaborator to Exelixis under this Agreement.

(d) Cooperation. Each Party agrees to cooperate fully in the preparation, filing, prosecution, maintenance, and defense, if any, of Patents under

Section 10.2 and in the obtaining and maintenance of any patent term extensions, supplementary protection certificates, and their equivalent with respect thereto, at its own cost (except as expressly set forth otherwise in this Article 10). Such cooperation includes: (i) executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, so as to enable the other Party to apply for and to prosecute patent applications in any country as permitted by Section 10.2; and (ii) promptly informing the other Party of any matters coming to such Party's attention that may affect the preparation, filing, prosecution, or maintenance of any such patent application and the obtaining of any patent term extensions, supplementary protection certificates, and their equivalent.

10.3 Patent Term Extensions in the Collaborator Territory. The JEC will discuss and recommend for which, if any, of the Patents within the Exelixis Patents, Collaborator Patents, or Joint Patents the Parties should seek patent term extensions in the Collaborator Territory. Exelixis in the case of the Exelixis Patents or any Joint Patents, and Collaborator in the case of the Collaborator Patents, shall have the final decision-making authority with respect to applying for any such patent term extension in the Collaborator Territory, and will act with reasonable promptness in light of the development stage of the Product to apply for any such patent term extension, where it so elects; provided, however, that if in the Collaborator Territory only one such Patent can obtain a patent term extension, then the Parties will consult in good faith to determine which such Patent(s) should be the subject of efforts to obtain a patent term extension. The Party that does not apply for an extension hereunder will cooperate fully with the other Party in making such filings or actions, for example and without limitation, making available all required regulatory Data and information and executing any required authorizations to apply for such patent term extension. All expenses incurred in connection with activities of each Party with respect to the Patent(s) for which such Party seeks patent term extensions pursuant to this Section 10.3 shall be the sole responsibility of such Party.

10.4 Patent Enforcement.

(a) Notice. Each Party shall notify the other within [*] of becoming aware of any alleged or threatened infringement by a Third Party of any of the Exelixis Patents (including Joint Patents) in the Collaborator Territory, which infringement adversely affects or is expected to adversely affect any Product, including any declaratory judgment, opposition, or similar action alleging the invalidity, unenforceability, or non-infringement of any of the Exelixis Patents (collectively "**Product Infringement**").

(b) Enforcement Right. Exelixis shall have the first right to bring and control any legal action in connection with such Product Infringement at its own expense as it reasonably determines appropriate. If Exelixis (i) decides not to bring such legal action against a Product Infringement (the decision of which Exelixis shall inform Collaborator promptly) or (ii) Exelixis otherwise fails to bring such legal action against a Product Infringement within [*] of first becoming aware of such Product Infringement,

Collaborator shall have the right to bring and control any legal action in connection with such Product Infringement at its own expense as it reasonably determines appropriate after consultation with Exelixis.

(c) Collaboration. Each Party shall provide to the enforcing Party reasonable assistance in such enforcement, at such enforcing Party's request and expense, including to be named in such action if required by Applicable Laws to pursue such action. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts and shall reasonably consider the other Party's comments on any such efforts, including determination of litigation strategy and filing of material papers to the competent court. The non-enforcing Party shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall at all times cooperate fully with the enforcing Party.

(d) Expense and Recovery.

(i) Except as set forth in clause (ii) below, the enforcing Party shall be solely responsible for any expenses incurred by such Party as a result of such enforcement action. If such Party recovers monetary damages in such enforcement action, such recovery shall be allocated first to the reimbursement of any expenses incurred by the enforcing Party in such enforcement action, second to the reimbursement of any expenses incurred by the other Party in such enforcement action, and any remaining amounts shall be retained by the enforcing Party.

(ii) Notwithstanding the foregoing, if Exelixis is the enforcing Party against a Product Infringement in the Collaborator Territory, Collaborator shall have the option to share [*] of the expense incurred by Exelixis in such enforcement action, which option may be exercised by Collaborator by providing written notice to Exelixis within [*] after receiving a notice from Exelixis that Exelixis decides to bring such action. If Collaborator exercises such option, then (1) Collaborator shall reimburse Exelixis for [*] of all expenses incurred by Exelixis in such enforcement action, within [*] from the date of invoice for such expenses provided by Exelixis; and (2) If Exelixis recovers any monetary damages in such enforcement action, such recovery shall be allocated [*] to Exelixis and [*] to Collaborator.

(e) Other Infringement. Except for Product Infringement as set forth above, each Party shall have the exclusive right to enforce its own Patent against any infringement anywhere in the world. For clarity, Exelixis shall have the exclusive right to enforce (i) the Exelixis Patents against any infringement in the Collaborator Territory that is not a Product Infringement, and (ii) the Exelixis Patents and Joint Patents against any infringement in the Exelixis Territory, in each case at its own expense as it reasonably determines appropriate. The Parties shall discuss global enforcement strategy for the Exelixis Patents and Collaborator Patents, including the defense of validity and enforceability challenges arising from any enforcement action.

10.5 Infringement of Third Party Rights. If any Product used or sold by Collaborator, its Affiliates or Sublicensees becomes the subject of a Third Party's claim or assertion of infringement of any intellectual property rights in a jurisdiction within the Collaborator Territory, Collaborator shall promptly notify Exelixis and the Parties shall promptly meet to consider the claim or assertion and the appropriate course of action and may, if appropriate, agree on and enter into a "common interest agreement" wherein the Parties agree to their shared, mutual interest in the outcome of such potential dispute. Absent any agreement to the contrary, and subject to claims for indemnification under Article 13, each Party shall defend itself from any such Third Party claim at its own cost and expense, provided, however, that the provisions of Section 10.3 shall govern the right of Collaborator to assert a counterclaim of infringement of any Exelixis Patents.

10.6 Patent Marking. Collaborator shall, and shall require its Affiliates and Sublicensees, to mark the Products sold by it hereunder (in a reasonable manner consistent with industry custom and practice) with appropriate Patent numbers or indicia to the extent permitted by Applicable Laws; provided, however, that Collaborator shall only be required to so mark such Products to the extent such markings or such notices would impact recoveries of damages or equitable remedies available under Applicable Laws with respect to infringements of Patents in the Collaborator Territory.

10.7 Patents Licensed From Third Parties. Each Party's rights under this Article 10 with respect to the prosecution and enforcement of any Exelixis Patent and Collaborator Patent shall be subject to the rights: (a) retained by any upstream licensor to prosecute and enforce such Patent Right, if such Patent Right is subject to an upstream license agreement; and (b) granted to any Third Party prior to such Patent Right becoming subject to the license grant under this Agreement.

10.8 Trademarks.

(a) Product Trademarks. Exelixis shall develop and adopt trademarks, including trade names, trade dresses, branding, and logos, to be used for the Products (the "**Product Marks**"). Exelixis shall own the Product Marks throughout the world and all goodwill in the Product Marks shall accrue to Exelixis. To the extent permitted by Applicable Laws, the Parties shall use CABOMETYX®, or an equivalent trademark in Japanese, for all indications. Exelixis shall be responsible for the registration, maintenance, defense, and enforcement of the Product Marks using counsel of its own choice in the Exelixis Territory and counsel mutually agreed to by the Parties in the Collaborator Territory. Collaborator shall reimburse Exelixis for all costs and expenses incurred with respect to the registration and maintenance of the Product Marks after the Effective Date in the Collaborator Territory, within [*] from the date of invoice for such costs and expenses provided by Exelixis. Exelixis shall keep Collaborator informed of material progress with regard to the registration, prosecution, maintenance, and defense, if any, of Product Marks in the Collaborator Territory, including content and timing of the filing of such Product Marks in the Collaborator Territory, sufficiently in

advance for Collaborator to be able to review any material documents, and Exelixis shall consult with, and consider in good faith the requests and suggestions of, Collaborator with respect to strategies for filing, prosecuting, and defending, if any, the Product Marks in the Collaborator Territory.

(b) Trademark License. Collaborator shall use the Product Marks selected by Exelixis to Commercialize the Product in the Collaborator Territory. Where use of the Product Mark is not permitted by Applicable Laws, the Parties shall agree on an alternative product trademark and such alternative product trademark shall be included as a Product Mark. In addition, unless prohibited by Applicable Laws, Collaborator shall include Exelixis' corporate trademark on the packaging and product information (i.e., SmPC) of the Products sold in the Collaborator Territory to indicate that the Product is licensed from Exelixis. Exelixis hereby grants to Collaborator a limited royalty-free license to use such Product Marks and Exelixis' corporate trademark solely in connection with the Commercialization of the Product in the Collaborator Territory during the Royalty Term under this Agreement. All use of the Product Marks and Exelixis' corporate trademark shall comply with Applicable Laws and regulations and shall be subject to Exelixis' review and approval. For clarity, Collaborator shall also include its (or its Affiliate's or Sublicensee's) corporate logo in the Product sold in the Collaborator Territory.

11. REPRESENTATIONS AND WARRANTIES

11.1 Mutual Representations and Warranties. Each Party represents and warrants to the other that, as of the Effective Date: (a) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof, (b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate or partnership action, (c) this Agreement is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument, or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body, or administrative or other agency having jurisdiction over it, and (d) it has the right to grant the licenses granted by it under this Agreement.

11.2 Covenants.

(a) Employees, Consultants, and Contractors. Each Party covenants that it has obtained or will obtain written agreements from each of its employees, consultants, and contractors who perform Development activities pursuant to this Agreement, which agreements will obligate such persons to obligations of

confidentiality and non-use and to assign (or, in the case of contractor, grant a license under) Inventions in a manner consistent with the provisions of this Agreement.

(b) Debarment. Each Party represents, warrants, and covenants to the other Party that it is not debarred or disqualified under the U.S. Federal Food, Drug and Cosmetic Act, as may be amended, or comparable laws in any country or jurisdiction other than the U.S., and it does not, and will not during the Term, employ or use the services of any person who is debarred or disqualified, in connection with activities relating to any Product. In the event that either Party becomes aware of the debarment or disqualification or threatened debarment or disqualification of any person providing services to such Party, including the Party itself or its Affiliates or Sublicensees, that directly or indirectly relate to activities contemplated by this Agreement, such Party shall immediately notify the other Party in writing and such Party shall cease employing, contracting with, or retaining any such person to perform any such services.

(c) Compliance. Each Party covenants as follows:

(i) In the performance of its obligations under this Agreement, each Party shall comply and shall cause its and its Affiliates' employees and contractors to comply with all Applicable Laws.

(ii) Each Party and its Affiliates' employees and contractors shall not, in connection with the performance of their respective obligations under this Agreement, directly or indirectly through Third Parties, pay, promise, or offer to pay, or authorize the payment of, any money or give any promise or offer to give, or authorize the giving of anything of value to a Public Official or Entity or other person for purpose of obtaining or retaining business for or with, or directing business to, any person, including such Party (and each Party represents and warrants that as of the Effective Date, such Party, and to its knowledge, its and its Affiliates' employees and contractors, have not directly or indirectly promised, offered, or provided any corrupt payment, gratuity, emolument, bribe, kickback, illicit gift, or hospitality or other illegal or unethical benefit to a Public Official or other entity or any other person in connection with the performance of such Party's obligations under this Agreement, and each Party covenants that it and its Affiliates' employees and contractors shall not, directly or indirectly, engage in any of the foregoing).

(iii) Each Party and its Affiliates, and their respective employees and contractors, in connection with the performance of their respective obligations under this Agreement, shall not cause its Indemnitees to be in violation of the FCPA, Export Control Laws, or any other Applicable Laws or otherwise cause any reputational harm to the other Party.

(iv) Each Party shall immediately notify the other Party if such Party has any information or suspicion that there may be a violation of the FCPA, Export

Control Laws, or any other Applicable Laws in connection with the performance of this Agreement or the Development, manufacture, or Commercialization of any Product.

(v) In connection with the performance of its obligations under this Agreement, each Party shall comply and shall cause its and its Affiliates' employees and contractors to comply with such Party's own anti-corruption and anti-bribery policy, a copy of which has been provided to the other Party prior to the Effective Date.

(vi) Each Party will have the right, upon reasonable prior written notice and during the other Party's regular business hours, to conduct, at its own expense, inspections of and to audit the other Party's books and records in the event of a suspected violation or to ensure compliance with the representations, warranties, or covenants of this Section 11.2(c); provided, however, that in the absence of good cause for such inspections and audits, such Party may only exercise this right on an annual basis.

(vii) In the event that either Party has violated or been suspected of violating any of the representations, warranties, or covenants in this Section 11.2(c), the other Party will cause its or its Affiliates' personnel or others working under its direction or control to submit to periodic training that such violating Party will provide on anti-corruption law compliance.

(viii) Either Party will, at the other Party's request, annually certify to the other Party in writing such Party's compliance, in connection with the performance of its obligations under this Agreement, with the representations, warranties, or covenants in this Section 11.2(c), which certification shall be issued by such Party's commercial head of its respective territory.

(ix) Each Party shall have the right to suspend or terminate this Agreement in its entirety where there is a credible finding, after a reasonable investigation, that the other Party, its Affiliates, or its Sublicensees, in connection with performance of the other Party's obligations under this Agreement, has violated the FCPA.

11.3 Additional Exelixis Representations, Warranties, and Covenants. Exelixis represents, warrants, and covenants, as applicable, to Collaborator that, as of the Effective Date:

(a) **Exhibit 1.31** lists all Patents Controlled by Exelixis in the Collaborator Territory as of the Effective Date that claim the composition of matter or use of the Compound;

(b) Exelixis has the right to grant all rights and licenses it purports to grant to Collaborator with respect to the Exelixis Technology under this Agreement;

(c) Exelixis has not granted any liens or security interests on the Exelixis Technology;

(d) Exelixis has not received any written notice from a Third Party that the Development of any Product conducted by Exelixis prior to the Effective Date has infringed any Patents of any Third Party;

(e) Exelixis has not as of the Effective Date, and will not during the Term, grant any right to any Third Party under the Exelixis Technology that would conflict with the rights granted to Collaborator hereunder;

(f) no claim or action has been brought or, to Exelixis' knowledge, threatened in writing, by any Third Party alleging that the Exelixis Patents are invalid or unenforceable, and no Exelixis Patent is the subject of any interference, opposition, cancellation or other protest proceeding;

(g) to Exelixis' knowledge, no Third Party is infringing or misappropriating or has infringed or misappropriated the Exelixis Technology in the Collaborator Territory;

(h) Exelixis has disclosed to Collaborator all clinical and non-clinical data in the Control of Exelixis that is necessary and/or material to the evaluation of the safety, efficacy and manufacturing process of the Product; and

(i) to Exelixis' knowledge, there are no issues or information, which to Exelixis' knowledge and reasonable opinion, are reasonably likely to have a material impact on the Development of the Product that have not been fully disclosed to Collaborator in the course of Collaborator's due diligence.

11.4 Additional Representations, Warranties and Covenants. Collaborator represents, warrants, and covenants to Exelixis that, as of the Effective Date, Collaborator has not granted, and will not grant during the Term, any right to any Third Party under the Collaborator Technology that would conflict with the rights granted to Exelixis hereunder. Collaborator further represents, warrants, and covenants to Exelixis that, as of the Effective Date, Collaborator does not own or control any Collaborator Patents.

11.5 Disclaimer. Except as expressly set forth in this Agreement, THE TECHNOLOGY AND INTELLECTUAL PROPERTY RIGHTS PROVIDED BY EACH PARTY HEREUNDER ARE PROVIDED "AS IS" AND EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES, IN ALL CASES WITH RESPECT THERETO. Without limiting the foregoing, (a) neither Party represents or

warrants that any data obtained from conducting Clinical Trials in one country or jurisdiction will comply with the laws and regulations of any other country or jurisdiction, and (b) neither Party represents or warrants the success of any study or test conducted by it pursuant to this Agreement, or the safety or usefulness for any purpose of the technology it provides hereunder.

12. INDEMNIFICATION

12.1 Indemnification by Exelixis. Exelixis hereby agrees to defend, indemnify, and hold harmless Collaborator and its Affiliates and their respective directors, officers, employees and agents (each, a "**Collaborator Indemnitee**") from and against any and all liabilities, expenses, and losses, including reasonable legal expenses and attorneys' fees (collectively, "**Losses**"), to which any Collaborator Indemnitee may become subject as a result of any claim, demand, action, or other proceeding by any Third Party to the extent such Losses arise out of: (a) the manufacturing, Development, use, handling, storage, Commercialization, or other disposition of any Compound or Product by Exelixis or its Affiliates or licensees or the contractors of any of them (excluding any activities by or on behalf of Collaborator or its Affiliates or Sublicensees), (b) the negligence or willful misconduct of any Exelixis Indemnitee, or (c) the breach by Exelixis of any warranty, representation, covenant, or agreement made by Exelixis in this Agreement; except, in each case (a)-(c), to the extent such Losses arise out of any activities set forth in Sections 12.2(a)-(c) for which Collaborator is obligated to indemnify the Exelixis Indemnitee under Section 12.2.

12.2 Indemnification by Collaborator. Collaborator hereby agrees to defend, indemnify, and hold harmless Exelixis, its Affiliates, and licensees and their respective directors, officers, employees, and agents (each, an "**Exelixis Indemnitee**") from and against any and all Losses to which any Exelixis Indemnitee may become subject as a result of any claim, demand, action, or other proceeding by any Third Party to the extent such Losses arise out of: (a) the manufacturing, Development, use, handling, storage, Commercialization, or other disposition of any Compound or Product by Collaborator, its Affiliates, or Sublicensees or the contractor of any of them, (b) the negligence or willful misconduct of any Collaborator Indemnitee, or (c) the breach by Collaborator of any warranty, representation, covenant, or agreement made by Collaborator in this Agreement; except, in each case (a)-(c), to the extent such Losses arise out of any activities set forth in Sections 12.1(a)-(c) for which Exelixis is obligated to indemnify the Collaborator Indemnitee under Section 12.1.

12.3 Procedure. A party that intends to claim indemnification under this Article 12 (the "**Indemnitee**") shall promptly notify the indemnifying Party (the "**Indemnitor**") in writing of any Third Party claim, demand, action, or other proceeding (each, a "**Claim**") in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have sole control of the defense or settlement thereof. The Indemnitee may participate, at its expense and using its own counsel, in the

Indemnitor's defense of and settlement negotiations for any Claim. The indemnity arrangement in this Article 12 shall not apply to amounts paid in settlement of any action with respect to a Claim if such settlement is effected without the consent of the Indemnitor, which consent shall not be unreasonably withheld or delayed. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any action with respect to a Third Party Claim shall only relieve the Indemnitor of its indemnification obligations under this Article 12 if and to the extent the Indemnitor is actually prejudiced thereby. The Indemnitee shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action with respect to a Claim covered by this indemnification.

12.4 Insurance. During the Term, each Party, at its own expense, shall maintain commercial general liability insurance, including public and product liability and other appropriate insurance (or self-insure) in an amount consistent with sound business practice and reasonable in light of its obligations under this Agreement. Each Party shall provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to the other Party upon request.

12.5 Limitation of Liability. EXCEPT FOR LIABILITY FOR BREACH OF ARTICLE 13, NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, LOST PROFIT OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER; provided, however, that the foregoing limitation shall not apply with respect to any amounts that may become payable as a result of Losses arising from a Third Party Claim.

13. CONFIDENTIALITY

13.1 Confidential Information. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, the Parties agree that, during the Term and for [*] thereafter, the receiving Party shall keep confidential and shall not publish or otherwise disclose, and shall not use for any purpose other than as expressly provided for in this Agreement, any Confidential Information of the other Party, and both Parties shall keep confidential and, subject to Sections 13.2 and 13.3 and 13.4, shall not publish or otherwise disclose the terms of this Agreement. Each Party may use the other Party's Confidential Information only to the extent required to accomplish the purposes of this Agreement, including exercising its rights or performing its obligations under this Agreement. Each Party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own of similar nature (but no less than reasonable care) to ensure that its officers, directors, employees, agents, consultants, contractors, and other representatives do not disclose or make any unauthorized use of the Confidential Information of the other Party. Each Party will promptly notify the other upon discovery of any unauthorized use or disclosure of the Confidential Information of the other Party.

[*] = 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.

13.2 Exceptions. The obligations of confidentiality and restriction on use under Section 13.1 will not apply to any information that the receiving Party can prove by competent evidence: (a) is as of the Effective Date, or hereafter becomes, through no act or failure to act on the part of the receiving Party, generally known or available to the public; (b) is known by the receiving Party or its Affiliate at the time of receiving such information hereunder, other than by previous disclosure of the disclosing Party, or its Affiliates, employees, agents, consultants, or contractors; (c) is hereafter furnished to the receiving Party or its Affiliate without restriction by a Third Party who has no obligation of confidentiality or limitations on use with respect thereto, as a matter of right; or (d) is independently discovered or developed by or on behalf of the receiving Party or its Affiliate without the use of Confidential Information belonging to the disclosing Party.

13.3 Authorized Disclosure. Each Party may disclose Confidential Information belonging to the other Party as expressly permitted by this Agreement or if and to the extent such disclosure is reasonably necessary in the following instances:

(a) filing, prosecuting, or maintaining Patents as permitted by this Agreement;

(b) filing Regulatory Filings for Products that such Party has a license or right to Develop and Commercialize hereunder in a given country or jurisdiction;

(c) prosecuting or defending litigation as permitted by this Agreement;

(d) complying with Applicable Laws or regulations (including regulations promulgated by securities exchanges) or orders from a court having competent jurisdiction or administrative orders;

(e) disclosure to potential and actual investors, acquirors, licensees, and other financial or commercial partners solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition, or collaboration, in each case under written obligations of confidentiality and non-use at least as stringent as those herein; and

(f) disclosure to its and its Affiliates' officers, directors, employees, consultants, contractors, and agents, to its licensees and sublicensees, in each case on a need-to-know basis in connection with the Development, manufacture, or Commercialization of the Compound and Products in accordance with the terms of this Agreement, in each case under written obligations of confidentiality and non-use at least as stringent as those herein. For the avoidance of any doubt, Collaborator shall not be permitted to disclose, for any reason, any Confidential Information of Exelixis to [*] or [*] without Exelixis' prior written consent.

Notwithstanding the foregoing, in the event that a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 13.3(c) or 13.3(d), it

will, except where impracticable, give reasonable advance notice to the other Party of such disclosure and use efforts to secure confidential treatment of such Confidential Information at least as diligent as such Party would use to protect its own confidential information, but in no event less than reasonable efforts. In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder. Any information disclosed pursuant to Section 13.3(c) or 13.3(d) shall remain Confidential Information and subject to the restrictions set forth in this Agreement, including the foregoing provisions of this Article 13.

13.4 Publications.

(a) Each Party shall have the right to review and comment on any material proposed for disclosure or publication by the other Party regarding results of and other information regarding the other Party's Development activities with respect to the [*], whether by oral presentation, manuscript, or abstract. Before any such material is submitted for publication, or presentation of any such material is made, the Party disclosing or submitting the proposed publication (the "**Submitting Party**") shall deliver a complete copy of the material proposed for disclosure to the other Party (the "**Responding Party**"), to the extent reasonably practicable, at least [*] (for oral presentations or abstracts) or [*] (for manuscripts) prior to submitting the material to a publisher or initiating any other disclosure. The Responding Party shall review any such material and give its comments to the Submitting Party within [*] (for oral presentations or abstracts) or [*] (for manuscripts) of the receipt of such material. Notwithstanding the foregoing, the Parties acknowledge that each Party may require expedited review with respect to oral presentation materials, abstracts, and manuscripts; accordingly, the Responding Party shall make reasonable efforts to expedite review of such materials, abstracts, and manuscripts, and shall return such items as soon as practicable to the Submitting Party with appropriate comments, if any. Following the expiration of the applicable time period for review, the Submitting Party shall be free to submit such proposed publication for publication or otherwise disclose to the public such information, subject to the procedures set forth in Section 13.4(b).

(b) If the Responding Party believes that the subject matter of the proposed publication or other disclosure contains Confidential Information or a patentable invention of the Responding Party, then prior to the expiration of the applicable time period for review, the Responding Party shall notify the Submitting Party in writing of its determination that such proposed publication or other disclosure, as applicable, contains such information or subject matter for which patent protection should be sought. Upon receipt of such written notice from the Responding Party, the Submitting Party shall delay public disclosure of such information or submission of the proposed publication for an additional period of [*] (or such other time period mutually agreed by the Parties in writing) to permit preparation and filing of a patent application on the disclosed subject matter. The Submitting Party shall thereafter provide the Responding Party with a copy of final version of publication materials and be free to

publish or disclose such information, except that the Submitting Party may not disclose any Confidential Information of the Responding Party in violation of Section 13.1.

13.5 Publicity; Public Disclosures. The Parties agree to issue a joint press release substantially in a form agreed by the Parties and attached to this Agreement as **Exhibit 13.5** announcing the signature of this Agreement at or shortly after the Effective Date within the time-period required by applicable securities laws. It is understood that each Party may desire or be required to issue subsequent press releases relating to this Agreement or activities hereunder. The Parties agree to consult with each other reasonably and in good faith with respect to the text and timing of such press releases prior to the issuance thereof, to the extent practicable, provided that a Party may not unreasonably withhold, condition, or delay consent to such releases by more than [*], and that either Party may issue such press releases or make such disclosures to the SEC or other applicable agency as it determines, based on advice of counsel, as reasonably necessary to comply with laws or regulations or for appropriate market disclosure. Each Party shall provide the other Party with advance notice of legally required disclosures to the extent practicable. The Parties will consult with each other on the provisions of this Agreement to be redacted in any filings made by a Party with the SEC or as otherwise required by Applicable Laws; provided that each Party shall have the right to make any such filing as it reasonably determines necessary under Applicable Laws. In addition, following the initial joint press release announcing this Agreement, either Party shall be free to disclose, without the other Party's prior written consent, the existence of this Agreement, the identity of the other Party, and those terms of the Agreement which have already been publicly disclosed in accordance herewith.

13.6 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that a Party would suffer upon unauthorized disclosure, use, or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages may not be a sufficient remedy for any breach of this Article 13. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 13.

14. TERM AND TERMINATION

14.1 Term.

(a) This Agreement shall commence on the Effective Date and, unless terminated earlier as provided in this Article 14 or by mutual written agreement of the Parties, shall continue until the expiration of the Royalty Term in the Collaborator Territory (the "**Term**").

(b) Notwithstanding anything herein, on a Product-by-Product basis, upon the expiration of the Royalty Term (i.e., all royalty payment obligations for a

[*] = 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.

Product in the Collaborator Territory), the licenses granted to Collaborator in Section 2.1 shall be deemed to be perpetual and fully paid-up with respect to such Product in the Collaborator Territory, but thereafter shall be on a non-exclusive basis.

(c) Notwithstanding anything herein, on a Product-by-Product basis, upon the expiration of the Royalty Term the licenses granted to Exelixis in Section 2.4 shall become perpetual and non-exclusive.

14.2 Termination for Cause.

(a) Material Breach. Each Party shall have the right to terminate this Agreement immediately in its entirety upon written notice to the other Party if such other Party materially breaches this Agreement and has not cured such breach to the reasonable satisfaction of the other Party within [*] ([*] with respect to any payment breach) after notice of such breach from the non-breaching Party. If the alleged breaching Party disputes in good faith the existence or materiality of a breach specified in a notice provided by the other Party, and such alleged breaching Party provides the other Party notice of such dispute within [*], then the other Party shall not have the right to terminate this Agreement under this Section 14.2(a) unless and until an arbitral panel, in accordance with Article 15, has determined that the alleged breaching Party has materially breached the Agreement and that such Party fails to cure such breach within the applicable cure period set forth above following such decision. In the event Exelixis commences an arbitration alleging material breach by Collaborator and Collaborator later delivers notice of voluntary termination under Section 14.3, then, at the election of Exelixis, the period of time set forth in Section 14.3 shall be reduced by an amount of time equal to the duration of time from the commencement of the arbitration to the delivery of such notice, [*].

(b) Bankruptcy. Each Party shall have the right to terminate this Agreement immediately in its entirety upon written notice to the other Party if such other Party makes a general assignment for the benefit of creditors, files an insolvency petition in bankruptcy, petitions for or acquiesces in the appointment of any receiver, trustee, or similar officer to liquidate or conserve its business or any substantial part of its assets, commences under the laws of any jurisdiction any proceeding involving its insolvency, bankruptcy, reorganization, adjustment of debt, dissolution, liquidation, or any other similar proceeding for the release of financially distressed debtors or becomes a party to any proceeding or action of the type described above and such proceeding is not dismissed within [*] after the commencement thereof.

(c) Patent Challenge. Exelixis shall have the right to terminate this Agreement immediately in its entirety upon written notice to Collaborator if Collaborator or any of its Affiliates or Sublicensees directly, or indirectly through any Third Party, commences any interference or opposition proceeding with respect to, challenges the

validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any Exelixis Patent.

(d) Safety Reasons. Either Party shall have the right to terminate this Agreement upon written notice to the other Party if the terminating Party reasonably determines, based upon additional information that becomes available or an analysis of the existing information at any time, that the medical risk/benefit of such Product is so unfavorable that it would be incompatible with the welfare of patients to Develop or Commercialize or to continue to Develop or Commercialize such Product. Prior to any such termination, the terminating Party shall comply with such internal review and management approval processes as it would normally follow in connection with the termination of the development and commercialization of its own products for safety reasons. The terminating Party shall document the decisions of such committees or members of management and the basis therefor and shall make such minutes and documentation available to the other Party promptly upon written request.

(e) Discontinuation of Clinical Trials. Collaborator may terminate this Agreement upon [*] advance written notice to Exelixis, if substantially all ongoing Clinical Trials of the Product are ordered or required to be terminated by the FDA or the MHLW.

14.3 Termination without Cause.

(a) Prior to Commercial Launch. At any time prior to August 1, 2023, the Parties may mutually agree that the PMDA is unlikely to grant approval of the MAA for the Product in any cancer indication in the Collaborator Territory. In such event, the Parties may agree to terminate this Agreement by mutual written agreement, such agreement to include a mutually acceptable plan to wind down and terminate the Agreement. Commencing on August 1, 2023, Collaborator shall have the right to terminate the Agreement without cause upon [*] prior written notice to Exelixis if the PMDA has not granted approval of the MAA for the Product in any cancer indication in the Collaborator Territory. For the purpose of this Section 14.3(a), if the PMDA grants such MAA Approval conditioned on the performance of additional Phase 3b or other studies, then the PMDA shall be deemed to have granted approval of such MAA. For clarification, this Section 14.3(a) shall not be construed as limiting a right of termination under Section 14.2.

(b) After Commercial Launch. Collaborator shall have the right to terminate this Agreement in its entirety without cause upon twelve (12) months' prior written notice after the First Commercial Sale of a Product in the Collaborator Territory; provided, however, that Collaborator may not terminate this Agreement pursuant to this Section 14.3(b) prior to the third (3rd) anniversary of the First Commercial Sale of such Product in the Collaborator Territory.

14.4 Effects of Termination (Except By Reason Of Exelixis Material Breach). Upon any termination of this Agreement by either Party for any reason other than termination under Section 14.2(a) resulting from a material breach of this Agreement by Exelixis, the following will apply: For clarity, during the pendency of any dispute regarding material breach and/or any termination notice period, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

(a) Licenses. All licenses granted by Exelixis to Collaborator will automatically terminate, including all sublicenses granted by Collaborator to any Sublicensee. All licenses granted by Collaborator to Exelixis shall survive such termination and shall automatically become worldwide and perpetual.

(b) Regulatory Materials; Data. Within [*] of the effective date of termination of this Agreement, Collaborator shall transfer and assign to Exelixis, at no cost to Exelixis, all Regulatory Filings and Regulatory Approvals for the Products, Data from all preclinical, non-clinical and clinical studies conducted by or on behalf of Collaborator, its Affiliates, or Sublicensees on the Products, and all pharmacovigilance data (including any adverse events database) on the Products. In the event any Regulatory Filings and/or Regulatory Approval for a Product cannot be transferred to Exelixis within such [*] period, Collaborator shall continue to maintain such Regulatory Fillings and/or Regulatory Approval until such time as Collaborator is permitted to transfer such Regulatory Filing or Regulatory Approval to Exelixis. In addition, at Exelixis' request, Collaborator shall provide Exelixis with reasonable assistance with any inquiries and correspondence with Regulatory Filings and Regulatory Authorities regarding the Product in the Collaborator Territory for a period of [*] after such termination. Exelixis shall be responsible for Collaborator's reasonable costs incurred directly in connection with any such Exelixis request.

(c) Development Wind-Down. Collaborator shall either, as directed by Exelixis, (i) wind-down any ongoing Development activities (including any Clinical Trials) of Collaborator and its Affiliates and Sublicensees with respect to any Product in the Collaborator Territory in an orderly fashion, or (ii) promptly transfer such Development activities to Exelixis or its designee, in compliance with all Applicable Laws.

(d) Cost of Ongoing Trials. If there is any ongoing Clinical Trial of the Product under the GDP for which Collaborator has committed to share the costs or be fully responsible for funding, then Collaborator shall continue to share the non-cancelable costs of or fund such Clinical Trial, as the case may be, until [*].

(e) Commercial Wind-Down. Collaborator shall, as directed by Exelixis, (i) continue certain ongoing Commercial activities of Collaborator and its Affiliates and Sublicensees with respect to any Product in the Collaborator Territory for a

period of up to [*] as determined by Exelixis, and (ii) handoff such Commercial activities to Exelixis or its designee, on a timetable to be set by Exelixis, not to exceed [*], and in compliance with all Applicable Laws. During such commercial wind-down period, Collaborator shall continue to book sales and pay royalties to Exelixis in accordance with Section 8.5. Except as necessary to conduct the foregoing activities as directed by Exelixis, Collaborator shall immediately discontinue its (and shall ensure that its Affiliates and Sublicensees immediately discontinue their) promotion, marketing, offering for sale, and servicing of the Product and its use of all Product Marks. In addition, Collaborator shall immediately deliver to Exelixis (at Collaborator's expense) all samples, demonstration equipment, sales materials, catalogs, and literature of Exelixis in Collaborator's possession or control.

(f) Transition Assistance. Collaborator shall use Commercially Reasonable Efforts to seek an orderly transition of the Development and Commercialization of the Compound and Products to Exelixis or its designee for so long as is necessary to ensure patient safety, including ensuring continuity of supply to any patients. Collaborator shall, at no cost to Exelixis, provide reasonable consultation and assistance for a period of no more than [*] after termination for the purpose of transferring or transitioning to Exelixis all Collaborator Know-How not already in Exelixis' possession and, at Exelixis' request, all then-existing commercial arrangements relating to the Products that Collaborator is able, using Commercially Reasonable Efforts, to transfer or transition to Exelixis or its designee, in each case, to the extent reasonably necessary or useful for Exelixis to continue the Development and/or Commercialization of the Compound and Products in the Collaborator Territory. If any such contract between Collaborator and a Third Party is not assignable to Exelixis or its designee (whether by such contract's terms or because such contract does not relate specifically to the Products) but is otherwise reasonably necessary or useful for Exelixis to continue the Development and/or Commercialization of the Compound and Products in the Collaborator Territory, or if Collaborator is performing such work for the Compound and Product itself (and thus there is no contract to assign), then Collaborator shall reasonably cooperate with Exelixis to negotiate for the continuation of such services for Exelixis from such entity, or Collaborator shall continue to perform such work for Exelixis, as applicable, for a reasonable period (not to exceed [*]) after termination at Exelixis' cost until Exelixis establishes an alternate, validated source of such services.

(g) Remaining Inventories. Exelixis shall have the right, at its discretion, to purchase from Collaborator any or all of the inventory of the Products held by Collaborator as of the date of termination at a price equal to the transfer price paid by Collaborator to acquire such inventory from Exelixis. Exelixis shall notify Collaborator within [*] after the date of termination whether Exelixis elects to exercise such right.

(h) Non-Compete. Following any termination of this Agreement by Collaborator pursuant to Section 14.3(b), or by Exelixis pursuant to Section 14.2, neither Collaborator nor any of its Affiliates shall (directly or indirectly, either with or without a

bona fide Collaborator or any other Third Party) (i) develop any Competing Product in the Collaborator Territory for a period of [*] following the effective date of such termination, or (ii) commercialize any Competing Product in the Collaborator Territory for a period of [*] following the effective date of such termination.

(i) No Generic Product. Following any termination of this Agreement by Collaborator pursuant to Section 14.3(b) or by Exelixis pursuant to Section 14.2, neither Collaborator nor any of its Affiliates shall (directly or indirectly, either with or without a bona fide Collaborator or any other Third Party) (i) develop any Generic Product in the Collaborator Territory for a period of [*] following the effective date of such termination or (ii) commercialize any Generic Product in the Collaborator Territory for a period of [*] following the effective date of such termination.

14.5 Effect of Termination (Material Breach by Exelixis). Upon any termination of this Agreement by Collaborator pursuant to Section 14.2(a) resulting from a material breach of this Agreement by Exelixis, then all of the provisions of Section 14.4 shall apply, except that (1) Sections 14.4 (d), (h) and (i) shall have no effect, and (2) to the extent Exelixis requests Collaborator's performance under any of the provisions of Sections 14.4 (b), (c), (e), (f) or (g), Exelixis shall reimburse Collaborator for all costs incurred by Collaborator in connection with such performance, including both its external costs plus its internal costs calculated on a reasonable FTE basis. For clarity, while Collaborator shall not be subject to Section 14.4(d) in such event, it shall remain subject to Section 14.4(c) subject to the reimbursement of costs by Exelixis.

14.6 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by one Party to the other Party are, and otherwise will be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws. The Parties agree that a Party that is a licensee of such rights under this Agreement will retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party to this Agreement under the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws, the other Party will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and same, if not already in its possession, will be promptly delivered to it (a) upon any such commencement of a bankruptcy or insolvency proceeding upon its written request therefor, unless the bankrupt Party elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under (a) above, following the rejection of this Agreement by or on behalf of the bankrupt Party upon written request therefor by the other Party.

14.7 Confidential Information. Upon expiration or termination of this Agreement in its entirety, except to the extent that a Party obtains or retains the right to use the other Party's Confidential Information, each Party shall promptly return to the other Party, or delete or destroy, all relevant records and materials in such Party's possession or control containing Confidential Information of the other Party; provided that a Party may keep one copy of such materials for archival purposes subject to continuing confidentiality obligations and other copies to the extent necessary for complying with Applicable Laws. All Collaborator Data and Regulatory Filings assigned to Exelixis upon termination of this Agreement will be deemed Exelixis' Confidential Information and no longer Collaborator's Confidential Information.

14.8 Additional Remedies. In case of termination by reason of either Party's material breach, unless otherwise expressly provided in the Agreement, the termination under this Article 14 will not be an exclusive remedy for the terminating Party, and will not preclude, limit, nor be in lieu of any other remedies available to the terminating Party under this Agreement or Applicable Laws as a result of any material breach by the other Party.

14.9 Survival. Expiration or termination of this Agreement shall not relieve the Parties of any obligation or right accruing prior to such expiration or termination. Except as set forth below or elsewhere in this Agreement, the obligations and rights of the Parties under the following provisions of this Agreement shall survive expiration or termination of this Agreement to the extent that the subject matter of such provision exists: Article 1 (Definitions); Article 9 (Payments, Records, Audits); Article 12 (Indemnification); Article 15 (Dispute Resolution); Article 16 (General Provisions); Section 2.5 (No Implied Licenses; Negative Covenant); Section 5.10 (Sunshine Reporting Laws); Section 10.1 (IP Ownership); Section 10.2(c) (Joint Patent Prosecution); Sections 13.1, 13.2, 13.3 and 13.6 (Confidentiality); Sections 14.1(b) and (c) (Term; in each case to the extent applicable); Sections 14.4 and 14.5 (Effects of Termination, in each case to the extent applicable); Section 14.6 (Rights in Bankruptcy; to the extent applicable); Section 14.7 (Confidentiality); Section 14.8 (Additional Remedies); and Section 14.9 (Survival).

15. DISPUTE RESOLUTION

15.1 Objective. The Parties recognize that disputes as to matters arising under, in connection with or relating to this Agreement or either Party's rights and obligations hereunder may arise from time to time. It is the objective of the Parties to establish procedures to facilitate the resolution of such disputes in an expedient and amicable manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Article 15 to resolve any such dispute if and when it arises.

15.2 Executive Mediation. The Parties will try to settle any dispute, controversy, or claim that arises out of, in connection with or relates to, any provision of the Agreement ("**Disputed Matter**") by first referring the Disputed Matter to the Parties' Executive Officers. Either Party may initiate such informal dispute resolution by sending written notice of the Disputed Matter to the other Party, and, within [*] after such notice, the Executive Officers (or their respective designees having the authority to settle such Disputed Matter) of the Parties will meet for attempted resolution by good faith negotiations. If the Executive Officers (or their respective designees) are unable to resolve such dispute within [*] of their first meeting for such negotiations, either Party may seek to have such dispute resolved in accordance with Section 15.3 below.

15.3 Dispute Resolution.

(a) If the Parties are unable to resolve a Disputed Matter using the process described in Section 15.2, then a Party seeking further resolution of the Disputed Matter will submit the Disputed Matter to resolution by final and binding arbitration. Whenever a Party will decide to institute arbitration proceedings, it will give written notice to that effect to the other Party. Arbitration will be held in [*], and administered by the International Chamber of Commerce pursuant to its ICC International Arbitration Rules then in effect (the "**Rules**"), except as otherwise provided herein and applying the substantive law specified in Section 16.1. The arbitration will be conducted by a panel of three (3) arbitrators appointed in accordance with the Rules; provided that each Party will, within [*] after the institution of the arbitration proceedings, appoint an arbitrator, and such arbitrators will together, within [*], select a third (3rd) arbitrator as the chairman of the arbitration panel. Each arbitrator must have significant business or legal experience in the pharmaceutical business. If the two (2) initial arbitrators are unable to select a third (3rd) arbitrator within such [*] period, the third (3rd) arbitrator will be appointed in accordance with Rules. In addition to the authority conferred by the Rules, the Parties hereby agree to engage in discovery of information and evidence that is or might be relevant to the claims, defenses, and issues in the dispute, including by means of discovery in the form of [*], subject to [*] being permitted by the panel of arbitrators on a showing of good cause. The Parties further agree to the ability, right, and power to subpoena Third Party witnesses for both discovery and hearing purposes. After conducting any hearing and taking any evidence deemed appropriate for consideration, the arbitrators will render their opinion within [*] of the final arbitration hearing. The panel of arbitrators will not have the power to award damages excluded pursuant to Section 12.5 under this Agreement and any arbitral award that purports to award such damages is expressly prohibited and void ab initio. Decisions of the panel of arbitrators that conform to the terms of this Section 15.3 will be final and binding on the Parties and judgment on the award so rendered may be entered in any court of competent jurisdiction. The losing Party, as determined by the panel of arbitrators, will pay all of the ICC administrative costs and fees of the arbitration and the fees and costs of the arbitrators, and the arbitrators will be directed to provide for payment or reimbursement of such fees and costs by the losing Party. If the panel of arbitrators determines that there

is no losing Party, the Parties will each be responsible for one-half of those costs and fees and the arbitrators' award will so provide. Notwithstanding the foregoing, each Party shall be responsible for its own attorneys' fees, expert or witness fees, and any other fees and costs, and no such fees or costs will be shifted to the other Party.

(b) Notwithstanding the terms of and procedures set forth in Section 15.2 or 15.3, any applications, motions, or orders to show cause seeking temporary restraining orders, preliminary injunctions or other similar preliminary or temporary legal or equitable relief ("**Injunctive Relief**") concerning a Disputed Matter (including, but not limited to, Disputed Matters arising out of a potential or actual breach of the confidentiality and non-use provisions in Article 13) may immediately be brought in the first instance and without invocation or exhaustion of the procedures set forth in subsections (a) and (b) for hearing and resolution in and by a court of competent jurisdiction. Alternatively, a party seeking Injunctive Relief may immediately institute arbitral proceedings without invocation or exhaustion of the procedures set forth in subsections (a) and (b), and any such Injunctive Relief proceedings will be administered by the ICC pursuant to its ICC emergency arbitration procedures then in effect and applying the substantive law specified in Section 16.1. In either event, once the Injunctive Relief proceedings have been conducted and a decision rendered thereon by the court or arbitral forum, the Parties will, if the Disputed Matter is not finally resolved by the Injunctive Relief, proceed to resolve the Disputed Matter in accordance with the terms of Section 15.2 and 15.3.

(c) Notwithstanding the foregoing, this Section 15.3 shall not apply to any dispute, controversy, or claim that concerns (i) the validity, enforceability, or infringement of a patent, trademark, or copyright; or (ii) any antitrust, anti-monopoly, or competition law or regulation, whether or not statutory.

16. GENERAL PROVISIONS

16.1 Governing Law. This Agreement, and all questions regarding the existence, validity, interpretation, breach, or performance of this Agreement, shall be governed by, and construed and enforced in accordance with, the laws of the State of Delaware, United States, without reference to its conflicts of law principles.

16.2 Entire Agreement; Modification. This Agreement, including the exhibits, is both a final expression of the Parties' agreement and a complete and exclusive statement with respect to all of its terms. This Agreement supersedes all prior and contemporaneous agreements and communications, whether oral, written, or otherwise, concerning any and all matters contained herein. This Agreement may only be modified or supplemented in a writing expressly stated for such purpose and signed by the Parties to this Agreement.

16.3 Relationship Between the Parties. The Parties' relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture, or similar business relationship between the Parties. Neither Party is a legal representative of the other Party, and neither Party can assume or create any obligation, representation, warranty, or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever.

16.4 Waiver. The waiver by either Party of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. Any waiver by a Party of a particular term or condition will be effective only if set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition.

16.5 Assignment. Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either Party without the prior written consent of the other Party (which consent shall not be unreasonably withheld); provided, however, that either Party may assign or otherwise transfer this Agreement and its rights and obligations hereunder without the other Party's consent:

(a) in connection with the transfer or sale of all or substantially all of the business or assets of such Party relating to the Compound and Products to a Third Party, whether by merger, consolidation, divesture, restructure, sale of stock, sale of assets, or otherwise, provided that in the event of any such transaction (whether this Agreement is actually assigned or is assumed by the acquiring Party by operation of law (e.g., in the context of a reverse triangular merger)), intellectual property rights of the acquiring Party to such transaction (if other than one of the Parties to this Agreement) shall not be included in the technology licensed hereunder; or

(b) to an Affiliate, provided that the assigning Party shall remain liable and responsible to the non-assigning Party hereto for the performance and observance of all such duties and obligations by such Affiliate.

The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties specified above, and the name of a Party appearing herein will be deemed to include the name of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Section 16.5. Any assignment not in accordance with this Section 16.5 shall be null and void and of no legal force or effect.

16.6 Severability. If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable, or illegal by a court of competent jurisdiction, such adjudication shall not affect or impair, in whole or in part, the validity, enforceability, or legality of any remaining portions of this Agreement. The Parties will in such an instance use their

best efforts to replace the invalid, unenforceable, or illegal provision(s) with valid, enforceable, and legal provision(s) that implement the purposes of this Agreement.

16.7 Notices. Any notice to be given under this Agreement must be in writing and delivered either in person, by (a) overnight courier by FedEx or DHL, or (b) facsimile confirmed thereafter by any of the foregoing, to the Party to be notified at its address(es) given below, or at any address such Party may designate by prior written notice to the other in accordance with this Section 16.7. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (i) the date of delivery; or (ii) if sent by facsimile, the date of confirmation of receipt if during the recipient's normal business hours, otherwise the next Business Day.

If to Collaborator, notices must be addressed to:

Takeda Pharmaceutical Company Limited
12-10, Nihonbashi 2-chome, Chuo-ku
Tokyo 103-8668, JAPAN
Attention: [*]
Facsimile: +[*]

with a copy to:

Takeda Pharmaceutical Company Limited
12-10, Nihonbashi 2-chome, Chuo-ku
Tokyo 103-8668, JAPAN
Attention: [*]
Facsimile: +[*]

Takeda Pharmaceutical Company Limited
1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, JAPAN
Attention: [*]

If to Exelixis, notices must be addressed to:

Exelixis, Inc.
210 East Grand Avenue,
So. San Francisco, CA 94080
USA
Attention: General Counsel
Facsimile: +[*]

16.8 Standstill.

(a) Commencing the Effective Date and expiring on the fifth (5^{th}) anniversary date of the Effective Date, unless such provision is terminated earlier by mutual written agreement of the Parties (the "**Standstill Period**"), neither Collaborator nor any of its Affiliates, without the prior consent of Exelixis or except as provided for in this Agreement or in any agreement referred to herein, or in any agreement executed after the Effective Date by Exelixis with Collaborator or any of its Affiliates, will:

(i) make, effect, initiate, cause or participate in:

(1) any acquisition of beneficial ownership of any securities of Exelixis or any securities of any subsidiary or other Affiliate of Exelixis (each, a "**Exelixis Entity**") such that following any such acquisition, Collaborator and its Affiliates then own more than [*] of the securities of such Exelixis Entity;

(2) any acquisition of any assets of any Exelixis Entity;

(3) any tender offer, exchange offer, merger, business combination, recapitalization, restructuring, liquidation, dissolution or extraordinary transaction involving an Exelixis Entity, or involving any securities or assets of a Exelixis Entity; or

(4) any "solicitation" of "proxies" (as those terms are used in the proxy rules of the Securities and Exchange Commission) or consents with respect to any securities of an Exelixis Entity;

(ii) form, join, or participate in a "group" (as defined in the Securities Exchange Act of 1934 and the rules promulgated thereunder) with respect to the beneficial ownership of any securities of an Exelixis Entity;

(iii) act, alone or in concert with others, to seek to control or influence the management, board of directors, or policies of an Exelixis Entity;

(iv) take any action that might require an Exelixis Entity to make a public announcement regarding any of the types of matters set forth in clause "(i)" of this Section 16.8(a);

(v) agree or offer to take, or encourage or propose (publicly or otherwise) the taking of, any action referred to in clause "(i)", "(ii)", "(iii)" or "(iv)" of this Section 16.8(a);

(vi) assist, induce or encourage any other person or entity to take any action of the type referred to in clause "(i)", "(ii)", "(iii)", "(iv)" or "(v)" of this Section 16.8(a); or

(vii) enter into any discussions, negotiations, arrangement, or agreement with any other person or entity relating to any of the foregoing.

For clarity, the expiration of the Standstill Period will not terminate or otherwise affect any of the other provisions of this Agreement.

(b) Notwithstanding the foregoing provisions, Collaborator or its Affiliates will not be subject to any of the restrictions set forth in this Section 16.8 with respect to an Exelixis Entity if either:

(i) such Exelixis Entity publicly announces its intention to pursue a proposed Acquisition Transaction (as defined below);

(ii) such Exelixis Entity shall have entered into an agreement in principle or definitive agreement providing for an Acquisition Transaction;

(iii) the board of directors of such Exelixis Entity shall have adopted a formal plan of liquidation or dissolution;

(iv) if a Third Party commences a tender or exchange offer or bid which, if successful, would result in such Third Party beneficially owning not less than [*] of the voting securities or equity interest in such Exelixis Entity; or

(v) if a Third Party makes a public announcement of a bona fide takeover bid to acquire the outstanding voting securities or equity interest in such Exelixis Entity.

"**Acquisition Transaction**" means (A) any direct or indirect acquisition or purchase of assets of the applicable Exelixis Entity at a purchase price representing [*] of the voting securities of or equity interest in such Exelixis Entity by any person or "group"; (B) any tender offer or exchange offer that if consummated would result in any person or "group" beneficially owning [*] or more of any class of equity securities of such Exelixis Entity; or (C) any merger, consolidation, business combination, sale of assets, recapitalization, or similar transaction involving such Exelixis Entity representing more than [*] of the market capitalization of such Exelixis Entity.

(c) Notwithstanding the foregoing, the Parties agree that Collaborator or its Affiliates shall not be prohibited from (i) initiating private discussions with, and submitting confidential private proposals to, the management or Chief Executive Officer of any Exelixis Entity; or (ii) proposing other collaborative research agreements or other commercial license agreements to Exelixis.

16.9 Force Majeure. Each Party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement (other than failure to make payment when due) by reason of any event beyond such Party's reasonable control,

including Acts of God, fire, flood, explosion, earthquake, tsunami, pandemic flu, or other natural forces, war, civil unrest, acts of terrorism, accident, destruction or other casualty, any lack or failure of transportation facilities, any lack or failure of supply of electricity, any lack or failure of supply of raw materials, or any other event similar to those enumerated above. Such excuse from liability shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the Party has not caused such event(s) to occur. Notice of a Party's failure or delay in performance due to force majeure must be given to the other Party within [*] after its occurrence. All delivery dates under this Agreement that have been affected by force majeure shall be tolled for the duration of such force majeure. In no event shall any Party be required to prevent or settle any labor disturbance or dispute.

16.10 Interpretation. The headings of clauses contained in this Agreement preceding the text of the sections, subsections, and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction. All references in this Agreement to the singular shall include the plural where applicable. Unless otherwise specified, references in this Agreement to any Article shall include all Sections, subsections, and paragraphs in such Article, references to any Section shall include all subsections and paragraphs in such Section, and references in this Agreement to any subsection shall include all paragraphs in such subsection. The word "including" and similar words means including without limitation. The word "or" means "and/or" unless the context dictates otherwise because the subject of the conjunction are mutually exclusive. The words "herein", "hereof", and "hereunder" and other words of similar import refer to this Agreement as a whole and not to any particular Section or other subdivision. All references to days in this Agreement mean calendar days, unless otherwise specified. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist. This Agreement has been prepared in the English language and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral, or other communications between the Parties regarding this Agreement shall be in the English language.

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

{SIGNATURE PAGE FOLLOWS}

IN WITNESS WHEREOF, the Parties hereto have caused this **COLLABORATION AND LICENSE AGREEMENT** to be executed and entered into by their duly authorized representatives as of the Effective Date.

EXELIXIS, INC.	**TAKEDA PHARMACEUTICAL COMPANY LIMITED**
By: /s/ Michael M. Morrissey	By: /s/ Authorized Representative
Name: Michael M. Morrissey, Ph.D.	Name: [*]
Title: President and Chief Executive Officer	Title: [*]

[*] = 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.

List of Exhibits:

Exhibit 1.2: Chemical Structure of cabozantinib

Exhibit 1.31: Exelixis Patents

Exhibit 4.2: Initial Global Development Plan and Budget

Exhibit 13.5: Press Release

[*] = 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.

List of Exhibits:

Exhibit 1.2: Chemical Structure of cabozantinib

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Exhibit 13.5: Press Release

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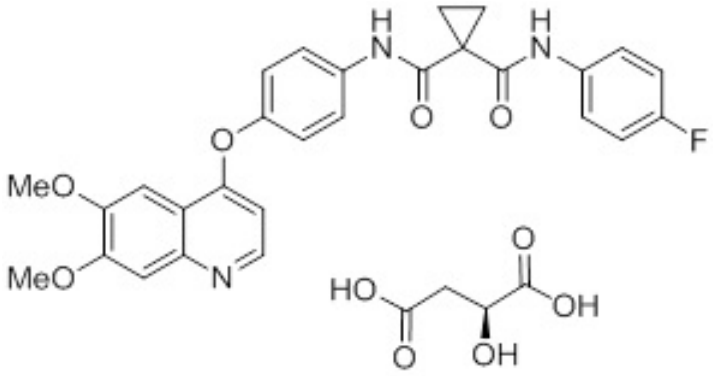
Exhibit 1.2
Chemical Structure of cabozantinib



Cabozantinib (*S*)-malate salt

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Exhibit 1.31
Exelixis Patents

{Redacted content comprises approximately 4 pages}
[*]

[*] = 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.

Exhibit 4.2
Initial Global Development Plan and Budget

{Redacted content comprises approximately 6 pages}

[*]

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Press Release

EXELIXIS AND TAKEDA ENTER INTO EXCLUSIVE LICENSING AGREEMENT TO COMMERCIALIZE AND DEVELOP NOVEL CANCER THERAPY CABOZANTINIB IN JAPAN

– Takeda's Rights to Include all Potential Indications for Cabozantinib, which is Marketed in the U.S. and European Union for Renal Cell Carcinoma and Medullary Thyroid Carcinoma –
– Exelixis Receives $50 Million Upfront Payment and is Eligible for Future Regulatory and Commercial Milestones –

South San Francisco, Calif., Cambridge, Mass. and Osaka, Japan – January 30 (PST) and (EST/JST), 2017 – Exelixis, Inc. (NASDAQ: EXEL) and Takeda Pharmaceutical Company Limited (TSE:4502) today announced an exclusive licensing agreement for the commercialization and further clinical development in Japan of cabozantinib, Exelixis' lead oncology medicine. With the signing of the agreement, Takeda gains exclusive commercial rights for all potential future cabozantinib indications in Japan, including advanced renal cell carcinoma (RCC), for which cabozantinib is marketed in the United States and European Union as CABOMETYX™ tablets. The two companies will collaborate on the future clinical development of cabozantinib in Japan.

Under the terms of the agreement, Exelixis will receive a $50 million upfront payment. Exelixis is eligible to receive development, regulatory, and first-sales milestones of $95 million for the first three planned indications. In addition, Exelixis will be eligible to receive royalties on sales by Takeda.

"As an organization with a strong focus on oncology innovation, our agreement with Exelixis brings a promising and well-studied solid-tumor therapy to our pipeline that may help patients in Japan suffering from RCC and potentially other equally devastating cancers," said Tsudoi Miyoshi, Head of Japan Oncology Business Unit of Takeda. "We intend to pursue regulatory approval for RCC indications as soon as we're able, and look forward to commencing the local clinical trial program to further strengthen the clinical profile of cabozantinib."

Exelixis and Takeda will partner on cabozantinib's clinical development in Japan and on translating existing and forthcoming clinical data for potential regulatory filings in the country. In the METEOR pivotal trial, cabozantinib demonstrated statistically significant improvements in overall survival, progression-free survival and objective response rate, meaningfully differentiating it from other therapies to treat advanced renal cell carcinoma following prior therapy. In addition to advanced RCC, future indications could include advanced hepatocellular cancer (HCC), the subject of the CELESTIAL global pivotal trial for which results are anticipated in 2017. Additional earlier-stage studies are under way through Exelixis' collaboration with the National Cancer Institute's Cancer Therapy Evaluation Program, and its ongoing Investigator-Sponsored Trial program. Through these two programs, there are more than 45 ongoing or planned studies including trials in advanced RCC, bladder cancer, colorectal cancer, non-small cell lung cancer, and endometrial cancer.

"Takeda is the ideal partner to advance cabozantinib in Japan and deliver this important treatment option to Japanese patients with cancer," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of

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Exelixis. “Takeda is widely respected for both its clinical development and commercial expertise. We look forward to supporting our new partner as it pursues Japanese regulatory approval for cabozantinib, while simultaneously working together to plan the next steps for clinical development in the country. This agreement further propels the global progress for cabozantinib development and commercialization, which now includes the recent first commercial sale of CABOMETYX in the United Kingdom, triggering a $10 million milestone payment from Ipsen to Exelixis.”

Cabozantinib is not approved for use in Japan. Previously, Exelixis and its collaborators conducted early-stage clinical trials in Japan, including a phase 1 trial in advanced solid tumors. Data from this trial were presented at the European Society for Medical Oncology 2012 Congress and the 2015 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics.

Exelixis maintains its exclusive rights to develop and commercialize cabozantinib in the United States, and its partner Ipsen maintains its exclusive commercialization rights for current and potential future cabozantinib indications outside of the United States and Japan.

About CABOMETYX™ (cabozantinib) Tablets
CABOMETYX is the tablet formulation of cabozantinib. Its targets include MET, AXL, and VEGFR-1, -2 and -3. In preclinical models, cabozantinib has been shown to inhibit the activity of these receptors, which are involved in normal cellular function and pathologic processes such as tumor angiogenesis, invasiveness, metastasis, and drug resistance.

CABOMETYX is available in 20 mg, 40 mg or 60 mg doses. The recommended dose is 60 mg orally, once daily.

On April 25, 2016, the FDA approved CABOMETYX tablets for the treatment of patients with advanced renal cell carcinoma who have received prior anti-angiogenic therapy. On September 9, 2016, the European Commission approved CABOMETYX tablets for the treatment of advanced renal cell carcinoma in adults who have received prior vascular endothelial growth factor (VEGF)-targeted therapy in the European Union, Norway and Iceland. On February 29, 2016, Exelixis and Ipsen jointly announced an exclusive licensing agreement for the commercialization and further development of cabozantinib indications outside of the United States, Canada and Japan. On December 20, 2016, Exelixis and Ipsen jointly announced an amendment to their exclusive licensing agreement for the commercialization and development of cabozantinib to include Canada.

U.S. Important Safety Information

Hemorrhage: Severe hemorrhage occurred with CABOMETYX. The incidence of Grade ≥3 hemorrhagic events was 2.1% in CABOMETYX-treated patients and 1.6% in everolimus-treated patients. Fatal hemorrhages also occurred in the cabozantinib clinical program. Do not administer CABOMETYX to patients that have or are at risk for severe hemorrhage.

Gastrointestinal (GI) Perforations and Fistulas: Fistulas were reported in 1.2% (including 0.6% anal fistula) of CABOMETYX-treated patients and 0% of everolimus-treated patients. GI perforations were reported in 0.9% of CABOMETYX-treated patients and 0.6% of everolimus-treated patients. Fatal perforations occurred in the cabozantinib clinical program. Monitor patients for symptoms of fistulas and perforations. Discontinue CABOMETYX in patients who experience a fistula that cannot be appropriately managed or a GI perforation.

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Thrombotic Events: CABOMETYX treatment results in an increased incidence of thrombotic events. Venous thromboembolism was reported in 7.3% of CABOMETYX-treated patients and 2.5% of everolimus-treated patients. Pulmonary embolism occurred in 3.9% of CABOMETYX-treated patients and 0.3% of everolimus-treated patients. Events of arterial thromboembolism were reported in 0.9% of CABOMETYX-treated patients and 0.3% of everolimus-treated patients. Fatal thrombotic events occurred in the cabozantinib clinical program. Discontinue CABOMETYX in patients who develop an acute myocardial infarction or any other arterial thromboembolic complication.

Hypertension and Hypertensive Crisis: CABOMETYX treatment results in an increased incidence of treatment-emergent hypertension. Hypertension was reported in 37% (15% Grade ≥3) of CABOMETYX-treated patients and 7.1% (3.1% Grade ≥3) of everolimus-treated patients. Monitor blood pressure prior to initiation and regularly during CABOMETYX treatment. Withhold CABOMETYX for hypertension that is not adequately controlled with medical management; when controlled, resume CABOMETYX at a reduced dose. Discontinue CABOMETYX for severe hypertension that cannot be controlled with anti-hypertensive therapy. Discontinue CABOMETYX if there is evidence of hypertensive crisis or severe hypertension despite optimal medical management.

Diarrhea: Diarrhea occurred in 74% of patients treated with CABOMETYX and in 28% of patients treated with everolimus. Grade 3 diarrhea occurred in 11% of CABOMETYX-treated patients and in 2% of everolimus-treated patients. Withhold CABOMETYX in patients who develop intolerable Grade 2 diarrhea or Grade 3-4 diarrhea that cannot be managed with standard antidiarrheal treatments until improvement to Grade 1; resume CABOMETYX at a reduced dose. Dose modification due to diarrhea occurred in 26% of patients.

Palmar-Plantar Erythrodysesthesia Syndrome (PPES): Palmar-plantar erythrodysesthesia syndrome (PPES) occurred in 42% of patients treated with CABOMETYX and in 6% of patients treated with everolimus. Grade 3 PPES occurred in 8.2% of CABOMETYX-treated patients and in <1% of everolimus-treated patients. Withhold CABOMETYX in patients who develop intolerable Grade 2 PPES or Grade 3 PPES until improvement to Grade 1; resume CABOMETYX at a reduced dose. Dose modification due to PPES occurred in 16% of patients.

Reversible Posterior Leukoencephalopathy Syndrome (RPLS): RPLS, a syndrome of subcortical vasogenic edema diagnosed by characteristic finding on MRI, occurred in the cabozantinib clinical program. Perform an evaluation for RPLS in any patient presenting with seizures, headache, visual disturbances, confusion, or altered mental function. Discontinue CABOMETYX in patients who develop RPLS.

Embryo-fetal Toxicity: CABOMETYX can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with CABOMETYX and for 4 months after the last dose.

Adverse Reactions: The most commonly reported (≥25%) adverse reactions are: diarrhea, fatigue, nausea, decreased appetite, PPES, hypertension, vomiting, weight decreased, and constipation.

Drug Interactions: Strong CYP3A4 inhibitors and inducers: Reduce the dosage of CABOMETYX if concomitant use with strong CYP3A4 inhibitors cannot be avoided. Increase the dosage of CABOMETYX if concomitant use with strong CYP3A4 inducers cannot be avoided.

Lactation: Advise a lactating woman not to breastfeed during treatment with CABOMETYX and for 4 months after the final dose.

Reproductive Potential: Contraception—Advise females of reproductive potential to use effective contraception during treatment with CABOMETYX and for 4 months after the final dose. Infertility —CABOMETYX may impair fertility in females and males of reproductive potential.

Hepatic Impairment: Reduce the CABOMETYX dose in patients with mild (Child-Pugh score [*] A) or moderate (C-P B) hepatic impairment. CABOMETYX is not recommended for use in patients with severe hepatic impairment.

Please see full Prescribing Information at https://cabometyx.com/downloads/cabometyxuspi.pdf.

About Takeda Pharmaceutical Company
Takeda Pharmaceutical Company Limited is a global, research and development-driven pharmaceutical company committed to bringing better health and a brighter future to patients by translating science into life-changing medicines. Takeda focuses its R&D efforts on oncology, gastroenterology and central nervous system therapeutic areas plus vaccines. Takeda conducts R&D both internally and with partners to stay at the leading edge of innovation. New innovative products, especially in oncology and gastroenterology, as well as our presence in Emerging Markets, fuel the growth of Takeda. More than 30,000 Takeda employees are committed to improving quality of life for patients, working with our partners in health care in more than 70 countries. For more information, visit http://www.takeda.com/news.

Additional information about Takeda is available through its corporate website, www.takeda.com, and additional information about Takeda Oncology, the brand for the global oncology business unit of Takeda Pharmaceutical Company Limited, is available through its website, www.takedaoncology.com.

About Exelixis
Exelixis, Inc. (Nasdaq: EXEL) is a biopharmaceutical company committed to the discovery, development and commercialization of new medicines with the potential to improve care and outcomes for people with cancer. Since its founding in 1994, three medicines discovered at Exelixis have progressed through clinical development to receive regulatory approval. Currently, Exelixis is focused on advancing cabozantinib, an inhibitor of multiple tyrosine kinases including MET, AXL and VEGF receptors, which has shown clinical anti-tumor activity in more than 20 forms of cancer and is the subject of a broad clinical development program. Two separate formulations of cabozantinib have received regulatory approval to treat certain forms of kidney and thyroid cancer and are marketed for those purposes as CABOMETYX™ tablets (U.S. and EU) and COMETRIQ® capsules (U.S. and EU), respectively. Another Exelixis-discovered compound, COTELLIC® (cobimetinib), a selective inhibitor of MEK, has been approved in major territories including the United States and European Union, and is being evaluated for further potential indications by Roche and Genentech (a member of the Roche Group) under a collaboration with Exelixis. For more information on Exelixis, please visit www.exelixis.com or follow @ExelixisInc on Twitter.

Exelixis Forward-Looking Statements
This press release contains forward-looking statements, including, without limitation, statements related to: the future clinical development of cabozantinib by Exelixis and Takeda in Japan; Exelixis' receipt of a $50 million upfront payment; Exelixis' eligibility to receive development, regulatory and first-sales milestones of $95 million for the first three planned indications; Exelixis' eligibility to receive royalties on sales of cabozantinib by Takeda; the clinical and therapeutic potential of cabozantinib for patients in Japan suffering from RCC and potentially other cancers; Takeda's intent to pursue regulatory approval for cabozantinib in RCC indications and commence a local clinical trial program; Exelixis' and Takeda's plan to translate existing and forthcoming clinical data for potential regulatory filings in Japan; advanced HCC as a potential future

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commercial indication; the timing of anticipated results from CELESTIAL; the continued development of cabozantinib through Exelixis' collaboration with the National Cancer Institute's Cancer Therapy Evaluation Program, and its ongoing Investigator-Sponsored Trial program; Exelixis' intent to support Takeda as it pursues Japanese regulatory approval for cabozantinib, while simultaneously working together to plan the next steps for clinical development in Japan; Exelixis' commitment to the discovery, development and commercialization of new medicines with the potential to improve care and outcomes for people with cancer; Exelixis' focus on advancing cabozantinib; and the continued development of cobimetinib. Words such as "potential," "further," "will," "eligible," "planned," "may," "intend," "look forward," "future," "could," "anticipated," "next," "committed," "focused," or other similar expressions identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements are based upon Exelixis' current plans, assumptions, beliefs, expectations, estimates and projections. Forward-looking statements involve risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in the forward-looking statements as a result of these risks and uncertainties, which include, without limitation: the complexities and challenges associated with regulatory review and approval processes; Exelixis' dependence on its relationship with Takeda, including, the level of Takeda's investment in the resources necessary to successfully commercialize cabozantinib in Japan; the degree of market acceptance of CABOMETYX and the availability of coverage and reimbursement for CABOMETYX; the risk that unanticipated developments could adversely affect the commercialization of CABOMETYX; Exelixis' ability to conduct clinical trials of cabozantinib sufficient to achieve a positive completion; risks related to the potential failure of cabozantinib to demonstrate safety and efficacy in clinical testing; Exelixis' dependence on its relationship with other collaborators, including Ipsen with respect to cabozantinib in territories outside of the United States and Japan and Genentech/Roche with respect to cobimetinib; Exelixis' dependence on third-party vendors; Exelixis' ability to protect the company's intellectual property rights; market competition; changes in economic and business conditions, and other factors discussed under the caption "Risk Factors" in Exelixis' quarterly report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 3, 2016, and in Exelixis' future filings with the SEC. The forward-looking statements made in this press release speak only as of the date of this press release. Exelixis expressly disclaims any duty, obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Exelixis' expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

Exelixis Contacts

Financial Community:
Susan Hubbard
EVP, Public Affairs and
Investor Relations
(650) 837-8194
shubbard@exelixis.com

Media:
For Exelixis, Inc.
Hal Mackins
(415) 994-0040
hal@torchcomllc.com

Takeda Contacts

Japanese Media:
Tsuyoshi Tada
Tel: +81 (0) 3-3278-2417
tsuyoshi.tada@takeda.com

Media Outside Japan:
Amy Atwood
+1 (617) 444-2147
amy.atwood@takeda.com

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Exhibit 10.2

CLINICAL TRIAL COLLABORATION AGREEMENT

This **CLINICAL TRIAL COLLABORATION AGREEMENT** (the "***Agreement***") is made and entered into effective as of February 24, 2017 (the "***Effective Date***") by and between Exelixis, Inc., a Delaware corporation, located at 210 East Grand Avenue, South San Francisco, CA 94080 ("***Exelixis***") and Bristol-Myers Squibb Company, a Delaware corporation, headquartered at 345 Park Avenue, New York, New York 10154 ("***BMS***"). Exelixis and BMS may be referred to herein individually as a "***Party***," or collectively as the "***Parties***."

RECITALS

WHEREAS, the Parties wish to collaborate with each other to sponsor one or more clinical trials of a combination therapy using Exelixis's tyrosine kinase inhibitor known as ***"Cabozantinib"***, certain rights to which are licensed by Exelixis to, and shared by Exelixis with Ipsen Pharma SAS (***"Ipsen")*** and Takeda Pharmaceutical Company Ltd. (***"Takeda"***), and BMS' human monoclonal antibody that binds PD-1 known as ***"Nivolumab"***, certain rights to which are licensed by BMS from, and shared by BMS with, Ono Pharmaceutical Co. Ltd. ("***Ono***"), with or without BMS's CTLA-4 monoclonal antibody known as "***Ipilimumab***".

NOW, THEREFORE, in consideration of the foregoing premises and the mutual promises and covenants contained herein, the Parties agree as follows:

ARTICLE 1

DEFINITIONS

The terms in this Agreement with initial letters capitalized, whether used in the singular or the plural, shall have the meaning set forth below or, if not listed below, the meaning designated in places throughout this Agreement.

1.1 "***Affiliates***" shall mean, with respect to a particular Party, an entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such Party. As used in this section, the term "controls" (with correlative meanings for the terms "controlled by" or "under common control with") means (a) that an entity or company owns, directly or indirectly, more than fifty percent (50%) of the voting stock of another entity, or (b) that an entity, person or group otherwise has the actual ability to control and direct the management of the entity, whether by contract or otherwise.

1.2 "***Aggregate Safety Information***" shall mean, with respect to a Party's Compound(s), the (a) safety and toxicity information for such Compound(s) that is Combined Therapy Study Data, plus (b) safety and toxicity information from all other clinical trials of such Compound(s), whether alone or in combination with another pharmaceutical agent, in each case including information related to serious adverse events, adverse drug reactions, adverse events,

discontinuations due to adverse events and Grade 3 and Grade 4 laboratory abnormalities. Aggregate Safety Information shall be provided by a Party to the other in the same format as is contained in the Investigators' Brochures prepared by such Party for its Compound(s) in each country where a Combined Therapy Trial will be conducted.

1.3 "***Agreement***" shall have the meaning set forth in the preamble to this Agreement, as it may be amended by the Parties from time to time.

1.4 "***Applicable Law***" shall mean all applicable laws, rules and regulations (whether federal, state or local) that may be in effect from time to time and applicable to conduct under this Agreement, including current Good Clinical Practices (GCP), Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP).

1.5 "***Arbitration Matter***" shall mean any disputed matter that relates to or arises out of the validity, interpretation or construction of, or the compliance with or breach of, this Agreement; *provided that* such disputed matter has been considered, but not resolved, by the Executive Officers as set forth in Section 13.3. For clarity, no JDC Dispute (other than a dispute relating to the above matters which is raised at the JDC), Publication Dispute, or any matter requiring mutual agreement of both Parties shall be an Arbitration Matter.

1.6 "***Bioanalysis Plan***" shall mean the bioanalysis plan for any Samples as may be contemplated by a Combined Therapy Trial Protocol or another subsequent written agreement between the Parties, as described in Section 8.5.

1.7 "***BMS***" shall have the meaning set forth in the preamble to this Agreement.

1.8 "***BMS Compound***" shall mean each of BMS's proprietary anti-PD-1 monoclonal antibody known as Nivolumab and BMS's proprietary CTLA-4 monoclonal antibody known as Ipilimumab. In the event that any provision of this Agreement refers to the BMS Compound(s) or to Compound(s) of BMS or otherwise imposes an obligation on, or grants a right to, BMS in relation to such Compound(s), this provision will be read to relate to Nivolumab alone, to Ipilimumab alone or to both of them jointly, as is required in order to give full effect to such provision.

1.9 "***BMS Indemnitees***" shall have the meaning set forth in Section 11.2 of this Agreement.

1.10 "***BMS Independent Patent Rights***" shall mean any Patent Rights Controlled by BMS (or its Affiliates) as of the Effective Date or during the Term through efforts outside of this Agreement that Cover the use (whether alone or in combination with other agents), manufacture, formulation or composition of matter of each of the BMS Compounds, but excluding any BMS Study Patent Rights and BMS' interest in any Combined Therapy Patent Right.

1.11 "***BMS Regulatory Documentation***" shall mean any Regulatory Documentation related to the BMS Compounds that exists as of the Effective Date or that is created during the Term through efforts outside this Agreement.

1.12 "***BMS Study Data***" shall have the meaning set forth in Section 8.2 of this Agreement.

1.13 "***BMS Study Invention***" shall mean any Invention that relates to (a) the composition of matter of any BMS Compound (and not the Exelixis Compound), (b) a method of manufacture or formulation of any BMS Compound (and not the Exelixis Compound) as a Single Agent, (c) a method of use of any BMS Compound as a monotherapy or as used in combination with agents, antibodies or compounds that are not the Exelixis Compound.

1.14 "***BMS Study Patent Rights***" shall mean any Patent Rights that Cover any BMS Study Invention (and not an Exelixis Study Invention or Combined Therapy Invention) or BMS Study Data, excluding BMS Independent Patent Rights and BMS Technology. For the avoidance of doubt, any Patent Rights that Cover both (x) a BMS Study Invention and (y) any other type of Invention is included within the Combined Therapy Patent Rights.

1.15 "***BMS Technology***" shall mean all Technology Controlled by BMS (or its Affiliates) as of the Effective Date or during the Term through efforts outside of this Agreement related to the BMS Compound(s) or the Combined Therapy and necessary for the conduct of the Combined Therapy Trials. For clarity, BMS Technology does not include (a) Inventions, (b) Study Data, or (c) Combined Therapy Trial Regulatory Documentation.

1.16 "***Business Day***" shall mean a day other than Saturday, Sunday or any day on which commercial banks located in New York, NY are authorized or obligated by Applicable Law to close.

1.17 "***Clinical Hold***" shall mean that (i) the FDA has issued an order to a Party pursuant to 21 CFR §312.42 to delay a proposed clinical investigation or to suspend an ongoing clinical investigation of the Combined Therapy or such Party's Single Agent Compound(s) in the United States or (ii) a Regulatory Authority other than the FDA has issued an equivalent order to the order in (i) in any other country or group of countries.

1.18 "***Combined Therapy***" shall mean a therapy using the Exelixis Compound on the one hand and a BMS Compound or the BMS Compounds on the other hand, only when used in combination, wherein each compound of the combination is used as an individual formulation, for use in the Field, with or without another agent.

1.19 "***Combined Therapy IND***" shall have the meaning set forth in Section 2.1(b).

1.20 ***"Combined Therapy Invention(s)"*** shall mean all Inventions that are not Exelixis Study Inventions or BMS Study Inventions. For the avoidance of doubt, Combination Therapy Inventions include any Invention comprising or claiming, whether generically or specifically, (a) one or both of the BMS Compounds and/or any other molecule(s) that is/are designed to selectively

bind to PD-1 or PD-L1 or CTLA-4 and (b) the Exelixis Compound and/or any other molecule(s) that is/are designed to selectively inhibit the activity of MET, VEGF receptors, AXL and RET.

1.21 "***Combined Therapy Patent Right(s)***" shall mean any Patent Rights that Cover any Combined Therapy Invention or Combined Therapy Study Data, excluding BMS Independent Patent Rights and Exelixis Independent Patent Rights.

1.22 "***Combined Therapy Study Data***" shall have the meaning set forth in Section 8.2 of this Agreement.

1.23 "***Combined Therapy Trial***" or "***Combined Therapy Trials***" shall have the meaning set forth in Section 2.1(a) of this Agreement.

1.24 "***Combined Therapy Trial Regulatory Documentation***" shall mean any Regulatory Documentation to be submitted for the conduct of a Combined Therapy Trial, but excluding (a) any Exelixis Regulatory Documentation and (b) any BMS Regulatory Documentation.

1.25 "***Commercially Reasonable Efforts***" means the level of effort and resources normally devoted by a Party to conduct a clinical trial for a biopharmaceutical product or compound that is owned by it or to which it has rights, which is of similar market potential, profit potential or strategic value and at a similar stage in its development or product life based on conditions then prevailing.

1.26 "***Conducting Party Compound(s)***" shall mean (i) in the case of BMS as the Conducting Party, the BMS Compound(s) and (ii), in the case of Exelixis as the Conducting Party, the Exelixis Compound.

1.27 "***Confidential Information***" shall have the meaning set forth in Section 9.1 of this Agreement.

1.28 "***Control***" or "***Controlled***" shall mean, with respect to particular information or intellectual property, that the applicable Party or any Affiliate of such Party owns or has a license to such information or intellectual property and has the ability to grant a right, license or sublicense to the other Party as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.

1.29 "***Cover***" means, with respect to a Patent, that, but for rights granted to a Person under such Patent, the practice by such Person of an invention described in such Patent would infringe a claim included in such Patent, or in the case of a Pat dewent that is a patent application, would infringe a claim in such patent application if it were to issue as a patent. "***Covered***" or "***Covering***" shall have correlative meanings.

1.30 "***CRO***" means any Third Party contract research organization used to conduct a Combined Therapy Trial, including laboratories and Third Parties used to maintain the safety

database from a Combined Therapy Trial, but, for clarity, excluding clinical trial sites and any Third Parties who are individuals.

1.31 ***"Effective Date"*** shall have the meaning set forth in the preamble to this Agreement.

1.32 "***Executive Officers***" shall mean the [*] of Exelixis and the [*] of BMS (or their respective designees).

1.33 ***"Exelixis"*** shall have the meaning set forth in the preamble to this Agreement.

1.34 ***"Exelixis Compound"*** shall mean Exelixis' tyrosine kinase inhibitor known as Cabozantinib.

1.35 ***"Exelixis Indemnitees"*** shall have the meaning set forth in Section 11.1 of this Agreement.

1.36 ***"Exelixis Independent Patent Rights"*** shall mean any Patent Rights Controlled by Exelixis (or its Affiliates) as of the Effective Date or during the Term through efforts outside of this Agreement that Cover the use (whether alone or in combination with other agents), manufacture, formulation, or composition of matter of the Exelixis Compound, but excluding any Exelixis Study Patent and Exelixis' interest in any Combined Therapy Patent Right.

1.37 ***"Exelixis Regulatory Documentation"*** shall mean any Regulatory Documentation related to the Exelixis Compound that exists as of the Effective Date or that is created during the Term through efforts outside this Agreement.

1.38 ***"Exelixis Study Data"*** shall have the meaning set forth in Section 8.2 of this Agreement.

1.39 ***"Exelixis Study Invention"*** **s**hall mean any Invention that relates to (a) the composition of matter of the Exelixis Compound (and not any BMS Compound), (b) a method of manufacture or formulation of the Exelixis Compound (and not any BMS Compound) as a Single Agent, or (c) a method of use of the Exelixis Compound as a monotherapy or as used in combination with agents, antibodies or compounds that are not one or both of the BMS Compounds.

1.40 ***"Exelixis Study Patent Rights"*** shall mean any Patent Rights that Cover any Exelixis Study Invention (and not a BMS Study Invention or Combined Therapy Invention) or Exelixis Study Data, excluding Exelixis Independent Patent Rights and Exelixis Technology. For the avoidance of doubt, any Patent Rights that cover both (x) an Exelixis Study Invention and (y) any other type of Invention is included within the Combined Therapy Patent Rights.

1.41 ***Exelixis Technology"*** shall mean all Technology Controlled by Exelixis (or its Affiliates) as of the Effective Date or during the Term through efforts outside of this Agreement related to the Exelixis Compound or the Combined Therapy and necessary for the conduct of the Combined Therapy Trials. For clarity, Exelixis Technology does not include (a) Inventions, (b) Study Data, or (c) Combined Therapy Trial Regulatory Documentation.

1.42 ***"Exelixis Territory"*** means the United States.

1.43 "***FDA***" shall mean the United States Food and Drug Administration, or any successor agency having the same or similar authority.

1.44 "***Field***" shall mean the treatment of patients with indication(s) to be studied in a Combined Therapy Trial as set forth in the Protocol(s).

1.45 ***"FTE"*** means the equivalent of the work of appropriately qualified individuals working in support of a Combined Therapy Trial for a total of [*] hours per year of dedicated effort. The billable FTEs shall equal the actual number of hours worked by such qualified individuals on the Combined Therapy Trial, divided by [*]. FTE efforts shall not include the work of general corporate or administrative personnel.

1.46 "***FTE Rate***" means the yearly rate of [*] U.S. Dollars ($[*]), which rate shall be increased [*] during the Term by [*] starting on January 1, 2018.

1.47 "***Global Safety Database***" shall mean the database containing serious adverse events, serious adverse drug reactions and pregnancy reports for the Combined Therapy, and shall be the authoritative data source for regulatory reporting and responding to regulatory queries.

1.48 "***Good Clinical Practices***" *or* "***GCP***" shall mean, as to the United States and the European Union, applicable good clinical practices as in effect in the United States and the European Union, respectively, during the Term and, with respect to any other jurisdiction, clinical practices equivalent to good clinical practices as then in effect in the United States or the European Union.

1.49 "***Good Laboratory Practices***" or "***GLP***" shall mean, as to the United States and the European Union, applicable good laboratory practices as in effect in the United States and the European Union, respectively, during the Term and, with respect to any other jurisdiction, laboratory practices equivalent to good laboratory practices as then in effect in the United States or the European Union.

1.50 "***Good Manufacturing Practices***" or "***GMP***" shall mean, as to the United States and the European Union, applicable good manufacturing practices as in effect in the United States and the European Union, respectively, during the Term and, with respect to any other jurisdiction, manufacturing practices equivalent to good manufacturing practices as then in effect in the United States or the European Union.

1.51 "***IND***" shall mean (a) an Investigational New Drug Application as defined in the United States Food, Drug and Cosmetic Act, as amended, and regulations promulgated thereunder, or any successor application or procedure required to initiate clinical testing of a drug in humans in the United States; (b) a counterpart of such an Investigational New Drug Application that is required in any other country before beginning clinical testing of a drug in humans in such country, including, for clarity, a "Clinical Trial Application" in the European Union; and (c) all supplements and amendments to any of the foregoing.

1.52 "***Initiation***" shall mean dosing of the first patient in any Combined Therapy Trial.

1.53 "***Invention***" shall mean any invention or Technology, whether or not patentable, that is made, conceived, generated or first actually reduced to practice by or on behalf of a Party (or an Affiliate thereof), or by or on behalf of the Parties (or Affiliates thereof) together (including by a Third Party in the performance of the Combined Therapy Trial), in the performance of a Combined Therapy Trial, Statistical Analysis Plan or Bioanalysis Plan to be conducted under this Agreement, but excluding any Study Data.

1.54 ***"Ipsen"*** shall have the meaning set forth in the recitals of this Agreement.

1.55 "***Ipsen-Exelixis Agreements"*** means that certain Collaboration and License Agreement between Exelixis and Ipsen dated as February 29, 2016, as amended from time to time, and agreements between Exelixis and Ipsen and their Affiliates relating thereto that may be in effect from time to time.

1.56 ***"Ipsen Territory"*** means all the countries of the world other than those in the Exelixis Territory and the Takeda Territory (i.e., all countries other than the United States and Japan).

1.57 ***"Manufacture" or "Manufacturing"*** shall mean manufacturing, processing, formulating, packaging, labeling, holding (including storage), and quality control testing of a Single Agent Compound or the Combined Therapy, in each case so as to be suitable for use in the Combined Therapy Trials under Applicable Law.

1.58 ***"Material Safety Issue"*** means a Party's good faith belief that there is an unacceptable risk for harm in humans based upon: (i) pre-clinical safety data, including data from animal toxicology studies; or (ii) the observation of serious adverse effects in humans after the Exelixis Compound or the BMS Compound, either as a Single Agent or in combination with another pharmaceutical agent (including as the Combined Therapy), has been administered to or taken by humans, such as during the Combined Therapy Trial.

1.59 ***"Non-Conducting Party Compound(s)"*** shall mean (i) in the case of BMS as the Non-Conducting Party, the BMS Compound(s) and (ii) in the case of Exelixis as the Non-Conducting Party, the Exelixis Compound.

1.60 ***"Ono"*** shall have the meaning set forth in the recitals of this Agreement.

1.61 "***Ono-BMS Agreements***" means those certain Collaboration Agreements between BMS and Ono dated as September 20, 2011 and as of July 23, 2014, as amended from time to time, and agreements between Ono and BMS and their Affiliates relating thereto that may be in effect from time to time.

1.62 ***"Ono Territory"*** means Japan, South Korea and Taiwan.

1.63 "***Party***" or "***Parties***" shall have the meaning set forth in the preamble to this Agreement.

1.64 "***Patent Rights***" shall mean any and all (a) United States or foreign patents; (b) United States or foreign patent applications, including all provisional applications, substitutions, continuations, continuations-in-part, divisions, renewals, and all patents granted thereon; (c) United States or foreign patents-of-addition, reissues, reexaminations (including without limitation, *ex parte* reexaminations, *inter partes* reviews, *inter partes* reexaminations, post grant reviews and supplemental examinations) and extensions or restorations by existing or future extension or restoration mechanisms, including supplementary protection certificates, patent term extensions, or the equivalents thereof; and (d) any other form of government-issued right substantially similar to any of the foregoing, and "***Patent***" shall mean any of the foregoing issued or granted rights.

1.65 "***PD-1***" shall mean programmed cell death protein 1.

1.66 "***PD-L1***" shall mean programmed death-ligand 1.

1.67 "***Person***" shall mean an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.68 "***Quarter***" shall mean a calendar quarter.

1.69 "***Regulatory Authority***" shall mean the FDA or any other governmental authority outside the United States (whether national, federal, provincial and/or local) that is the counterpart to the FDA, including the European Medicines Agency for the European Union.

1.70 "***Regulatory Documentation***" shall mean, with respect to a product containing a BMS Compound as monotherapy, the BMS Compounds as a combination therapy or the Exelixis Compound as monotherapy, all submissions to Regulatory Authorities in connection with the development of such product, including all INDs and amendments thereto, BLAs, NDAs and amendments thereto, drug master files, correspondence with regulatory agencies, periodic safety update reports, adverse event files, complaint files, inspection reports and manufacturing records, in each case together with all supporting documents (including documents with respect to clinical data).

1.71 "***Right of Cross-Reference***" shall mean, with regard to a Party, allowing the applicable Regulatory Authority in a country to have access to relevant information (by cross-reference, incorporation by reference or otherwise) contained in Regulatory Documentation (and any data contained therein) filed with such Regulatory Authority with respect to a Party's Compound(s) (and, in the case of the Non-Conducting Party, the Right to Cross-Reference the Combined Therapy IND), only to the extent necessary for the conduct of a Combined Therapy Trial in such country or as otherwise expressly permitted or required under this Agreement to enable a Party to exercise its rights or perform its obligations hereunder, and, except as to information contained in

the Combined Therapy IND relating to the Combined Therapy, without the disclosure of such information to such Party.

1.72 "***Samples***" shall mean biological specimens collected from Combined Therapy Trial study subjects (including [*]).

1.73 ***"Single Agent Compound"*** or ***"Compound"*** shall mean, (a) with respect to Exelixis, the Exelixis Compound, and (b) with respect to BMS, each of the BMS Compounds, in each case as monotherapy.

1.74 ***"Statistical Analysis Plan"*** shall mean the set of analyses (including statistical analysis) of the Study Data for each Combined Therapy Trial conducted hereunder prepared by the Conducting Party (in consultation with the Non-Conducting Party) and approved by the JDC and shall include safety analyses for the Combined Therapy in each Combined Therapy Trial. The Statistical Analysis Plan document for a Combined Therapy Trial must be approved by the JDC before database lock.

1.75 ***"Takeda"*** shall have the meaning set forth in the recitals of this Agreement.

1.76 "***Takeda-Exelixis Agreements"*** means that certain Collaboration and License Agreement between Exelixis and Takeda dated as January 30, 2017, as amended from time to time, and agreements between Exelixis and Takeda and their Affiliates relating thereto that may be in effect from time to time.

1.77 ***"Takeda Territory"*** means Japan.

1.78 ***"Technology"*** shall mean information, inventions, discoveries, trade secrets, knowledge, technology, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, specifications, data and results not generally known to the public (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and know-how, including study designs and protocols), in all cases, whether or not patentable, in written, electronic or any other form now known or hereafter developed, materials, data and results, including Regulatory Documentation.

1.79 ***"Third Party"*** shall mean any Person or entity other than Exelixis and BMS and their respective Affiliates.

1.80 ***"Third Party License Payments"*** shall mean any payments (e.g., upfront payments, milestones, royalties) due to any Third Party under license agreements or other written agreements granting rights to intellectual property owned or controlled by such Third Party to the extent that such rights are necessary for (i) the making, using or importing of a Party's Compound(s) for the conduct of any Combined Therapy Trial, or (ii) the conduct of any Combined Therapy Trial.

1.81 ***"United States" or "U.S."*** shall mean the United States of America, and its territories, districts and possessions.

Additional Definitions. In addition to those terms defined above, definitions for each of the following terms are found in the body of this Agreement as indicated below:

Defined Term	Section
Alliance Manager	**2.6**
Breaching Party	**12.2(a)**
CDA	**9.1**
Tyrosine Kinase Inhibitor Trial	**5.4(d)**
Co-Chair	**2.3(a)**
Cure Period	**12.2(a)**
Dispute	**13.3(a)**
Exclusive Discussion Period	**5.4(d)**
GAAP	**4.1(a)**
ICF	**2.5(a)**
Indemnify	**11.1**
Infringe or Infringement	**6.3(a)**
Initial Trials	**2.1(a)**
IRBs	**9.3(d)**
JCS-WG or Joint Clinical Study Working Group	**2.4(a)**
JDC or Joint Development Committee	**2.3**
JDC Dispute	**2.7**
Conducting Party	**2.1(b)**
License Agreement	**13.1**
Licensee	**13.10(b)**
Losses	**11.1**
Non-Breaching Party	**12.2(a)**
Non-Conducting Party	**5.1(b)**
Non-Prosecuting Party	**6.1(c)**
Officials	**10.9**
Operational Matters	**2.5(a)**
Packaging and Labeling Cost	**4.2(b)**
Payment	**10.9**
Pharmacovigilance Agreement	**2.2**
POTV	**9.7(a)**
Prosecuting Party	**6.1(c)**
Protocol	**2.1(a)**
Publication Dispute	**9.6(b)**

Quality Agreement	**4.3**
Quarterly Report	**7.2(a)**
Results	**9.6(b)**
Section 4.1(b) Costs	**4.1(b)**
Section 4.2(b) Costs	**4.2(b)**
Shared Costs	**7.1**
Site/CRO List	**2.5(c)**
Study Data	**8.1**
Sunshine Laws	**9.7(c)**
Supply Agreement	**4.4**
Term	**12.1**
Third Party Claim	**11.1**
True-up Payment	**7.2(a)**

ARTICLE 2

COLLABORATION SCOPE; GOVERNANCE

2.1 Scope of Collaboration; Governance of Agreement.

(a) The Parties intend, pursuant to this Agreement, to collaborate to conduct (i) the clinical trials identified in Exhibit A (referred to as the "***Initial Trials***") and (ii) such other clinical trials evaluating a Combined Therapy of the BMS Compound(s) with the Exelixis Compound as the Parties may agree to conduct pursuant to the terms of this Agreement (any such trial in (i) or (ii), a "***Combined Therapy Trial***"). A clinical study protocol (including a clinical protocol synopsis) for each Combined Therapy Trial will be approved by the JDC (each, a "***Protocol***"). The Parties will also use good faith efforts to consult with each other and to finalize the Protocol for the Initial Trial for Renal Cell Carcinoma based on the draft clinical protocol synopsis set forth in Exhibit B and the Protocol for the Initial Trial for Hepatocellular Carcinoma based on the draft clinical protocol synopsis set forth in Exhibit C) as promptly as practicable after the Effective Date. Each Combined Therapy Trial shall be conducted in accordance with its Protocol. The Protocol for each Combined Therapy Trial shall be drafted by the Conducting Party (in consultation with the Non-Conducting Party), and shall be subject to review and approval of the JDC before such Combined Therapy Trial can be Initiated. Protocol amendment(s) shall be subject to review and approval of the JDC, although the JDC may discuss and agree in writing upon circumstances where it may be feasible for the Conducting Party to make specific Protocol amendments without the need for JDC approval or mutual written agreement.

(b) The Party primarily responsible for the conduct of a Combined Therapy Trial (such Party, with respect to such Combined Therapy Trial, the "***Conducting Party***") for each of the Initial Trials is identified in Exhibit A. The Parties shall determine, through the JDC, which Party shall be the Conducting Party for any other Combined Therapy Trial. Subject to the oversight of the JDC, as between the Parties, the Conducting Party shall have decision-making authority with

respect to all non-material operational issues in the conduct of the Combined Therapy Trial, pursuant to Section 5.1(a), and shall be the regulatory lead and the sponsor of record with respect to a Combined Therapy Trial. Each Combined Therapy Trial shall be conducted under a combination IND unless a Regulatory Authority requires otherwise, for which the Conducting Party will be the sponsor of record (the "***Combined Therapy IND***"). BMS shall have a beneficial one-half interest in such Combined Therapy IND and Exelixis shall have a beneficial one-half interest in such Combined Therapy IND; provided, however, that: (i) in no event will a Party be required to obtain the consent of the other Party to transfer or encumber its interest in the Combined Therapy IND; *provided*, that the transferee or encumbrance holder agrees to abide by the terms and conditions of this Agreement, and provided, that any transfer occurs only in connection with, and to the same transferee of, a transfer of all of a Party's rights in its Single Agent Compound, (ii) the Conducting Party shall be the sole holder of all legal interests in the Combined Therapy IND, and no Party shall have any obligation to share with the other Party any consideration received in connection with the sale, license or use of the Combined Therapy IND where permitted by this Agreement, and (iii) no Party shall be permitted to grant any Third Party any Right of Cross-Reference with respect to any portion of the Combined Therapy IND relating to the other Party's Single Agent Compound(s) for use as monotherapy or for use in combination with any other molecules (other than, in the case of BMS, for use with the BMS Compound(s) (alone or in combination with other BMS-controlled molecules), and, in the case of Exelixis, for use with the Exelixis Compound (alone or in combination with other Exelixis-controlled molecules), in each case as permitted by this Agreement. For clarity, each Party shall have a Right of Cross-Reference to all Combined Therapy INDs, whether such Party is the Conducting Party or the Non-Conducting Party, on its own behalf. Each Party shall provide to the other Party a Right of Cross-Reference to its existing respective IND for its respective Single Agent Compound(s) as necessary to allow a Combined Therapy Trial to be conducted under the Combined Therapy IND. For the avoidance of doubt, each Party shall be responsible for (i) drafting and updating as necessary the investigator's brochure for its respective Single Agent Compound(s), and (ii) filing all necessary Regulatory Documentation to the existing IND for its respective Single Agent Compound(s), including, but not limited to, the submission to such existing IND of serious adverse event and adverse drug reaction cases emerging from any Combined Therapy Trial, as required by a Regulatory Authority and/or Applicable Law.

(c) Promptly after the Effective Date, if not previously provided pursuant to the CDA and continuing until finalization of the Protocol for the applicable Initial Trial, the Conducting Party shall provide the Non-Conducting Party with the following relating to the Conducting Party Compound(s): (i) the latest investigator's brochure, (ii) new and/or changing safety signals and safety issues pertinent to the Initial Trials, and (iii) new and/or changing toxicology and efficacy signals and/or issues pertinent to the Initial Trials. The Conducting Party shall also provide such other safety data on the Conducting Party Compound(s) as set forth in the Pharmacovigilance Agreement. The Non-Conducting Party shall use any such data provided pursuant to this Section 2.1(c)(1) or pursuant to the Pharmacovigilance Agreement solely to evaluate the safety and efficacy of (1) the Conducting Party Compound(s) for use in Combined Therapy Trials and (2) the Combined Therapy. All such information and disclosures, to the extent pertaining to the Conducting Party

Compound(s) as monotherapy (or used with agents other than the Non-Conducting Party Compound(s)), are Confidential Information of the Conducting Party.

(d) The Conducting Party shall provide the Non-Conducting Party with the following relating to the Combined Therapy: (i) safety analyses for each Combined Therapy Trial where required by and in accordance with the applicable Protocol, and/or Statistical Analysis Plan, (ii) new and/or changing safety signals and safety issues pertinent to the Combined Therapy Trials and such other safety data for each Combined Therapy as set forth in the Pharmacovigilance Agreement (as defined in Section 2.2), and (iii) new and/or changing toxicology and efficacy signals and/or issues pertinent to the Combined Therapy Trials. The Conducting Party shall also provide the Non-Conducting Party with the Study Data and the final Clinical Study Reports (CSRs) for all Protocol arms relating to this Agreement. Each final CSR shall comply with the requirements of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and shall be approved by the JDC. Each Party shall use any such data provided pursuant to this Section 2.1(d) solely: (A) to evaluate the safety and efficacy of the Combined Therapy in Combined Therapy Trials, (B) to meet any regulatory requirements pertaining to its Compound(s) and to the conduct of the Combined Therapy Trials, and (C) as permitted elsewhere in this Agreement. All such information and disclosures: (x) to the extent pertaining to a Combined Therapy, are Confidential Information of all of the Parties, (y) to the extent pertaining to the Exelixis Compound as monotherapy (or used with agents other than the BMS Compound(s)), are Confidential Information of Exelixis and (z) to the extent pertaining to the BMS Compound(s) as monotherapy (or used with agents other than the Exelixis Compounds), are Confidential Information of BMS.

(e) The Conducting Party shall provide the Non-Conducting Party with the following relating to the Non-Conducting Party Compound(s): (i) safety analyses for the Non-Conducting Party Compound(s) as monotherapy from each Combined Therapy Trial if required by and in accordance with the applicable Protocol, and/or Statistical Analysis Plan, and (ii) such other safety data for the Non-Conducting Party Compound(s) as set forth in the Pharmacovigilance Agreement. The Non-Conducting Party may use such information for any purpose. All such information and disclosures to the extent pertaining to the BMS Compound(s) as monotherapy (or used with agents other than the Exelixis Compound), shall be Confidential Information of BMS and all such information and disclosures to the extent pertaining to the Exelixis Compound as monotherapy (or used with agents other than the BMS Compound(s)), shall be Confidential Information of Exelixis.

(f) Promptly after the Effective Date, if not previously provided pursuant to the CDA and continuing until finalization of the Protocol for the applicable Initial Trial, the Non-Conducting Party shall provide the Conducting Party with the following relating to the Non-Conducting Party Compound(s): (i) the latest investigator's brochure, (ii) any new and/or changing safety signals and safety issues pertinent to the Initial Trial, and (iii) new and/or changing toxicology and efficacy signals and/or issues pertinent to the Initial Trial. The Non-Conducting Party shall also provide such other safety data on the Non-Conducting Party Compound(s) as set forth in the Pharmacovigilance Agreement. The Conducting Party shall use any such data provided pursuant

to this Section 2.1(f) or pursuant to the Pharmacovigilance Agreement solely (A) to evaluate the safety and efficacy of (1) the Non-Conducting Party Compound(s) for use in Combined Therapy Trials and (2) the Combined Therapy and (B) to meet any regulatory requirements pertaining to the conduct of the Combined Therapy Trials. All such information and disclosures are Confidential Information of the Non-Conducting Party.

(g) Any amendment to this Agreement, a Bioanalysis Plan, a Statistical Analysis Plan, the Pharmacovigilance Agreement, the CRO Agreement (to the extent provided in Section 2.4(o)) or Quality Agreement shall require the written mutual agreement of the Parties and shall be executed in the form of a written amendment in accordance with Section 13.7.

(h) If further studies, including but not limited to toxicity studies, are required or suggested by a Regulatory Authority as a prerequisite for conducting any of the Combined Therapy Trials, then the Parties agree to hold good faith discussions in a timely manner to agree upon a protocol for such studies, each of which will be considered a Combined Therapy Trial and conducted on substantially the same terms as set forth herein; *provided that*, if the Parties are unable to agree upon a protocol for such study or if the conduct of such study shall cause a delay deemed unsatisfactory by a Party, then any disputed matters precluding agreement shall be referred to the Executive Officers (or their respective designees) for resolution. If the Executive Officers are unable to reach resolution within [*] after such referral to them (and do not mutually agree to an extension of time to arrive at such resolution), then this Agreement shall automatically terminate following the conclusion of any then-active Combined Therapy Trial (unless and until the Protocol for such required/suggested study(ies) is finalized by mutual agreement prior to the completion of such Combined Therapy Trial) and the provisions of Section 12.5 shall apply to any such termination.

2.2 Safety Data Exchange. The Parties shall use diligent efforts to define and finalize the processes the Parties shall employ to protect patients and promote their well-being in connection with the use of the Combined Therapy. Subject to the terms of this Agreement, within [*] or [*] after the full execution of this Agreement, or as soon as practicable subsequent to the full execution date, as agreed to by the Parties and prior to dosing the first study patient in a Combined Therapy Trial, Exelixis and BMS (under the guidance of their Pharmacovigilance Departments, or equivalent thereof) shall execute a written pharmacovigilance agreement ("***Pharmacovigilance Agreement***") to ensure the exchange of relevant safety data within appropriate timeframes and in appropriate format to enable the Parties to fulfill local and international regulatory reporting obligations. Such Pharmacovigilance Agreement shall (a) provide that the Conducting Party shall hold and be responsible for the maintenance of the Global Safety Database for the Combined Therapy and safety reporting for the Combined Therapy, and shall lead all pharmacovigilance activities for the Combined Therapy, and (b) include guidelines and procedures acceptable to the Parties for the receipt, investigation, recordation, communication, and exchange (as between the Parties) of Adverse Event reports, pregnancy reports, and any other information concerning the safety of the Combined Therapy arising from or related to the use of the BMS Compound(s) and Exelixis Compound in the Combined Therapy Trial consistent with Applicable Law. Furthermore, such agreed procedures shall be consistent with relevant International Council for Harmonization (ICH)

guidelines, except where said guidelines may conflict with existing local regulatory safety reporting requirements, in which case local reporting requirements shall prevail. Until such guidelines and procedures are set forth in the Pharmacovigilance Agreement, the Party responsible for pharmacovigilance prior to execution of this Agreement shall have sole pharmacovigilance responsibility for its Compound(s) subject to all Applicable Law. In the event that this Agreement is terminated, the Parties agree to implement the necessary procedures and practices to ensure that any outstanding pharmacovigilance reporting obligations are fulfilled. To the extent any provision set forth in the Pharmacovigilance Agreement conflicts with any provision in this Agreement, the provision set forth in the Pharmacovigilance Agreement shall control as related to the exchange and reporting of safety information associated with use of the products in a Combined Therapy Trial as well as product safety surveillance.

2.3 Joint Development Committee. Promptly after the Effective Date, the Parties shall form a Joint Development Committee (the "***JDC***").

(a) Composition: The JDC shall consist of [*] representatives, with [*] representatives from BMS, on the one hand, and [*] representatives from Exelixis, on the other hand, plus an Alliance Manager from each Party as non-voting members; provided, that the JDC may agree to increase or decrease the number by mutual agreement. Each Party shall be responsible for determining the qualifications and substitutions of its JDC members but shall be composed of cross functional and highly experienced representatives of appropriate seniority from Exelixis and BMS. The JDC shall be co-chaired by two (2) chairpersons, with one chairperson designated by BMS and the other chairperson to be designated by Exelixis (each, a "***Co-Chair***").

(b) Meetings: The JDC shall meet at least [*] per year, or at such other frequency as the JDC agrees (and it may appoint subteams to meet more frequently), *provided that* either BMS or Exelixis through its Co-Chair may request a meeting of the JDC at any time upon [*] notice to the other Party, with the understanding that the other Party will use reasonable efforts to comply with such request but such other Party will not be in breach of this Agreement in the event that it is unable to comply with such request but is using reasonable efforts to conduct a JDC meeting as promptly as practicable. Upon request by either Party, such meetings will be held by audio or video teleconference; provided that face-to-face meetings shall occur at least [*]. There must be a minimum of [*] representatives from each of BMS, on the one hand, and Exelixis, on the other hand, at any meeting of the JDC. No fewer than [*] prior to each meeting, and in any event as soon as reasonably practicable, each of BMS and Exelixis shall use good faith efforts to disclose to the other any proposed agenda items together with appropriate supporting information. The Alliance Managers shall alternate responsibility for preparing and circulating definitive minutes of each meeting of the JDC. Such minutes shall provide a description, in reasonable detail, of the discussions at the meeting, a list of material actions and decisions made by the JDC, a list of action items made by the JDC and a list of material issues not resolved by the JDC. The Alliance Manager who drafts the minutes shall provide the Co-Chairs and the other Alliance Manager with the initial draft meeting minutes, who shall return the draft with any proposed changes, and this process shall be repeated until a final version of the meeting minutes is agreed upon and signed (or acknowledged

as final via email) by the two Co-Chairs. The Parties shall reasonably cooperate to complete and agree upon a final version of meeting minutes within [*] from the date of the relevant meeting. The final version of the meeting minutes shall be signed (or acknowledged as final via email) by the two Co-Chairs, and each Party shall be provided with a copy of the final meeting minutes for its safekeeping. A reasonable number of additional representatives of a Party may attend meetings of the JDC in advisory capacity with the prior written consent of the other Party. All representatives to the JDC or attending JDC meetings shall be subject to confidentiality and nonuse restrictions at least as restrictive as those set forth herein.

(c) Responsibilities of the Joint Development Committee: The JDC shall be responsible for:

(i) The constitution of the Joint Clinical Study Working Group (as defined below) and the establishment of such other subcommittees and working groups as the JDC decides is necessary.

(ii) Overseeing the activities of, and providing guidance and directives to, the Joint Clinical Study Working Group and resolving any disputes arising at the Joint Clinical Study Working Group level.

(iii) Reviewing the regulatory strategy regarding each Combined Therapy Trial.

(iv) Resolving any disputes between the Parties relating to execution of the Combined Therapy Trials.

(v) Consulting and reviewing in relation to the overall management of the Combined Therapy Trials and on all significant matters relating to the Combined Therapy Trials.

(vi) Monitoring the nature, progress and results of the Combined Therapy Trials;

(vii) Selecting and approving independent data monitoring committees and independent radiologic reviews;

(viii) Approving the Protocols (including any Statistical Analysis Plan) and any proposed amendments thereto for the Combined Therapy Trials together with a budget for each Combined Therapy Trial (including the Shared Costs) and any material amendments thereto;

(ix) Approving the Bioanalysis Plan and any amendments thereto;

(x) Monitoring the key milestones of each Combined Therapy Trial proposed by the Joint Clinical Study Working Group;

(xi) Approving the final clinical trial report (and/or final statistical analysis in accordance with the Statistical Analysis Plan) from each Combined Therapy Trial;

(xii) Approving the material communication strategies with any Regulatory Authority regarding the conduct of the Combined Therapy Trials, and to the extent reasonably possible, approving timing for scheduled meetings with any Regulatory Authority;

(xiii) Approving any Combined Therapy IND to be submitted to a Regulatory Authority and any material amendments thereto;

(xiv) Discussing additional Combined Therapy Trials of the BMS Compound(s) with the Exelixis Compound, *provided* that no Party shall be obligated to collaborate with the other Party or agree on terms with the other with respect to any additional clinical trials pursuant to this Section 2.3(c)(xii); and

(xv) Discussing whether any pre-clinical studies are needed to explore or support any clinical trial for the Combined Therapy, especially for clinical trials for indications other than those for the Initial Trials.

In the event the JDC determines that any pre-clinical study is needed to explore or support any clinical trial for the Combined Therapy, any such pre-clinical study will only be conducted if the Parties enter into a separate agreement for the conduct of such pre-clinical study.

(d) Joint Development Committee Authority. The JDC shall take action by unanimous consent, with each of BMS, on the one hand, and Exelixis, on the other hand, having a single vote, irrespective of the number of its representatives actually in attendance at a meeting. In the absence of a formal meeting, the [*]. The JDC shall have the right to make only those determinations expressly enumerated as decisions of the JDC in this Agreement; *provided that* such determinations are documented in the written minutes signed (or acknowledged as final via email) by the JDC Co-Chairs. Notwithstanding anything to the contrary in this Agreement, the JDC will have no power (i) to amend this Agreement, the Supply Agreement, the Pharmacovigilance Agreement or the Quality Agreement, or (ii) to modify any Party's obligations with regard to the conduct of the Combined Therapy Trials without such Party's prior written consent; in each case, except by a writing signed by all Parties.

2.4 Joint Clinical Study Working Group:

(a) General. A joint clinical study working group (***"Joint Clinical Study Working Group"*** or ***"JCS-WG"***) shall be appointed by the JDC. The JCS-WG shall be composed of highly experienced representatives of Exelixis and BMS, and may include a reasonable number (as agreed to by BMS and Exelixis) of representatives of Ipsen; provided, however before attending or participating in any meeting or telephone conference of the JCS-WG, each such representative (i) must be identified in advance to the Alliance Managers, (ii) must have executed a form of

confidentiality and invention assignment agreement mutually acceptable to the Parties that will cover the proceedings of the JCS-WG and that will have been reviewed and approved by Ipsen, and (iii) must be highly experienced with respect to the matters for which the JCS-WG has responsibility. The JCS-WG will be co-chaired by one Exelixis representative and one BMS representative. The JCS-WG will meet at least [*] (or at a frequency reasonably considered necessary at the request of either Party) to provide an update on progress of the Combined Therapy Trials to the JDC. Except for decisions expressly reserved to the JDC, the JCS-WG shall be responsible for the coordination and execution of all joint operational matters (i.e., clinical drug supply, response to regulatory agency questions, data exchange, pharmacovigilance, etc.). The Conducting Party shall provide such update on progress of the Combined Therapy Trials in writing to the Non-Conducting Party members of the JCS-WG on a [*] basis, which update shall contain information about overall progress, recruitment status, interim analysis (if results available), final analysis and other information relevant to the conduct of the Combined Therapy Trials.

(b) Specific Responsibilities of the JCS-WG. Each Party shall keep the JCS-WG informed about activities performed by that Party hereunder. The JCS-WG (or in the absence of a formal meeting, the Co-Chairs of the JCS-WG) shall be specifically responsible, without limitation, for the following:

(i) overseeing the activities of the Parties with respect to the Combined Therapy Trials, and providing a forum for the Parties to discuss, monitor and coordinate all activities and communications regarding the Combined Therapy Trials;

(ii) reviewing the progress of each Combined Therapy Trial, (ii) reviewing and approving the proposed plan for medical monitoring and exchange information on planned site audits, and (iii) reviewing the results of such medical monitoring and site audits and agreeing on any actions in response to same;

(iii) preparing, reviewing and proposing to the JDC for its approval (i) the applicable Protocol and the Statistical Analysis Plan, and any proposed amendment thereto and (ii) any Bioanalysis Plan not set forth in the Protocol, and any amendments thereto;

(iv) preparing, reviewing and proposing to the JDC for its approval the communication strategies with any Regulatory Authority regarding the conduct of the Combined Therapy Trials and, to the extent they are materially inconsistent with the applicable Protocol(s) or previously-approved strategies (or involve patient safety or relate to the BMS Compound(s) or Exelixis Compound), reviewing and approving such proposed communications and communication strategies;

(v) preparing, reviewing and endorsing for approval by the JDC any Combined Therapy IND to be submitted to a Regulatory Authority, as well as reviewing material submissions to any such IND in accordance with Article 5 and, to the extent they are materially inconsistent with the applicable Protocol(s) (or involve patient safety or relate to the BMS Compound or the Exelixis Compound), reviewing and approving such submissions;

(vi) preparing, reviewing and approving any material Combined Therapy Trial Regulatory Documentation, or portions thereof, that relate to the Combined Therapy, in accordance with Article 5, and, to the extent they are materially inconsistent with the applicable Protocol(s), reviewing and approving such Combined Therapy Trial Regulatory Documentation, or portions thereof;

(vii) preparing, reviewing and approving in advance, any additional analyses of, or that include, the Combined Therapy Study Data proposed by either Party that are not included in the Statistical Analysis Plan; *provided*, that, for clarity, such review and approval shall not apply to analyses by a Party of the monotherapy data for its own Compound(s) from a Combined Therapy Trial.

(viii) preparing, reviewing and approving use of any Samples in accordance with Section 8.5 that are not described in the Protocol and ICF for a given Initial Trial, so long as the JDC/JCS-WG remains in force and effect (and if not in force and effect, by mutual written agreement of the Parties);

(ix) reviewing and approving the template ICF form, the template case report form and template clinical site study agreement (or minimum language to be included therein) (all such templates will be based on the applicable Conducting Party template) to be used in a given Combined Therapy Trial. The Conducting Party may authorize changes to such template or minimum wording without review and approval of the JCS-WG, so long as (1) such changes are not materially substantive changes relative to, and the form/agreement remains otherwise generally consistent with, the original wording, (2) in the case of Exelixis as the Conducting Party, such changes do not relate to or adversely affect the BMS Technology or BMS Independent Patent Rights (or the enforcement or defense thereof), the Combined Therapy, or the BMS Compound(s) as monotherapy, (3) in the case of BMS as the Conducting Party, such changes do not relate to or adversely affect the Exelixis Technology or Exelixis Independent Patent Rights (or the enforcement or defense thereof), the Combined Therapy, or the Exelixis Compound as monotherapy, (4) such changes do not impose a new obligation, whether direct, indirect, or contingent, upon the Non-Conducting Party, (5) any changes to the ICF template do not relate to use of Samples or the information to be disclosed regarding the Non-Conducting Party Compound(s), (6) such changes do not confer a benefit upon the Conducting Party that is not also conferred upon the Non-Conducting Party and (7) such changes do not conflict with this Agreement;

(x) proposing, reviewing and approving the countries in which each Combined Therapy Trial will be conducted in accordance with Section 2.5(c), which shall be limited to those countries in which both the BMS Compound(s) and the Exelixis Compound that are the subject of such Combined Therapy Trial are being commercialized and those countries in which it is intended for both the BMS Compound(s) and the Exelixis Compound that are the subject of such Combined Therapy Trial to be commercialized when one or more of such Compounds is not being commercialized in those countries (such countries, collectively the ***"Available Countries"***);

(xi) preparing, reviewing and approving the final clinical trial report (and/or final statistical analysis in accordance with the Statistical Analysis Plan) from each Combined Therapy Trial, prior to provision to the JDC for final approval in accordance with Section 2.3(c)(xi) above;

(xii) discussing any other topics or issues relating to the Combined Therapy Trials that either Party requests that cannot be resolved at the working team level.

(xiii) reviewing each Party's drug supply forecasts for each Combined Therapy Trial;

(xiv) approving any immunogenicity analysis for each Combined Therapy Trial, including the protocol and the entity to do the analysis, to the extent not part of the Protocol for a Combined Therapy Trial;

(xv) reviewing and approving any provisions deemed necessary to be included in the CRO agreement to ensure consistency with this Agreement and in particular with Section 5.2(b) hereof;

(xvi) agreeing on the selection of study sites pursuant to Section 2.5(c), and agreeing on any material communications to study sites or IRBs relating to patient safety or early termination/cessation of the Combined Therapy Trial; and

(xvii) appointing, if needed, working teams to conduct work within the charter of the JCS-WG and to report to the JCS-WG, and resolving any disputes arising within the working teams.

2.5 Conducting Party Operational Authority Generally.

(a) The Conducting Party for a Combined Therapy Trial shall, subject to the oversight and determinations of the JDC and JCS-WG as provided in Sections 2.3 and 2.4, the terms of the applicable Protocol, the decisions and guidance of applicable Committee or working group, and applicable terms and conditions of this Agreement, the Quality Agreement, the Pharmacovigilance and the Supply Agreement: (i) manage and be primarily responsible for the conduct of such Combined Therapy Trial; (ii) be the Sponsor and regulatory lead with respect to such Combined Therapy Trial; and (iii) as between the Parties, be the lead with respect to (1) the selection and management of clinical study sites (including the negotiation and execution of clinical site study agreements and related budgets, timelines and contingency planning), (2) conducting clinical study start-up activities, communicating with and obtaining approval from institutional review boards and/or ethics committees, as applicable, and drafting the template informed consent form ("***ICF***") or other relevant documents for such Combined Therapy Trial (for review and, if applicable, approval as provided in this Agreement), (3) subject recruitment and retention activities, (4) ongoing site monitoring and quality assurance audits, (5) subject to the terms of the Pharmacovigilance Agreement, management of safety reporting by contract research organizations and clinical study sites, (6) ongoing medical monitoring, (7) management, monitoring and audits

of CROs in connection with each CRO (if any) involved in the conduct of such Combined Therapy Trial, (8) inquiries from clinical study subjects, (9) packaging, labeling and distributing the Combined Therapy for use in such Combined Therapy Trial, and (10) manage health authority inspections at clinical trial sites ((1)-(10), collectively, the "***Operational Matters***"). The Conducting Party shall use Commercially Reasonable Efforts to perform such Operational Matters. The JDC shall set up a mechanism for the Non-Conducting Party to be informed and updated on a timely periodic basis regarding Operational Matters, so that if the Non-Conducting Party has any significant concerns or material disagreements regarding same, the matter can be escalated to the JDC for review. Notwithstanding anything to the contrary in this Agreement, in the event that the Conducting Party receives a telephonic communication from a Regulatory Authority requesting an immediate response that the Conducting Party reasonably determines must be immediately given to protect patient safety or to prevent undue and significant disruption in the conduct of a Combined Therapy Trial, the Conducting Party will be entitled to provide such response as it deems advisable (and that is otherwise consistent with the terms of this Agreement); *provided*, that it immediately notifies the Non-Conducting Party Co-Chair (or other Non-Conducting Party member of the JDC if that person is not available) of same and subsequently either (i) obtains the written consent of the Non-Conducting Party Co-Chair to the action taken or (ii) if the Non-Conducting Party does not provide its consent, notifies the Regulatory Authority that the response is being changed; *provided, further*, that in no event shall the Conducting Party make any response relating to the Non-Conducting Party Compound(s) as monotherapy without the Non-Conducting Party's prior written consent.

(b) If the conduct of any Combined Therapy Trial requires a Third Party License Payment, then the Party required to make such Payment shall be responsible for same.

(c) Each Combined Therapy Trial may only be conducted in countries outside the Ono Territory that are Available Countries. The Conducting Party, after discussion with the Non-Conducting Party, will create and provide the JDC with a proposed list of potential clinical trial site(s), countries, CROs and investigators that may be used to conduct each Combined Therapy Trial, with the final list to be subject to JDC (or Co-Chairs) approval (such approval will be completed within [*] after receipt of the list and shall not be unreasonably withheld) (such JDC-approved list being the "***Site/CRO List***"). The proposed Site/CRO List will be provided to the JCS-WG prior to the Conducting Party initiating site selection negotiations or visits (for sites/investigators) or CRO negotiations (for CROs). The Conducting Party shall have the authority to select the final clinical trial sites, CROs and investigators from the approved Site/CRO List. In the event that additional sites need to be added after the initial list is approved, a new CRO/Study Site List will be created that includes the new sites and such list will be provided to the JCS-WG for its approval (or by its Co-Chairs) per this Section 2.5(c).

2.6 Alliance Managers. Each of BMS, on the one hand, and Exelixis, on the other hand, will appoint one representative to act as its Alliance Manager (each, an "***Alliance Manager***"). The role of the Alliance Manager is to act as a primary point of contact between the Parties to assure a successful relationship between the Parties. Each Alliance Manager shall be permitted to attend meetings of the JDC and its subcommittees and working groups as appropriate as non-voting

participants. An Alliance Manager may bring any matter concerning a Party's performance under this Agreement to the attention of the JDC if the Alliance Manager reasonably believes that such attention is warranted. BMS may replace its Alliance Manager with an alternative representative at any time with prior written notice to Exelixis, and Exelixis may replace their Alliance Manager with an alternative representative at any time with prior written notice to BMS. Any Alliance Manager may designate a substitute to temporarily perform the functions of such Alliance Manager upon written notice to the other Alliance Manager. Each Alliance Manager will be charged with creating and maintaining a collaborative work environment within the JDC. Each Alliance Manager also will:

(a) provide a point of communication both internally within the Parties' organizations and between the Parties regarding the Combined Therapy Trials;

(b) assist in coordinating any collaborative efforts under this Agreement, if any, and any external communications;

(c) take responsibility for ensuring that JDC and JCS-WG activities, such as the conduct of required JDC meetings, occur as set forth in this Agreement and that relevant action items, if any, resulting from such meetings are appropriately carried out or otherwise addressed; and

(d) be the point of first referral in all matters of contract interpretations and dispute resolution in accordance with Section 13.3.

2.7 Dispute Resolution. The representatives of the JDC shall attempt in good faith to reach consensus on all matters properly brought before the JDC. Except as otherwise provided in this Agreement, if, after a good faith, reasonable and open discussion among the members of the JDC, the JDC is unable to agree on a matter that has been properly before it for a period of [*] and that calls for a decision, any Party may refer the dispute (a "***JDC Dispute***") to the Executive Officers for resolution. If the Executive Officers are unable to reach a resolution within [*] of such referral, then the JDC Dispute will be referred to the [*] of Exelixis and the [*] of BMS or their respective designees for attempted resolution by good faith negotiations within [*] after such referral is made. If they are unable to reach a resolution within [*] of such referral, then (a) if such JDC Dispute relates to an amendment requiring mutual agreement proposed by either Party to the agreed upon Protocol or protocol synopsis (including any immunogenicity analysis), CRO Agreement, Bioanalysis Plan or Statistical Analysis Plan, there shall be no decision on the matter and the then existing terms of the applicable Protocol, protocol synopsis, CRO Agreement, Bioanalysis Plan or Statistical Analysis Plan shall govern, and (b) for all other JDC Disputes, this Agreement will be terminated, upon written notice from either BMS to Exelixis or from Exelixis to BMS, as of the later of (1) the expiration of such [*] period for resolution by the [*] of Exelixis and the [*] of BMS or their respective designees or (2) the conclusion of any then-active Combined Therapy Trial (in each of (1) or (2) unless and until such JDC Dispute is resolved by mutual agreement prior to the effective date of such termination); provided, that any such termination notice must be

provided prior to the applicable termination date in (1) or (2). The provisions of Section 12.5 shall apply to any such termination. Disputes with respect to matters properly before the JDC will not be subject to the dispute resolution procedures set forth in Section 13.3.

2.8 Conduct. Each Party shall use Commercially Reasonable Efforts to perform and fulfill its respective activities under this Agreement, and shall do so in accordance with Applicable Law, including GCP, GLP and GMP.

ARTICLE 3

LICENSE GRANTS

3.1 Grant by BMS.

(a) Subject to the terms of this Agreement, BMS hereby grants, and shall cause its Affiliates to grant, to Exelixis a non-exclusive, worldwide (other than within the Ono Territory), non-transferable, royalty-free license (with the right to sublicense solely pursuant to the terms of and subject to the limitations of Section 3.3) under the BMS Independent Patent Rights, BMS Technology, and BMS Regulatory Documentation to use the BMS Compound(s), solely to the extent necessary to discharge Exelixis' obligations under this Agreement with respect to the conduct of the Combined Therapy Trials.

(b) To the extent that a CRO, contractor or Combined Therapy Trial study site assigns or licenses to BMS any title, rights or interests in any intellectual property rights for which some or all of such intellectual property rights are to be owned by or licensed to Exelixis pursuant to the terms of this Agreement, BMS will, where and to the extent expressly provided in this Agreement, assign or license same to Exelixis as provided in this Agreement and will confirm same in writing if requested by Exelixis.

3.2 Grant by Exelixis.

(a) Subject to the terms of this Agreement, Exelixis hereby grants, and shall cause its Affiliates to grant, to BMS a non-exclusive, worldwide, non-transferable, royalty-free license (with the right to sublicense solely pursuant to the terms of and subject to the limitations of Section 3.3) under the Exelixis Independent Patent Rights, Exelixis Technology, and Exelixis Regulatory Documentation to use the Exelixis Compound, solely to the extent necessary to discharge BMS's obligations under this Agreement with respect to the conduct of the Combined Therapy Trials.

(b) To the extent that a CRO, contractor or Combined Therapy Trial study site assigns or licenses to Exelixis any title, rights or interests in any intellectual property rights for which some or all of such intellectual property rights are to be owned by or licensed to BMS pursuant to the terms of this Agreement, Exelixis will, where and to the extent expressly provided in this

Agreement, assign or license same to BMS as provided in this Agreement and will confirm same in writing if requested by BMS.

3.3 Sublicensing.

(a) Each Party shall have the right to grant sublicenses, under the licenses granted to it under Section 3.1 and Section 3.2, to Affiliates and to Third Parties, solely to the extent required for a Third Party to perform its duties with respect to the conduct of the Combined Therapy Trials (and, for Third Party sublicenses, if agreed to by the other Party, such consent not to be unreasonably withheld, conditioned or delayed), solely as necessary to assist a Party in carrying out its responsibilities with respect to the Combined Therapy Trials.

(b) For the avoidance of doubt, (i) in no event shall BMS (or any of its sublicensees) have the right to grant Ono or any of Ono's Affiliates any sublicense under the licenses granted to BMS in Section 3.2, without the prior written consent of Exelixis, and (ii) in no event shall Exelixis (or any of its sublicensees) have the right to grant Ipsen, Takeda or any of their respective Affiliates any sublicense under the licenses granted to Exelixis in Section 3.2, without the prior written consent of BMS.

(c) With regard to any such sublicenses permitted and made under this Agreement, (i) such sublicensees, except Affiliates (so long as they remain Affiliates of a Party), shall be subject to written agreements that bind such sublicensees to obligations that are consistent with a Party's obligations under this Agreement including, but not limited to, confidentiality and non-use provisions no less restrictive than those set forth in Sections 8.2 and 8.3 and Article 9, and provisions regarding intellectual property that ensure that the Parties will have the rights provided under this Agreement to any intellectual property created by such sublicensee, (ii) each Party shall provide written notice to the other of any such sublicense (and obtain approval for sublicenses to Third Parties); and (c) the licensing Party shall remain liable for all actions of its sublicensees.

3.4 No Implied Licenses. Except as specifically set forth in this Agreement, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, in any intellectual property of the other Party, including Confidential Information disclosed to it under this Agreement or under any Patent Rights Controlled by the other Party or its Affiliates.

ARTICLE 4

MANUFACTURE AND SUPPLY

4.1 Exelixis Compound.

(a) Manufacture and Supply. Exelixis shall Manufacture or have Manufactured the Exelixis Compound in drug product and/or drug substance form (as necessary) in reasonable quantities and at the points in time as agreed by the JDC for each Combined Therapy Trial, and, as applicable, shall supply such Exelixis Compound to BMS or its designee for use in the Combined Therapy Trials. As applicable, BMS will package and label the Exelixis Compound

for use in the Combined Therapy Trial, subject to Section 4.1(b). The cost of Manufacture and supply (including shipping, taxes and duty, if applicable) of Exelixis Compound for the Combined Therapy Trials shall be borne solely by Exelixis, and Exelixis shall bear the risk of loss for the Exelixis Compound until delivery of the Exelixis Compound to the common carrier for delivery to BMS or its designee. Exelixis shall also be responsible for the payment of any Third Party License Payments that may be due exclusively on the supply of Exelixis Compound for the Combined Therapy Trials. Exelixis shall also be responsible for the payment of any Third Party License Payments that may be due based on the manufacture, supply and use of the Exelixis Compound used in the Combined Therapy Trials. The Exelixis Compound shall be manufactured in accordance with Applicable Law (including GMP) and shall be of similar quality to the Exelixis Compound used by Exelixis for its other clinical trials of the Exelixis Compound. Exelixis shall deliver certificates of analysis, and any other documents specified in the Quality Agreement between Exelixis and BMS. Exelixis shall be responsible for the quality of the Exelixis Compound provided to BMS with the appropriate regulatory filings in the countries where each of the Combined Therapy Trials are performed, pursuant to the Quality Agreement. The Parties shall cooperate in accordance with Applicable Law to minimize indirect taxes (such as value added tax, sales tax, consumption tax and other similar taxes) relating to the Exelixis Compound in connection with this Agreement. Exelixis will inform BMS as to the GMP Manufacturing and testing site of bulk drug substance for the Exelixis Compound, as well as the Exelixis Compound drug product GMP Manufacturing and testing site, prior to the start of the Combined Therapy Trials and provide [*] advance written notice of any change to these site(s).

(b) Packaging Costs for Exelixis Compound. Notwithstanding Section 4.1(a), Exelixis will reimburse BMS for the costs incurred by it for any packaging and labeling by BMS of the Exelixis Compound provided by Exelixis for use in the Combined Therapy Trials ("***Section 4.1(b) Costs***"). For purposes of this Agreement, "***Section 4.1(b) Costs***" shall mean fully-burdened costs, as determined by BMS [*] in accordance with generally accepted accounting principles in the United States ("***GAAP***"), [*].

(c) Use of Exelixis Compound Supplied by Exelixis to BMS. BMS shall use the quantities of Exelixis Compound supplied to it under this Agreement solely as necessary for, and in accordance with, this Agreement and the Protocols, and for no other purpose, including without limitation as a reagent or tool to facilitate its internal research efforts, for any commercial purpose, or for other research unrelated to the Combined Therapy Trials. Except as may be required under this Agreement, a Bioanalysis Plan, or a Protocol, BMS shall not perform, and shall not allow any Third Parties to perform, any analytical testing of the quantities of Exelixis Compound supplied to it under this Agreement.

4.2 BMS Compound(s).

(a) Manufacture and Supply. BMS shall Manufacture or have Manufactured the BMS Compound(s) in drug substance and/or drug product form (as necessary) in reasonable quantities and at the points in time as agreed by the JDC for each Combined Therapy Trial, and, as applicable, shall supply such BMS Compound(s) in unmarked vials or as labeled commercial product

to Exelixis or its designee for use in the Combined Therapy Trials. As applicable, Exelixis will package and label the BMS Compound(s) for use in the Combined Therapy Trial, subject to Section 4.2(b). The cost of Manufacture and supply (including shipping, taxes and duty, if applicable) of the BMS Compound(s) for the Combined Therapy Trials shall be borne solely by BMS, and BMS shall bear the risk of loss for the BMS Compound(s) until delivery of the BMS Compound(s) to the common carrier for delivery to Exelixis or its designee. BMS shall also be responsible for the payment of any Third Party License Payments that may be due to Ono or to others exclusively on the supply of BMS Compound(s) hereunder for the Combined Therapy Trials. BMS shall be responsible for the payment of any Third Party License Payments that may be due based on the manufacture, supply and use of the BMS Compound(s) used in the Combined Therapy Trials. The BMS Compound(s) shall be Manufactured in accordance with Applicable Law (including GMP) and shall be of similar quality to the BMS Compound(s) used by BMS for its other clinical trials of the BMS Compound(s). BMS shall deliver certificates of analysis, and any other documents specified in the Quality Agreement. BMS shall be responsible for the regulatory compliance of the quality of the BMS Compound(s) provided to Exelixis with the regulatory filings in the countries where each of the Combined Therapy Trials are performed, pursuant to the Quality Agreement. The Parties shall cooperate in accordance with Applicable Law to minimize indirect taxes (such as value added tax, sales tax, consumption tax and other similar taxes) relating to the BMS Compound(s) in connection with this Agreement. Exelixis. BMS will inform Exelixis to the GMP Manufacturing and testing site of bulk drug substance for the BMS Compound(s), as well as the BMS Compound(s) drug product GMP Manufacturing and testing site, prior to the start of the Combined Therapy Trials and provide [*] advance written notice of any change to these site(s).

(b) Packaging Costs for the BMS Compounds. Notwithstanding Section 4.2(a), BMS will reimburse Exelixis for the costs incurred by it for any packaging and labeling by Exelixis of the vials of the BMS Compound(s) for use in the Combined Therapy Trials ("***Section 4.2(b) Costs***"). For purposes of this Agreement, "***Section 4.2(b) Costs***" shall mean fully-burdened costs, as determined by Exelixis [*] in accordance with GAAP, [*].

(c) Use of BMS Compound(s) Supplied by BMS to Exelixis. Exelixis shall use the quantities of BMS Compound(s) supplied to it under this Agreement solely as necessary for, and in accordance with, this Agreement and the Protocols, and for no other purpose, including without limitation as a reagent or tool to facilitate its internal research efforts, for any commercial purpose, or for other research unrelated to the Combined Therapy Trials. Except as may be required under this Agreement, a Bioanalysis Plan, or a Protocol, Exelixis shall not perform, and shall not allow any Third Parties to perform, any analytical testing of the quantities of BMS Compound(s) supplied to it under this Agreement.

4.3 Quality Agreement/Quality Addendum. Within [*] after the Effective Date, but in no event later than the date on which the first shipment of bulk Exelixis Compound or bulk BMS Compound is supplied for use in the Combined Therapy Trials, the Parties shall enter into a quality agreement or quality addendum (in either case, the "***Quality Agreement***"). In addition, the Quality Agreement shall detail the documentation required for each shipment of BMS Compound supplied

to Exelixis and Exelixis Compound supplied to BMS, or their respective designees, for use in the Combined Therapy Trials. The Quality Agreement shall also indicate whether any required transfer from BMS to Exelixis of analytical methods will be necessary to support identity testing of the BMS Compound(s) by Exelixis and vice versa.

4.4 Supply Agreement. Within [*] after the Effective Date but in no event later than the date on which the first shipment of bulk Exelixis Compound or bulk BMS Compound is supplied for use in the Combined Therapy Trials, the Parties shall enter into a supply agreement (the "***Supply Agreement***") governing forecasting, ordering, procedures for acceptance and rejection, and other customary provisions for the supply of the BMS Compound(s) and the Exelixis Compound for the Combined Therapy Trials.

4.5 Customs Valuation. The Conducting Party will provide the Non-Conducting Party in writing with a list of all countries participating in a Combined Therapy Trial prior to study start Initiation of such Combined Therapy Trial. During the conduct of such Combined Therapy Trial, the Conducting Party will send in writing any changes to the list of participating countries to the Non-Conducting Party [*] prior to the end of each Quarter. If no changes are sent to the Non-Conducting Party by the Conducting Party for a particular Quarter, the prior Quarter's participating country list will be used as the basis for customs valuation for that Quarter. The Non-Conducting Party will provide the Conducting Party with its Compound country-specific customs valuations initially prior to study start initiation of Combined Therapy Trial(s) and at the end of each Quarter during the conduct of the Combined Therapy Trial. The Conducting Party will use the Non-Conducting Party provided values for the import/export process to the listed participating countries and not make any change to such valuations without the Non-Conducting Party's prior written consent.

ARTICLE 5

RESPONSIBILITIES

5.1 Specific Responsibilities of the Parties. Subject to the terms of this Agreement, each Party shall use Commercially Reasonable Efforts to (i) supply the quantities of its Compound(s) as needed to conduct a Combined Therapy Trial on a timely basis, and package and deliver same to study sites, in accordance with the time frame(s) established by the JDC ; (ii) to conduct and complete each Combined Therapy Trial and any Statistical Analysis Plans and Bioanalysis Plans relating thereto on a timely basis in accordance with the Protocol, Bioanalysis Plans, Statistical Analysis Plans and Third Party agreements relating thereto, (iii) to timely provide Rights of Cross-Reference where required by this Agreement, and (iv) in the case of the Conducting Party, to provide sufficient resources and personnel to conduct and perform the Combined Therapy Trial for which it is the Conducting Party, and to adequately fund the Combined Therapy Trial, on a timely basis in accordance with the Protocol for same and the terms of this Agreement.

Each Party shall be responsible for activities assigned to it by the JDC in furtherance of the conduct of a Combined Therapy Trial, or the Statistical Analysis Plan that such Party is not otherwise obligated to perform by this Agreement, *provided that*, except as expressly set forth in this Agreement, in no event shall either Party be obligated to perform any such assigned activities without its prior written consent (which may be reflected in the minutes of meetings of the JDC and signed by both representatives). As of the Effective Date, each Party shall be responsible for the following activities:

(a) Responsibilities of the Conducting Party. Subject to JDC direction and oversight as provided in Section 2.4, the Conducting Party shall be responsible for the following activities (except as expressly provided in Article 4 with respect to the Manufacture and supply of the Non-Conducting Party Compound(s)):

(i) (A) manufacturing, packaging and labeling GMP-grade quantities of the Conducting Party Compound(s), and packaging and labeling of the Combined Therapy for use in the Combined Therapy Trials, (B) packaging and labeling the vials, if applicable, provided by the Non-Conducting Party of the Non-Conducting Party Compound(s) for use in the Combined Therapy Trials, (C) providing the JDC with prompt notice of any Manufacturing and supply issues with respect to the Conducting Party's Compound that may adversely impact the conduct or timelines of a Combined Therapy Trial, and (D) providing the Non-Conducting Party with clinical drug supply forecasts and drug delivery dates for the Non-Conducting Party Compound(s) (which shall be set forth more fully in the Supply Agreement);

(ii) with the cooperation of the Non-Conducting Party, compiling, amending and filing all necessary Combined Therapy Trial Regulatory Documentation with Regulatory Authority(ies), maintaining and acting as the sponsor of record as provided in 21 CFR 312.50 (and applicable comparable ex-US laws) with responsibility, unless otherwise delegated in accordance with 21 CFR 312.52 (and applicable comparable ex-US laws), for each Combined Therapy Trial and making all required submissions to Regulatory Authorities related thereto on a timely basis;

(iii) with Non-Conducting Party cooperation, and subject to the provisions of Section 9.6, listing any Combined Therapy Trial required to be listed on a public database on www.clinicaltrials.gov or other public registry in any country in which such Combined Therapy Trial is being conducted in accordance with Applicable Law and in accordance with each Party's internal policies relating to clinical trial registration;

(iv) providing the Non-Conducting Party with reasonable advance notice of scheduled meetings or other material non-written communications with a Regulatory Authority and the opportunity to participate in each such meeting (to the extent permitted by Applicable Law and such Regulatory Authority) or other non-written communication, to the extent that it relates to the conduct of the Combined Therapy Trial or the Non-Conducting Party Compound(s) and providing such opportunity to participate in such meetings (to the extent permitted by Applicable Law and such Regulatory Authority) to Ipsen (only for meetings with Regulatory Authorities in the

Ipsen Territory) and Takeda (only for meetings with Regulatory Authorities in the Takeda Territory) where Exelixis is the Non-Conducting Party and Ono (only for meetings with Regulatory Authorities in the Ono Territory) where BMS is the Non-Conducting Party provided that the Non-Conducting Party provides advance notice to Ipsen, Takeda or Ono, as applicable, of such opportunity, however, before participating in any such meeting, each representative of Ipsen, Takeda or Ono, as applicable, must be bound by a written agreement having confidentiality and use obligations that apply to Confidential Information of BMS and/or Exelixis, that are at least as restrictive as those binding upon Exelixis and BMS in this Agreement and that cover the meetings with the applicable Regulatory Authority, and, unless otherwise agreed by the JDC, providing the Non-Conducting Party with the opportunity to review, provide comments to the Conducting Party within [*] on, and, if inconsistent with the applicable Protocol(s) or JDC guidance, approve all submissions and written correspondence with a Regulatory Authority that relates to the conduct of the Combined Therapy Trial or the Non-Conducting Party Compound(s); *provided*, *however*, in no event shall the Conducting Party or any Affiliate of the Conducting Party communicate with any Regulatory Authority solely with respect to the Non-Conducting Party Compound(s) without the prior written consent of the Non-Conducting Party and *provided further that* the Non-Conducting Party shall step out of any portions of such meetings or other non-written communications with a Regulatory Authority that relate solely to the Conducting Party Compound(s) and the Conducting Party shall step out of any portions of such meetings or other non-written communications with a Regulatory Authority that relate solely to the Non-Conducting Party Compound(s);

(v) unless otherwise agreed by the JDC, providing to the Non-Conducting Party a written summary of meetings or other non-written communications with a Regulatory Authority within [*] of such meeting or communication, and copies of any official correspondence to or from a Regulatory Authority within [*] of a Party's receipt or provision of such correspondence, in each case to the extent that it relates to the Combined Therapy or the Non-Conducting Party Compound(s) (or, to the extent the communication would adversely impact the performance of the Combined Therapy Trial, the Conducting Party Compound(s)), and copies of all Combined Therapy Trial Regulatory Documentation that relate to the Combined Therapy or the Non-Conducting Party's Compound(s) within [*] of submission to Regulatory Authorities;

(vi) drafting, and, subject to the terms of this Agreement, providing to the Non-Conducting Party (through the JDC or otherwise) for its review and approval, each Protocol (including any immunogenicity analysis plan) and investigator's brochure for a Combined Therapy Trial, and the related template informed consent form, template clinical site agreement, Bioanalysis Plan and Statistical Analysis Plan, and any amendments to each of the foregoing.

(vii) unless otherwise agreed by the JDC, coordinating with the Non-Conducting Party and providing to the JDC (or a subcommittee or working group designated by the JDC for such purpose) [*] in advance of submission (timeline may be shortened if required per Regulatory Authority request and if agreed by JDC), drafts of (1) submissions to the Combined Therapy IND (if applicable); and (2) Combined Therapy Trial Regulatory Documentation, or portions thereof, that relate to the Combined Therapy or the Non-Conducting Party Compound(s),

for JDC review and approval, and providing the Non-Conducting Party with the opportunity to review, comment on and approve all other written correspondence with a Regulatory Authority relating to the Combined Therapy Trials, to the extent such correspondence relates to the Combined Therapy or the Non-Conducting Party Compound(s);

(viii) managing the operations of the Combined Therapy Trials in accordance with the applicable Protocol, including overseeing compliance by any CRO with the terms of its agreement with the Conducting Party relating to the Combined Therapy Trial;

(ix) subject to the terms of this Agreement, providing to the Non-Conducting Party a list of all proposed clinical trial sites and principal investigator(s) for each Combined Therapy Trial;

(x) subject to the terms of this Agreement, ensuring that all clinical trial service agreements and clinical trial site agreements (A) contain intellectual property provisions that retain each of the Parties' respective intellectual property rights in the Exelixis Compound, the BMS Compound(s) and Combined Therapy, and (B) allow for BMS, Exelixis to the extent permitted by applicable law and any Third Party confidentiality restrictions or obligation, to audit Combined Therapy Trial study sites for quality assurance and to inspect and copy all data, documentation and work products relating to the activities performed by the site, including, without limitation, the medical records of any patient participating in any clinical study. This right to inspect and copy all data, documentation, and work products of a study site may be exercised at any time during the term of this Agreement, or such longer period as shall be required by Applicable Law; provided, however, that where the Non-Conducting Party wants to exercise any of such rights with respect to the Combined Therapy Trial for which it is the Non-Conducting Party, it must first discuss the right(s) it wants to exercise and the Conducting Party must agree to the exercise of such right(s) before the Non-Conducting Party can exercise those rights.

(xi) providing the Non-Conducting Party with copies of each final site template ICF (if requested by the Non-Conducting Party);

(xii) providing the Non-Conducting Party with minutes from any and all external drug safety monitoring boards for the Combined Therapy Trials, if applicable, within [*] after receipt by BMS;

(xiii) providing the Non-Conducting Party with updates on the status of the Combined Therapy Trials at each teleconference for the clinical execution working group, or upon the Non-Conducting Party's reasonable request, including but not limited to information regarding the number and status of study sites, the number of screened subjects (actual to target), the number of randomized subjects (actual to target), the number of dosed, ongoing, discontinued and completed subjects, and any safety updates as contemplated by the applicable Protocol, Pharmacovigilance Agreement, and/or routinely performed by a Party in its normal course of trial management and reporting;

(xiv) subject to the provisions of Section 2.2 and the Pharmacovigilance Agreement, owning and being responsible for (or appointing a Third Party reasonably acceptable to the Non-Conducting Party to be responsible for) the maintenance of the Global Safety Database and safety reporting for the Combined Therapy, collecting, evaluating and reporting serious adverse events, other safety data and any further pharmacovigilance information from the Conducting Party sponsored Combined Therapy Trials, and providing the Non-Conducting Party with the opportunity to participate in and comment on such pharmacovigilance activities;

(xv) providing the Non-Conducting Party with prompt notice and copy of any updates to the Investigator's Brochure for the Conducting Party Compound(s)) and an opportunity to discuss same with a senior Conducting Party executive responsible for same if requested by the Non-Conducting Party;

(xvi) analyzing the Study Data in a timely fashion and providing the Non-Conducting Party with access to the Study Data from the applicable Combined Therapy Trial as follows:

(1) pursuant to an appropriate timetable determined by the JDC: (A) sharing with the Non-Conducting Party for review and comment drafts of interim and/ or final clinical trial report (and/or statistical analysis in accordance with the Statistical Analysis Plan) from each Combined Therapy Trial and (B) providing the raw Study Data in electronic or other mutually agreed format;

(2) when the final clinical trial report, CSR, or other final summary, such as a Summary of Clinical Safety, for a Combined Therapy Trial is provided to the Non-Conducting Party, the Conducting Party shall also provide to the Non-Conducting Party the Study Data Tabulation Model (SDTM) and the Analysis Data Model (ADaM) data sets used to generate such report or summary, Define.xml files for the SDTM and the ADaM data sets, a Study Data Reviewers Guide, an Analysis Data Reviewers Guide, a blank CRF, and an SDTM-annotated CRF; all data and information for cohorts that are not part of the Combined Therapy Trial will be redacted from the foregoing; and prior to the finalization of such final CSR or other final summary, the Conducting Party shall provide to the Non-Conducting Party up to two blinded drafts (from which data and information for cohorts that are not part of the Combined Therapy Trial are redacted) of the Study Data Tabulation Model (SDTM) and the Analysis Data Model (ADaM) data sets used to generate the report or summary unless the Protocol for such Combined Therapy Trial provides otherwise or the JDC agrees otherwise that more than two drafts will be provided and/or that one or both drafts will not be blinded;

(3) within [*] after database lock, access to safety databases that will be used for an interim review by an external consultant (or drug safety monitoring board, if required) to be agreed upon by the Parties;

(4) within [*] after database lock, access to case report forms or patient profiles for all patients in each Combined Therapy Trial; and

(5) within [*] of the creation of a clean database for the Combined Therapy Trial, copies of the Form 1572s, financial disclosures and other relevant documents required to meet regulatory requirements related to the Combined Therapy Trials (including without limitation any data or documents that may be required to provide Aggregate Safety Information to a Regulatory Authority with respect to the Non-Conducting Party Compound(s);

(6) within [*] of the creation of an electronic clean database for the Combined Therapy Trial, an electronic copy of the clean database (it being understood that the form and format of the clean database must be reasonable acceptable to all Parties and shall be determined by the JDC); and

(7) subject to any third party requirements, providing the Non-Conducting Party with any programs or SAS codes to be used for the Statistical Analysis Plan for the Combined Therapy Trial;

(xvii) obtaining supplies of any co-medications, to the extent any such co-medications are required for use in any Combined Therapy Trial, and providing to the Non-Conducting Party any information related to each Combined Therapy Trial that is provided to the manufacturer of any co-medication pursuant to Section 9.5 herein within [*] after the provision of the information to the manufacturer;

(xviii) providing the Non-Conducting Party with any information regarding the pharmacokinetics, efficacy and safety of the Conducting Party Compound(s) alone or in combination with the Non-Conducting Party Compound(s);

(xix) performing either directly or through third parties collection of Samples;

(xx) providing the Non-Conducting Party, where and to the extent provided in the Quality Agreement and based on the Non-Conducting Party sampling instructions, with samples of the Non-Conducting Party Compound(s) (bulk and post packaging material) for analytical identification testing performed by the Non-Conducting Party; and

(xxi) such other responsibilities as may be agreed to by the Parties or determined by the JDC.

(b) Responsibilities of the Non-Conducting Party. Subject to JDC direction as provided in Section 2.4, the Party that is not the Conducting Party for a Combined Therapy Trial (the "***Non-Conducting Party***") shall be responsible for the following activities, subject in each case (except as expressly provided in Article 4 with respect to the Manufacture and supply of the Non-Conducting Party Compound(s)) to sharing by the Parties of the Shared Study Costs related to such activities in accordance with Section 7.1:

(i) manufacturing and supplying GMP-grade quantities of of the Non-Conducting Party Compound(s), as further described in Article 4 above, and, where and to the extent provided in the Quality Agreement, providing necessary GMP information and documentation that enables the Conducting Party to release the Non-Conducting Party Compound(s) for the Combined Therapy Trial;

(ii) where and to the extent provided in the Quality Agreement, providing for the release by a Qualified Person (as such term will be defined in the Quality Agreement) or providing the necessary documentation in support of such quality release, of the Non-Conducting Party Compound(s) if such release is required for any Combined Therapy Trial;

(iii) performing analytical/biological testing of samples taken by the Conducting Party for the purpose of identification of the Non-Conducting Party Compound(s) after receipt at the Conducting Party and after clinical packaging by the Conducting Party. The Non-Conducting Party will provide the results to the Conducting Party that allows the Conducting Party a timely release of the Non-Conducting Party Compound(s) for packaging operation and shipment to the clinical sites.

(iv) promptly reviewing and approving each Protocol (including any immunogenicity analysis plan) and investigator's brochure for a Combined Therapy Trial, and the related template informed consent form, Bioanalysis Plan and Statistical Analysis Plan, and any amendments to each of the foregoing (provided that the Non-Conducting Party shall provide the Conducting Party with written notice of any comments or objections within [*] of the date on which the Conducting Party provides the applicable document to the Non-Conducting Party);

(v) to the extent necessary for the conduct of any Combined Therapy Trial, providing a Right of Cross-Reference to the relevant Regulatory Documentation for the Non-Conducting Party Compound(s), provided that, except as provided in Section 3.1 and Section 3.2 (as applicable), such Right of Cross-Reference shall terminate upon the expiration or termination of this Agreement for purposes of conducting any new clinical studies (except as otherwise expressly provided in this Agreement), except that in the case of termination for a Material Safety Issue pursuant to Section 12.4, such Right of Cross-Reference shall remain in effect solely (1) to the extent necessary to permit the Conducting Party to comply with any outstanding obligations required by a Regulatory Authority and/or Applicable Law or (2) as necessary to permit the Conducting Party to continue to dose subjects enrolled in each Combined Therapy Trial through completion of the applicable Protocol if required by the applicable Regulatory Authority(ies) and/or Applicable Laws;

(vi) unless otherwise agreed by the JDC, jointly reviewing, providing comments to the Conducting Party within [*] on, and approving all Combined Therapy Trial Regulatory Documentation and providing the Conducting Party with copies of the Non-Conducting Party Regulatory Documentation, as both Parties agree is necessary or reasonably expected to be necessary, and is requested by the Conducting Party, (1) to obtain and maintain the IND for the Combined Therapy Trials and prepare and file any Combined Therapy Trial Regulatory

Documentation in accordance with this Agreement, or (2) to comply with Applicable Law with regard to the Conducting Party Compound(s) and the Combined Therapy Trials, which may include information regarding the pharmacokinetics, efficacy and safety of the Non-Conducting Party Compound(s) alone or in combination with the Conducting Party Compound(s) (provided that the Non-Conducting Party shall provide the Conducting Party with written notice of any such comments (and, where applicable, approvals or rejections) within [*] of the date on which the Conducting Party provides the applicable document to the Non-Conducting Party;

(vii) analyze clinical PK Samples with the Non-Conducting Party Compound(s) assay and provide data and data analysis to the Conducting Party;

(viii) providing comment and input on the management of each Combined Therapy Trial pursuant to the applicable Protocol;

(ix) reviewing and, if applicable, suggesting alternatives to the Conducting Party's proposed list of principal investigator(s) for each Combined Therapy Trial;

(x) providing the Conducting Party with access to an investigator's brochure for the Non-Conducting Party Compound(s) as determined by the Non-Conducting Party (and any updates thereto);

(xi) providing and making available as necessary information and/or persons with knowledge concerning the Non-Conducting Party Compound(s) to support the Combined Therapy Trial, including any interactions with a Regulatory Authority;

(xii) providing to the JDC (or a subcommittee or working group designated by the JDC for such purpose) with prompt notice of any interactions with Regulatory Authorities relating to the Non-Conducting Party Compound(s) that might reasonably be expected to materially impact Combined Therapy Trial; and

(xiii) such other responsibilities as may be agreed to by the Parties or determined by the JDC.

5.2 Documents and Combined Therapy Trial Contracts.

(a) The Parties agree that the Conducting Party shall bear as a sponsor, primary responsibility for conduct of each Combined Therapy Trial and the analysis of the Study Data under the applicable Statistical Analysis Plan. In consultation with the Non-Conducting Party, the Conducting Party shall draft the Protocols and Statistical Analysis Plans, and any amendments to each of the foregoing, and shall provide such documents to the Non-Conducting Party for review, comment, and if applicable, approval as provided in this Agreement. The Non-Conducting Party shall have [*] from the date on which the Conducting Party provides the applicable document to the Non-Conducting Party to provide any comments and if applicable, approvals or rejections, to the Conducting Party concerning the applicable draft Protocol or Statistical Analysis Plan, or any amendment to each of the foregoing.

(b) Subject to the terms of this Agreement, the Conducting Party shall be responsible for negotiating and entering into contracts for services relating to the Combined Therapy Trials, including selecting vendors, approving contract deliverables and managing contract performance, including site contracts, obtaining IRB approval for site informed consent forms, obtaining signed informed consents, monitoring plans, etc. The Conducting Party will be responsible for ensuring that any such contracts (i) do not conflict with the terms of this Agreement, (ii) allow the Conducting Party to provide the Non-Conducting Party with access to and use of Study Data, Samples, and other information and documents as required pursuant to this Agreement (and in no event not less than the same access or use as is granted the Conducting Party) (iii) in the case of Exelixis as Conducting Party, do not adversely affect the BMS Technology or BMS Independent Patent Rights (or the enforcement or defense thereof), the Combined Therapy, or the BMS Compound as monotherapy, (iv) in the case of BMS as Conducting Party, do not adversely affect the Exelixis Technology or Exelixis Independent Patent Rights (or the enforcement or defense thereof), the Combined Therapy, or the Exelixis Compound as monotherapy, (v) do not impose a new obligation, whether direct, indirect, or contingent, upon the Non-Conducting Party that is not set forth in this Agreement, and (vi) do not confer a benefit upon the Conducting Party that is not also conferred upon the Non-Conducting Party.

5.3 Other Clinical Trials. Except for the Combined Therapy Trials, each clinical trial for the BMS Compound(s) and the Exelixis Compound, alone or in combination with other pharmaceutical agents, is independently conducted and shall not be subject to this Agreement (but without limiting each Party's obligation to share relevant safety information as provided in this Agreement, the Quality Agreement or the Pharmacovigilance Agreement). BMS Compound(s) provided to Exelixis and Exelixis Compound provided to BMS under this Agreement shall not be used for such other clinical trials. Nothing in this Agreement shall preclude a Party from conducting any such other clinical trials as it may determine in its discretion, so long as it does not use or rely on the Confidential Information of the other Party in doing so.

5.4 Additional Combined Therapy Trials If the Parties jointly agree to conduct any further Combined Therapy Trials beyond the Initial Trials, if necessary, the Pharmacovigilance Agreement and the Quality Agreement shall be amended to provide for such Combined Therapy Trial under the terms thereof. In addition, the Parties agree to discuss whether it may be useful or desirable to include Ono, Ipsen and/or Takeda as part of any such further Combined Therapy Trial.

ARTICLE 6

INTELLECTUAL PROPERTY

6.1 Inventions. All rights to Inventions shall be allocated as follows:

(a) Exelixis Ownership. Subject to the terms of this Agreement, all Exelixis Study Inventions shall be owned by Exelixis, and Exelixis will have the full right to exploit such Exelixis Study Inventions without the consent of, or any obligation to account to, BMS. BMS shall assign and hereby assigns (and shall cause its Affiliates and contractors to assign) all right, title and

interest in any Exelixis Study Inventions to Exelixis. Any assignments necessary to accomplish the foregoing are hereby made, and BMS shall execute such further documents and provide other assistance as may be reasonably requested by Exelixis to perfect Exelixis's rights in such Exelixis Study Inventions, all at Exelixis's expense (as applicable). Exelixis shall have the sole right but not the obligation to prepare, file, prosecute (including any proceedings relating to reissues, reexaminations, protests, interferences, oppositions, post-grant reviews or similar proceedings and requests for patent extensions) and maintain any Exelixis Study Patent Rights at its own expense.

(b) BMS Ownership. Subject to the terms of this Agreement, all BMS Study Inventions shall be owned solely by BMS, and BMS will have the full right to exploit such BMS Study Inventions without the consent of, or any obligation to account to, Exelixis. Exelixis shall assign and hereby assigns (and shall cause its Affiliates and contractors to assign) all right, title and interest in any BMS Study Inventions to BMS. Any assignments necessary to accomplish the foregoing are hereby made, and Exelixis shall execute such further documents and provide other assistance as may be reasonably requested by BMS to perfect BMS' rights in such BMS Study Inventions, all at BMS' expense. BMS shall have the sole right but not the obligation to prepare, file, prosecute (including any proceedings relating to reissues, reexaminations, protests, interferences, oppositions, post-grant reviews or similar proceedings and requests for patent extensions) and maintain any BMS Study Patent Rights at its own expense.

(c) Combined Therapy Inventions. All Combined Therapy Inventions shall be jointly owned by the Parties (BMS to own 50% and Exelixis to own 50%), and any Party shall have the right to freely practice and exploit the Combined Therapy Inventions and Combined Therapy Patent Rights worldwide, both within and outside the scope of this Agreement, without accounting or any other obligation to the other Party (except as expressly set forth in Section 6.1(d) and Section 6.3(d) with regard to the filing, prosecution, maintenance and enforcement of Combined Therapy Patent Rights) and each Party may use, exploit and grant licenses worldwide (with right to sublicense) to Third Parties under its interest in such Combined Therapy Trial Inventions and Combined Therapy Patent Rights without the consent of the other Party or any consideration or any accounting or any other obligation to the other Party. For the avoidance of doubt, neither Party shall acquire any other license or other intellectual property interest, by implication or otherwise, in any intellectual property of the other Party under this Section 6.1(c), including but not limited to Exelixis Independent Patent Rights, Exelixis Study Patent Rights, BMS Independent Patent Rights, or BMS Study Patent Rights.

(d) Prosecution of Combined Therapy Patent Rights. The Parties shall agree as to which of BMS or Exelixis, using outside counsel acceptable to the other Party, shall be responsible for preparing and prosecuting Patent applications and maintaining Patents within the Combined Therapy Patent Rights. The Party drafting and prosecuting any Combined Therapy Patent Right (the "***Prosecuting Party***") shall keep the other Party (the "***Non-Prosecuting Party***") advised as to material developments and all steps to be taken with respect to any such Patents and shall furnish the Non-Prosecuting Party with copies of applications for such Patents, amendments thereto and other related correspondence to and from Patent offices, and permit the Non-Prosecuting

Party a reasonable opportunity to review and offer comments. The Non-Prosecuting Party shall reasonably assist and cooperate in obtaining, prosecuting and maintaining the Combined Therapy Patent Rights. Notwithstanding the foregoing, the Prosecuting Party shall not take any position in a submission to a Patent office that interprets the scope of a Patent or Patent application of the Non-Prosecuting Party without the prior written consent of such Non-Prosecuting Party. The Prosecuting Party shall be reimbursed for any costs and expenses incurred in prosecuting Combined Therapy Patent Rights and the subsequent maintenance of Combined Therapy Patent Rights by the Non-Prosecuting Party such that BMS shall be responsible for [*] of such costs and Exelixis shall be responsible for [*] of such costs. In case either BMS or Exelixis decides not to file or maintain a Combined Therapy Patent Right application in a given country (and also elects not to reimburse the other Party for [*] of the costs of prosecution and maintenance of such Combined Therapy Patent Right in such country), the other Party shall have the right to file or maintain such patent application in such country in its own name and at its own expense upon the prior consent of the other Party, which shall not be unreasonably withheld or delayed. In this case, the Party who decides not to file or maintain (and also decides not to reimburse the other Party for its share of the costs of) a joint application for a given country shall promptly assign its rights to the joint invention in said country to the Party who wishes to file or maintain said patent application. The Party who does not wish to file or maintain a patent application in any country shall assist in the timely provision of all documents required under national provisions to register said assignment of rights with the corresponding national authorities at the sole expense of the Party who wishes to file or maintain such patent application in that given country. If the Parties cannot agree with respect to the decision to file or maintain a Combined Therapy Patent Right within [*] subsequent to the initiation of the Parties' good faith efforts to resolve any disagreement, then either BMS or Exelixis shall have the right to file or maintain any patent application for the Combined Therapy Patent Right in the names of the Parties, provided that: (i) any resulting Patent shall be deemed to be a Combined Therapy Patent Right hereunder and shall be jointly owned by BMS and Exelixis and subject to the freedom to use and operate under such Combined Therapy Patent Right as set forth in the first sentence of this Section 6.1(c), and the Non-Prosecuting Party shall reimburse the Prosecuting Party for its 50% share of the patent costs.

(e) Separation of Patent Rights. In order to more efficiently enable the prosecution and maintenance of the BMS Study Patent Rights, Exelixis Study Patent Rights and Combined Therapy Patent Rights relating to Inventions as described above, the Parties will use good faith efforts to separate BMS Study Patent Rights, Exelixis Study Patent Rights, Combined Therapy Patent Rights, BMS Independent Patent Rights and Exelixis Independent Patent Rights into separate patent filings to the extent possible and without adversely impacting such prosecution and maintenance.

6.2 Disclosure and Assignment of Inventions. Each Party shall disclose promptly to the other Party in writing and on a confidential basis all Inventions, prior to any public disclosure or filing of Patent applications and allowing sufficient time for comment by the other Party. In addition, each Party shall, and does hereby, assign, and shall cause its Affiliates and contractors to so assign, to the applicable Party, without additional compensation, such right, title and interest in

and to any Inventions as well as any intellectual property rights with respect thereto, as is necessary to fully effect, as applicable, the sole ownership provided for in Sections 6.1(a) and 6.1(b) and the joint ownership provided for in Section 6.1(c).

6.3 Infringement of Patent Rights by Third Parties.

(a) Notice. Each Party shall promptly notify the other Party in writing of any alleged or threatened (in writing) infringement, or misappropriation by a Third Party, of Combined Therapy Patent Rights, of which its in-house patent counsel becomes aware (such infringement, "***Infringement***," and "***Infringe***" shall be interpreted accordingly).

(b) Infringement of Exelixis Study Patent Rights. For all Infringement of Exelixis Study Patent Rights anywhere in the world, Exelixis shall have the exclusive right to prosecute such Infringement as it may determine in its sole and absolute discretion, and Exelixis shall bear all related expenses and retain all related recoveries. BMS shall reasonably cooperate with Exelixis or their designee (to the extent BMS has relevant information arising out of this Agreement), at the request and expense of Exelixis, in any such action.

(c) Infringement of BMS Study Patent Rights. For all Infringement of BMS Study Patent Rights anywhere in the world, BMS shall have the exclusive right to prosecute such Infringement as it may determine in its sole and absolute discretion, and BMS shall bear all related expenses and retain all related recoveries. Exelixis shall reasonably cooperate with BMS or its designee (to the extent Exelixis has relevant information arising out of this Agreement), at BMS' request and expense, in any such action.

(d) Infringement of Combined Therapy Patent Rights.

(i) With respect to Infringement of Combined Therapy Patent Rights, the Parties shall mutually agree as to whether to bring an enforcement action to seek the removal or prevention of such Infringement and damages therefor and, if so, which Party shall bring such action, with any costs and expenses relating thereto to be allocated in accordance with Section 6.3(d)(ii).

(ii) Regardless of which Party brings an enforcement action pursuant to Section 6.3(d)(i), the other Party hereby agrees to cooperate reasonably in any such action, including, if required, by bringing a legal action or furnishing a power of attorney. If the Parties mutually agree to bring an enforcement action, BMS shall be responsible for [*], and Exelixis shall be responsible for [*], of the reasonable and verifiable costs and expenses incurred in connection with any such action. If any Party recovers monetary damages from any Third Party in an action approved by the Parties and brought under this Section 6.3(d)(ii), such recovery shall be allocated first to the reimbursement of any actual, unreimbursed costs and expenses incurred by the Parties in such litigation (including, for this purpose, a reasonable allocation of expenses of internal counsel) pro rata in accordance with the aggregate amounts spent by both Parties, and any remaining amounts shall be split [*] to

Exelixis and [*] to BMS, unless the Parties agree in writing to a different allocation. In connection with any proceeding under this Section 6.3(d), neither Party shall enter into any settlement without the prior written consent of the other Party.

6.4 Infringement of Third Party Rights.

(a) Notice. If the activities relating to the Combined Therapy Trials become the subject of a claim of infringement of a patent, copyright or other proprietary right by a Third Party anywhere in the world, the Party first having notice of the claim shall promptly notify the other Party and, without regard to which Party is charged with said infringement and the venue of such claim, the Parties shall promptly confer to discuss the claim.

(b) Defense. If all of the Parties are charged with infringement pursuant to a claim described in Section 6.4(a), the Parties shall defend such claim jointly, unless they agree otherwise. If only one Party is charged with infringement, such Party will have the first right but not the obligation to defend such claim. If the charged Party does not commence actions to defend such claim within [*] after being so charged, then the other Party shall have the right, but not the obligation, to defend any such claim. In any event, a non-defending Party shall reasonably cooperate with the Party conducting the defense of the claim and shall have the right to participate with separate counsel at its own expense, and the defending Party shall consider comments and suggestions on strategy for defending the action by a non-defending Party in good faith. The Party defending the claim shall bear the cost and expenses of the defense of any such Third Party infringement claim and shall have sole rights to any recovery. If the Parties jointly defend the claim, Exelixis shall bear [*], and BMS shall bear [*] of any costs and expenses of the defense of any such Third Party infringement claim; provided, however, that, notwithstanding the foregoing, if the claim relates solely to either the BMS Compound(s) or the Exelixis Compound, BMS or Exelixis (as applicable) will bear [*] of the costs and expenses of the defense of such claim and shall have the sole right, but not the obligation, to defend, settle and otherwise handle the disposition of such claim. No Party shall enter into any settlement concerning activities under this Agreement or the Combined Therapy that affects the other Party's rights under this Agreement or imposes any obligations on the other Party, including any admissions of wrongdoing on behalf of the other Party, without such other Party's prior written consent, not to be unreasonably withheld or delayed, except that (i) Exelixis may settle any claim that solely relates to the Exelixis Compound without the consent of BMS as long as BMS's rights under this Agreement are not materially adversely impacted (in which case, it will obtain BMS's prior written consent, not to be unreasonably withheld or delayed) and (ii) BMS may settle any claim that solely relates to the BMS Compound(s) without the consent of Exelixis as long as Exelixis rights under this Agreement are not materially adversely impacted (in which case, it will obtain Exelixis prior written consent, not to be unreasonably withheld or delayed).

6.5 Combined Therapy Trial Regulatory Documentation. Subject to the license and other rights granted by each Party to the other Party pursuant to this Agreement, the Parties shall jointly own (BMS to own 50% and Exelixis to own 50%) all right, title and interest in and to the Combined Therapy Trial Regulatory Documentation; *provided*, *however*, that BMS shall retain sole and exclusive ownership of any BMS Regulatory Documentation provided to Exelixis under this

Agreement that is submitted with or referenced in the Combined Therapy Trial Regulatory Documentation and that Exelixis shall retain sole and exclusive ownership of any Exelixis Regulatory Documentation that is submitted with or referenced in the Combined Therapy Trial Regulatory Documentation. This Section 6.5 is without limitation of any other disclosure obligations under the Pharmacovigilance Agreement or this Agreement.

6.6 No Other Use. Except as expressly provided in Section 6.1 Exelixis agrees to make no patent application based on BMS Confidential Information, and to give no assistance to any Third Party for such application without BMS's prior written authorization, and BMS agrees to make no patent application based on Exelixis Confidential Information, and to give no assistance to any Third Party for such application without Exelixis' prior written authorization.

6.7 Joint Research Agreement. The Parties acknowledge and agree that this Agreement is a "Joint Research Agreement" as defined in 35 USC § 100 (h).

ARTICLE 7

COLLABORATION COSTS AND EXPENSES

7.1 Combined Therapy Trial Expenses. BMS and Exelixis will share the Shared Costs (in accordance with Section 7.2), with BMS responsible for fifty percent (50%) and Exelixis responsible for fifty percent (50%) of the Shared Costs for each control arm and each double therapy arm (i.e., Cabozantinib + Nivolumab or Cabozantinib + Ipilimumab) of each Combined Therapy Trial and with BMS responsible for sixty-seven percent (67%) and Exelixis responsible for thirty-three percent (33%) of the Shared Costs for each triple therapy arm (i.e., Cabozantinib + Nivolumab + Ipilimumab) of a Combined Therapy Trial. The cost allocation (on a percent basis) for the Shared Costs of each Combined Therapy Trial will be calculated prior to the initiation or an amendment of such Combined Therapy Trial and will be the weighted percentages for BMS' share and for Exelixis's share of such Combined Therapy Trial, with such weighted percentages calculated on the basis of [*] and the applicable allocation percentages above in this Section 7.1 for each arm of such Combined Therapy Trial. The weighted percentages calculated before the initiation of a Combined Therapy Trial will not change and will be applied to all of the Shared Costs of such Combined Therapy Trial unless the number of arms in such Combined Therapy Trial increases or decreases, in which case the weighted percentages will be recalculated and applied to all subsequent Shared Costs for such Combined Therapy Trial (with the weighted percentages being recalculated and applied thereafter whenever there is a change in the number of arms in such Combined Therapy Trial). By way of illustration, if there are [*], then the weighted percentage for BMS at the initiation of such Combined Therapy Trial would be calculated as follows:

[*].

The weighted percentage for Exelixis would be [*].

7.2 Each Party shall calculate Shared Costs in accordance with GAAP. "***Shared Costs***" means the costs directly attributable or reasonably allocable by each Party (both out-of-pocket and internal) for the conduct of the Combined Therapy Trial (including but not limited to [*]) based on [*]. The Shared Costs shall be incurred consistent with the JDC-approved budget for such Shared Costs. The final budget for each Combined Therapy Trial will be based on the final Protocol for such Combined Therapy Trial and will be subject to approval by the JDC. For clarity, expenses incurred as described in Article 4 (regarding manufacturing and supply), and Article 6 (regarding intellectual property) shall not be considered "Shared Costs" but shall be borne or shared by the Parties as provided in such Articles. In addition, each Party shall bear its own Third Party License Payments as set forth in Section 2.5(b). For the avoidance of doubt, nothing in this Agreement herein shall be considered to establish an employment relationship between a Party and the FTEs of the other Party funded by such Party pursuant to this Agreement.

7.3 Invoicing; Payment.

(a) Reporting and Invoicing. Each Party shall report to the other Party, within [*] after the end of each Quarter with regard to Shared Costs and Section 4.1(b) Costs or Section 4.2(b) Costs (as applicable) actually incurred during such Quarter by such Party (a "***Quarterly Report***"). Such report shall specify in reasonable detail such Shared Costs and Section 4.1(b) Costs or Section 4.2(b) Costs (as applicable) during such Quarter. The Parties shall seek to resolve any questions related to such reports within [*] following receipt by each Party of the other Party's report hereunder. Based on these reports, the Parties finance teams will determine the amount, if any, owed by BMS, on the one hand, and Exelixis on the other hand, for such Quarter and a "***True-Up Payment***" will be made by BMS if owing same or Exelixis if owing same within [*] after the receipt of an invoice for such True-Up Payment from BMS or Exelixis, whichever is applicable.

(b) Budget Overruns. Any costs for a given budget that are incurred by a Party that are [*] greater than the JDC-approved budget shall require approval of the JDC for payment. The Parties shall bear the cost of any such overrun equally; *provided*, however, that if the reason for the costs exceeding the JDC-approved budget by more than [*] is attributable to [*], then the costs incurred that are more than [*] greater than the JDC-approved budget for such item shall be [*].

7.4 Audit. At the request (and expense) of a Party, the other Party shall permit an independent certified public accountant appointed by the requesting Party and reasonably acceptable to such other Party, at reasonable times and upon reasonable notice, to examine only those records as may be reasonably necessary to determine, with respect to any calendar year ending not more than [*] prior to such Party's request, the correctness or completeness of any invoice submitted to the such other Party or other payment made to the such other Party pursuant to this Agreement. The foregoing right of review may be exercised only once per year and only once with respect to each such periodic report and payment. Results of any such examination shall be (a) made available to both Parties and (b) subject to Article 9. The Party requesting the audit shall bear the full cost of the performance of any such audit, unless such audit discloses a variance to the detriment of the auditing Party of more than [*] from the amount of the original report, royalty or payment

calculation, in which case, the Party being audited shall bear the full cost of the performance of such audit.

ARTICLE 8

RECORDS AND STUDY DATA

8.1 Records. Each Party shall maintain complete and accurate records of all work conducted with respect to the Combined Therapy Trials and of all results, information, data, data analyses, reports, records, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences and developments made by or provided to either Party, or by the Parties together, in the course of such Party's efforts with respect to the Combined Therapy Trials (including the Statistical Analysis Plan and any Bioanalysis Plan to be conducted pursuant to this Agreement) (such results, information, data, data analyses, reports, case report forms, adverse event reports, trial records, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, developments, and each Combined Therapy Trial protocol referred to as the "***Study Data***"). Such records shall fully and properly reflect all work done and results achieved in the performance of the Combined Therapy Trials in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes.

8.2 Ownership of Study Data. BMS shall own the Study Data to the extent that it relates exclusively to the BMS Compound ("***BMS Study Data***"), and Exelixis shall own the Study Data to the extent that it relates exclusively to the Exelixis Compound ("***Exelixis Study Data***"). The Parties shall jointly own (BMS to own 50% and Exelixis to own 50%) any Study Data that does not relate exclusively to the Exelixis Compound or the BMS Compound ("***Combined Therapy Study Data***"). Each Party shall, and does hereby, assign, and shall cause its Affiliates to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Study Data as is necessary to fully effect the foregoing, and agrees to execute all instruments as may be reasonably necessary to effect same.

8.3 Use of **Study Data.**

(a) Use of a Party's Own Study Data. BMS may use and analyze the BMS Study Data for any purpose without obligation or accounting to Exelixis. Exelixis may use and analyze the Exelixis Study Data for any purpose without obligation or accounting to BMS.

(b) Use of Combined Therapy Study Data by BMS. BMS, Ono and their respective Affiliates and (sub)licensees of the BMS Compound shall have the right to use and analyze the Combined Therapy Study Data for any and all purposes without the consent of, or any obligation to account to, Exelixis, including (x) in connection with their independent development, commercialization or other exploitation of the BMS Compound(s) (alone or in combination with the Exelixis Compound and/or other pharmaceutical agents) and/or for inclusion in the safety

database for the BMS Compound, and (y) to conduct studies with Samples pursuant to Section 8.5. Subject to Section 8.5, the results of all such uses or analyses shall be owned by BMS, including any intellectual property arising out of same, unless the Parties shall have agreed otherwise in writing.

(c) Use in Regulatory Filings by BMS. In addition, BMS, Ono and their respective Affiliates and (sub)licensees of the BMS Compound(s) shall be entitled to use the Combined Therapy Study Data during and following the term of this Agreement to (1) submit regulatory filings and seek approvals for the BMS Compound(s), either as monotherapy or as part of the Combined Therapy and (2) following the applicable approval of the Combined Therapy, to promote indications based on, and to disseminate, the Combined Therapy Study Data for the benefit of the BMS Compound(s) as part of the Combined Therapy, where permitted by and in accordance with Applicable Law. In the case where BMS submits Combined Therapy Study Data to a Regulatory Authority in a filing for approval for the use of the BMS Compound(s) in combination with the Exelixis Compound (including any reference to the Combined Therapy Study Data in its label) or if required by the applicable Regulatory Authority, then BMS shall be granted a Right of Cross-Reference to the relevant Regulatory Documentation Controlled by Exelixis for the Exelixis Compound and the Combined Therapy solely to the extent required for the purpose of such approval (which right shall survive any expiration or termination of this Agreement). In such case, Exelixis shall reasonably cooperate with BMS and make written authorizations and other filings with the applicable Regulatory Authority reasonably required to effect such Right of Cross-Reference. Such grant to BMS of a Right of Cross-Reference shall not include a Right of Cross-Reference for use in the Takeda Territory, without Exelixis' prior written consent.

(d) Use of Combined Therapy Study Data by Exelixis. Exelixis and its Affiliates and licensees of the Exelixis Compound shall have the right to use and analyze the Combined Therapy Study Data for any and all purposes without the consent of, or any obligation to account to, BMS, including (x) in connection with their independent development, commercialization or other exploitation of the Exelixis Compound (alone or in combination with the BMS Compound(s) and/or other pharmaceutical agents and/or for inclusion in the safety database for the Exelixis Compound, and (y) to conduct studies with Samples pursuant to Section 8.5. Subject to Section 8.5, the results of all such uses or analyses shall be owned by Exelixis, including any intellectual property arising out of same, unless the Parties shall have agreed otherwise in writing.

(e) Use in Regulatory Filings by Exelixis. In addition, Exelixis and its Affiliates and licensees of the Exelixis Compound shall be entitled to use the Combined Therapy Study Data during and following the term of this Agreement to (1) submit regulatory filings and seek approvals for the Exelixis Compound, either as monotherapy or as part of the Combined Therapy and (2) following the applicable approval of the Combined Therapy, to promote indications based on, and to disseminate, the Combined Therapy Study Data for the benefit of the Exelixis Compound as part of the Combined Therapy, where permitted by and in accordance with Applicable Law. In the case where Exelixis submits Combined Therapy Study Data to a Regulatory Authority

in a filing for approval for the use of the Exelixis Compound in combination with the BMS Compound(s) (including any reference to the Combined Therapy Study Data in its label), then Exelixis shall be granted a Right of Cross-Reference to the relevant Regulatory Documentation Controlled by BMS for the BMS Compound and the Combined Therapy solely to the extent required for the purpose of such approval (which right shall survive any expiration or termination of this Agreement) or if required by the applicable Regulatory Authority. In such case, BMS shall reasonably cooperate with Exelixis and make written authorizations and other filings with the applicable Regulatory Authority reasonably required to effect such Right of Cross-Reference. Such grant to Exelixis of a Right of Cross-Reference shall not include a Right of Cross-Reference for use in the Ono Territory, without BMS' prior written consent.

(f) Biomarker/Dx Agent Development. Each Party may use and disclose to a Third Party the Combined Therapy Study Data and its Compound(s)'s Study Data, under obligations of confidentiality consistent with this Agreement, to develop and commercialize a biomarker or diagnostic test for use with its Compound(s) and/or the Combined Therapy, and, unless otherwise mutually agreed by the Parties in writing, will own any intellectual property arising out of the work funded or conducted by it with or through such Third Party. The Parties will discuss in good faith any opportunities to jointly participate in the development of any such biomarker or diagnostic test for use with the Combined Therapy.

(g) No Other Uses. All other uses of Study Data are limited solely to those permitted by this Agreement, and neither Party may use Study Data for any other purpose without the consent of the other Party during and after the Term of this Agreement.

8.4 Access to Study Data. Subject to the provisions of Sections 5.1, and the Pharmacovigilance Agreement, each Party shall have access to all Study Data (including, but not limited to, de-identified patient records) as soon as such Study Data is available to or generated by the Party responsible for generating or collecting such Study Data.

8.5 Samples. Samples collected in the course of activities conducted under this Agreement shall be jointly owned by the Parties (BMS to own 50% and Exelixis to own 50%) (to the extent not owned by the patient and/or the clinical trial site). Any such Samples shall be collected in accordance with the applicable Protocol and ICFs. Except as set forth in a Bioanalysis Plan, no Party shall be permitted to use such Samples for any purpose without the prior written consent of the other Party, which consent shall not be unreasonably withheld if such use is directed to the Combined Therapy and with the terms of such use to be set forth in a written agreement between the Parties setting forth the Samples to be used, and any appropriate terms/restrictions on such use. Any data and intellectual property arising out of such Sample use shall be owned by the Party conducting such study using same; *provided*, that to the extent that any such data or intellectual property relates solely to the Combined Therapy (or biomarkers solely for use with the Combined Therapy), shall be considered Combined Therapy Study Data or Combined Therapy Inventions/Combined Therapy Patent Rights, as the case may be. Samples [*] will be stored for future use [*], *provided*, that [*], *provided further* that [*]. If no Party has any further use for the Samples, then the remaining Samples will be destroyed pursuant to the respective Party's standard operating

procedures for sample retention and destruction, subject to the terms of and permission(s) granted in the informed consent forms signed by the subjects contributing the Samples in the Combined Therapy Trials.

8.6 For the avoidance of doubt, all bioanalytical results for the BMS Compound(s) and the Exelixis Compound(s) from Samples from Combined Therapy Trial subjects are deemed to be Study Data. All data derived pursuant to the Protocol from such Samples from Combined Therapy Trial subjects are deemed to be Study Data.

8.7 Where a Combined Therapy Trial is added to a pre-existing clinical trial of one of the Parties, none of the cohorts of such pre-existing clinical trial shall be part of the Combined Therapy Trial and none of the results, information, data, data analyses, reports, records, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences and developments from such cohorts will be Study Data unless the Protocol expressly provides that any such cohort and any such results, information, data, data analyses, reports, records, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences and developments are part of the Combined Therapy Trial or Study Data, respectively. Where a cohort of a Combined Therapy Trial is a monotherapy cohort with just the Exelixis Compound or with just one of the BMS Compounds or is a double therapy cohort with just the BMS Compounds, then the Study Data from such cohort will be Exelixis Study Data in the case where such cohort is a monotherapy cohort with just the Exelixis Compound and BMS Study Data in the case where such cohort is a monotherapy cohort with just one of the BMS Compounds or is a double therapy cohort with just the BMS Compounds, and such Exelixis Study Data will be made available to BMS and such BMS Study Data will be made available to Exelixis upon request by BMS or Exelixis, respectively, and shall be used by BMS and Exelixis, respectively, solely to analyze and estimate the contribution of components in the Combined Therapy, and such Exelixis Study Data and such BMS Study Data is Confidential Information of Exelixis and Confidential Information of BMS, respectively.

ARTICLE 9

CONFIDENTIALITY

9.1 Nondisclosure of Confidential Information. Prior to the Effective Date of this Agreement, Exelixis and BMS entered into a certain Confidentiality Agreement having an effective date of June 9, 2016, as amended by Amendment No. 1 to Confidentiality Agreement having an effective date of February 2, 2017 ("***CDA***"). As it relates to disclosures involving the BMS Compound and the Exelixis Compound only, the CDA is hereby terminated and replaced by the terms of this Agreement. Any Confidential Information relating thereto previously disclosed by the Parties pursuant to the CDA shall now be Confidential Information for purposes of this Agreement and the Parties shall treat it as such in accordance with the terms hereof. All written, visual, oral and electronic data, information, know-how or other proprietary information or materials, both technical and non-technical, disclosed by one Party to any other Party pursuant to

this Agreement that (a) if in tangible form, is labeled in writing as “proprietary” or “confidential” (or similar reference); or (b) if in oral or visual form, is identified as proprietary or confidential or for internal use only at the time of disclosure or within [*] thereafter shall be “***Confidential Information***” of the disclosing Party, and all Study Data and Inventions shall be the Confidential Information of the Party owning such Study Data or Invention (as provided in Section 8.2 with regard to Study Data and Section 6.1 with regard to Inventions). For purposes of this Agreement, regardless of which Party discloses such Confidential Information to the other, (i) all Exelixis Study Inventions, Exelixis Technology and Exelixis Regulatory Documentation shall be Confidential Information of Exelixis and BMS shall be the receiving Party, (ii) all BMS Study Inventions, BMS Technology, and BMS Regulatory Documentation shall be Confidential Information of BMS and Exelixis shall be the receiving Parties. Except to the extent expressly authorized in this Section 9.1 and Sections 9.2, 9.3 and 9.6 below, or as otherwise agreed in writing by the Parties, each Party agrees that, for the Term of this Agreement and for a period of [*] thereafter (or for any Confidential Information that is identified in writing at the time of disclosure as a trade secret related to each Party’s Compound(s), for as long as it is not part of the public domain), it shall (x) keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as expressly provided for in this Agreement any Confidential Information owned solely by any other Party, (y) treat any other Party’s solely-owned Confidential Information with the same degree of care the receiving Party uses for its own confidential information but in no event with less than a reasonable degree of care; and (z) reproduce a disclosing Party’s solely-owned Confidential Information solely to the extent necessary to accomplish the receiving Party’s obligations under this Agreement, with all such reproductions being considered the disclosing Party’s Confidential Information; *provided*, that [*], Confidential Information that was [*]. Notwithstanding anything to the contrary in this Section 9.1, and subject to Section 8.3, the receiving Party may disclose a disclosing Party’s Confidential Information to its employees, consultants, agents or permitted sublicensees solely on a need-to-know basis for the purpose of fulfilling the receiving Party’s obligations or exercising the receiving Party’s rights under this Agreement; *provided*, *however*, that (1) any such employees, consultants, agents or permitted sublicensees are bound by obligations of confidentiality at least as restrictive as those set forth in this Agreement, and (2) the receiving Party remains liable for the compliance of such employees, consultants, agents or permitted sublicensees with such obligations. Each receiving Party acknowledges that in connection with its and its representatives examination of the Confidential Information of the disclosing Party, the receiving Party and its representatives may have access to material, non-public information, and that the receiving Party is aware, and will advise its representatives who are informed as to the matters that are the subject of this Agreement, that State and Federal laws, including, without limitation, United States securities laws, impose restrictions on the dissemination of such information and trading in securities when in possession of such information. Each receiving Party agrees that it will not, and will advise its representatives who are informed as to the matters that are the subject of this Agreement to not, purchase or sell any security of the disclosing Party on the basis of the Confidential Information to the extent such Confidential Information constitutes material non-public information about the disclosing Party or such security.

Combined Therapy Study Data shall be treated as Confidential Information of each Party and shall not be disclosed to Third Parties unless it falls within the exceptions set forth in Section 9.2 below or is reasonably necessary to be disclosed in order for a Party to exercise its rights under Section 8.3(b), 8.3(c), 8.3(d) or 8.3(e).

9.2 Exceptions. The obligations in Section 9.1 shall not apply with respect to any portion of Confidential Information that the receiving Party can demonstrate by contemporaneous tangible records or other competent proof:

(a) was already known to the receiving Party (or its Affiliates), other than under an obligation of confidentiality, either (a) at the time of disclosure by the disclosing Party, or (b) if applicable, at the time that it was generated hereunder, whichever ((a) or (b)) is earlier;

(b) was generally available to the public or otherwise part of the public domain either (a) at the time of its disclosure to the receiving Party, or (b) if applicable, at the time that it was generated hereunder, whichever ((a) or (b)) is earlier;

(c) became generally available to the public or otherwise part of the public domain after its disclosure (including via publication under Section 9.6) and other than through any unauthorized act or omission of the receiving Party in breach of this Agreement;

(d) was disclosed to the receiving Party (or its Affiliates), other than under an obligation of confidentiality, by a Third Party who had no obligation to the Party owning or Controlling the information not to disclose such information to others; or

(e) was independently discovered or developed by the receiving Party (or its Affiliates) without the use of or reference to the Confidential Information belonging to the disclosing Party.

9.3 Authorized Disclosure. Notwithstanding any other provision of this Agreement, each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following instances:

(a) filing or prosecuting Patent Rights claiming an Invention owned by such Party;

(b) prosecuting or defending litigation;

(c) complying with Applicable Law or the rules or regulations of any securities exchange on which such Party's stock is listed;

(d) disclosure, in connection with the performance of this Agreement, to Affiliates, permitted sublicensees, contractors, ethics committees and institutional review boards (collectively, "***IRBs***"), CROs, academic institutions, consultants, agents, investigators, and employees and contractors engaged by Study sites and investigators involved with the Combined

Therapy Trials, each of whom prior to disclosure must be bound by similar terms of confidentiality and non-use at least equivalent in scope to those set forth in this Article 9;

(e) disclosure of the Combined Therapy Study Data, Combined Therapy Inventions and Combined Therapy Patent Rights to Regulatory Authorities in connection with the development of the Combined Therapy, the Exelixis Compound or the BMS Compound; and

(f) disclosure of relevant safety information contained within the Combined Therapy Study Data to investigators, institutional review boards and/or ethics committees and Regulatory Authorities that are involved in other clinical trials of the Exelixis Compound with respect to Exelixis, and the BMS Compound with respect to BMS, and (in the event of a Material Safety Issue) to Third Parties that are collaborating with Exelixis or BMS, respectively in the conduct of such other clinical trials of the Exelixis Compound or the BMS Compound(s), in each case solely to the extent necessary for the conduct of such clinical trials and/or to comply with Applicable Law and regulatory requirements.

Notwithstanding the foregoing, if a Party is required or otherwise intends to make a disclosure of any other Party's Confidential Information pursuant to Section 9.3(b) and/or Section 9.3(c), it shall give advance notice to such other Party of such impending disclosure and endeavor in good faith to secure confidential treatment of such Confidential Information and/or reasonably assist the Party that owns such Confidential Information in seeking a protective order or other confidential treatment.

9.4 Disclosure to Ono. Notwithstanding any other provision of this Agreement, Exelixis hereby expressly authorizes BMS to disclose to Ono (i) this Agreement, the Protocols, Combined Therapy Inventions and Combined Therapy Patent Rights and (ii) any other Exelixis Confidential Information necessary for BMS to fulfill its obligations to Ono under the Ono-BMS Agreements; *provided that* Ono is under confidentiality obligations at least as restrictive as set forth herein. BMS shall be free to disclose the BMS Study Data and the Combined Therapy Study Data to Ono as BMS may determine as provided in Section 8.3(b) or 8.3(c) and otherwise to fulfill its obligations under the Ono-BMS Agreements.

9.5 Disclosure to Ipsen and Takeda. Notwithstanding any other provision of this Agreement, BMS hereby expressly authorizes Exelixis to disclose to Ipsen and Takeda (i) this Agreement, the Protocols, Combined Therapy Inventions and Combined Therapy Patent Rights and (ii) any other BMS Confidential Information necessary for Exelixis to fulfill its obligations to Ipsen and Takeda under the Ipsen-Exelixis Agreements and the Takeda-Exelixis Agreements; *provided that* Ipsen and Takeda are each under confidentiality obligations at least as restrictive as set forth herein. Exelixis shall be free to disclose the Exelixis Study Data and the Combined Therapy Study Data to Ipsen and Takeda as Exelixis may determine as provided in Section 8.3(d) or 8.3(e) and otherwise to fulfill its obligations under each of the the Ipsen-Exelixis Agreements and the Takeda-Exelixis Agreements.

9.6 Disclosure to Third Party Co-Medication Manufacturer. Notwithstanding any other provision of this Agreement, the Non-Conducting Party hereby authorizes the Conducting

Party to disclose to the manufacturer of any co-medication necessary for each Combined Therapy Trial the applicable Protocol and any related Confidential Information necessary for such manufacturer to update its product label if such disclosure is necessary to obtain the co-medication for use in such Combined Therapy Trial; *provided*, *however*, that all materials delivered to such manufacturer will be redacted of all non-public information related to the Non-Conducting Party's Compound(s). Any such disclosure shall be subject to confidentiality obligations at least as restrictive as those set forth herein and shall restrict the manufacturer to using the information provided solely to make regulatory filings relating to the use of the applicable co-medication in such Combined Therapy Trial.

9.7 Press Releases and Publications.

(a) The Parties shall jointly agree to the content and timing of all external communications with respect to this Agreement (including, without limitation, an initial press release, the content of which shall be as attached hereto as Exhibit D, subsequent press releases, Q&As, and the content and wording for of any listing any Combined Therapy Trial required to be listed on a public database or other public registry such as www.clinicaltrials.gov). For clarity, if either Party terminates this Agreement pursuant to Section 12.4, the Parties shall mutually agree upon any external communication related to such termination, which shall not include the rationale for such termination unless (and to the extent) mutually agreed by the Parties; *provided that* either Party shall be permitted to publicly disclose information that such Party determines in good faith is necessary to be disclosed to comply with Applicable Law or the rules or regulations of any securities exchange on which such Party's stock may be listed, or pursuant to an order of a court or governmental entity.

(b) Exelixis and BMS agree to collaborate to publicly disclose, publish or present (1) top-line results from each Combined Therapy Trial, limited if possible to avoid jeopardizing the future publication of the Study Data at a scientific conference or in a scientific journal, solely for the purpose of disclosing, as soon as reasonably practicable, the safety or efficacy results and conclusions that are material to any Party under applicable securities laws, and (2) the conclusions and outcomes (the "***Results***") of each Combined Therapy Trial at a scientific conference as soon as reasonably practicable following the completion of such Combined Therapy Trial, subject in the case of (2) to the following terms and conditions. The Party proposing to disclose, publish or present the Results shall deliver to each other Party a copy of the proposed disclosure, publication or presentation at least [*] before submission to a Third Party. Each reviewing Party shall determine whether any of its Confidential Information that may be contained in such disclosure, publication or presentation should be modified or deleted, whether to file a patent application on any Exelixis Study Invention (solely with respect to Exelixis) or BMS Study Invention (solely with respect to BMS) or Combined Therapy Invention disclosed therein. The disclosure, publication or presentation shall be delayed for an additional [*] (i.e., a total of [*] from the initial proposal) if a reviewing Party reasonably requests such extension to allow time for the preparation and filing of relevant patent applications. If a reviewing Party reasonably requests modifications to the disclosure, publication or presentation to prevent the disclosure of a material trade secret or proprietary business

information, the publishing Party shall edit such publication to prevent the disclosure of such information prior to submission of the disclosure, publication or presentation. In the event of a disagreement as to content, timing and/or venue or forum for any disclosure, publication or presentation of the Results, such dispute (a "***Publication Dispute***") shall be referred to the Executive Officers (or their respective designees); *provided that*, in the absence of agreement after such good faith discussions, and upon expiration of the additional [*], (A) academic collaborators engaged by the Conducting Party in connection with the performance of the Combined Therapy Trials may publish Combined Therapy Study Data obtained by such academic collaborator solely to the extent that such ability to publish such Combined Therapy Study Data is set forth in an agreement between the Conducting Party and such academic collaborator relating to the conduct of Combined Therapy Trials and (B) the publishing Party may proceed with the disclosure, publication or presentation provided that such disclosure, publication or presentation is consistent with its internal publication guidelines and customary industry practices for the publication of similar data. Authorship of any publication shall be determined based on the accepted standards used in peer-reviewed academic journals at the time of the proposed disclosure, publication or presentation. The Parties agree that they shall make reasonable efforts to prevent publication of a press release that could jeopardize the future publication of Study Data at a scientific conference or in a scientific journal but in no way will this or any other provision of this Agreement supersede the requirements of any Applicable Law or the rules or regulations of any securities exchange or listing entity on which a Party's stock is listed (including, but not limited to, any such rule or regulation that may require a Party to make public disclosures about interim results of a Combined Therapy Trial). Notwithstanding the foregoing, Exelixis hereby authorizes disclosure to Ono in accordance with Section 9.4 above, and BMS hereby authorized disclosure to Ipsen and Takeda in accordance with Section 9.5 above. Notwithstanding the foregoing, nothing herein shall prevent or restrict Ono, Ipsen or Takeda from making any disclosures of published Study Data disclosed to it by BMS pursuant to Section 9.4 or Exelixis pursuant to Section 9.5 of the existence of this Agreement, in each case in order for Ono, Ipsen or Takeda to comply with requirements of Applicable Law, the rules or regulations of any securities exchange or listing entity on which its stock may be traded or pursuant to an order of a court or governmental entity to publicly disclose the existence of the Agreement and the Study Data.

9.8 Compliance with Sunshine Laws.

(a) For purposes of compliance with reporting obligations under Sunshine Laws, as between the Parties, the Conducting Party will report payments or other transfers of value ("***POTV***") made by the Conducting Party or the CRO related to the conduct of the Combined Therapy Trials and any applicable associated contractor engagements as required under the Sunshine Laws for each Combined Therapy Trial. Interpretation of the Sunshine Laws for purposes of reporting any POTV by a Party shall be in such Party's sole discretion so long as the interpretation complies with Applicable Law.

(b) The Conducting Party (i) will provide (to the extent in the possession of the Conducting Party), or will utilize Commercially Reasonable Efforts to obligate and ensure that each CRO and other applicable Third Party contractors for a Combined Therapy Trial provides, the Non-

[*] = 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.

Conducting Party with any information requested by the Non-Conducting Party as the Non-Conducting Party may reasonably determine for the Non-Conducting Party to comply with its reporting obligations under Sunshine Laws (with such amounts paid to, or at the direction of, each Recipient to be reported to the Non-Conducting Party within a reasonable time period specified by the Non-Conducting Party) and (ii) will reasonably cooperate with, and will utilize Commercially Reasonable Efforts to obligate and ensure that each CRO and other applicable Third Party contractors for a Combined Therapy Trial reasonably cooperates with, the Non-Conducting Party in connection with its compliance with such Sunshine Laws. The form in which the Conducting Party provides any such information shall be mutually agreed but sufficient to enable the Non-Conducting Party to comply with its reporting obligations and the Non-Conducting Party may disclose any information that it believes is necessary to comply with Sunshine Laws. Without limiting the foregoing, the Non-Conducting Party shall have the right to allocate payments or other transfers of value in connection with this Agreement in any required reporting under Sunshine Laws in accordance with its normal business practices. These obligations shall survive the expiration and termination of the agreement to the extent necessary for the Non-Conducting Party to comply with Sunshine Laws.

(c) For purposes of this Section 9.7, "***Sunshine Laws***" means Applicable Laws requiring collection, reporting and disclosure of POTVs to certain healthcare providers, entities and individuals. These Applicable Laws may include, without limitation, relevant provisions of the Patient Protection and Affordable Health Care Act of 2010 and implementing regulations thereunder. "***Recipients***" means healthcare providers, teaching hospitals and/or any other persons for whom transfers of value or payments must be reported under Sunshine Laws.

9.9 Destruction of Confidential Information. Upon expiration or termination of the Agreement, the receiving Party shall, upon request by the other Party, immediately destroy or return all of the other Party's Confidential Information relating solely to its Compound(s) as monotherapy (but not to the Combined Therapy or the Combined Therapy Study Data) in its possession; *provided*, *however*, that the receiving Party shall be entitled to retain one (1) copy of Confidential Information solely for record-keeping purposes and shall not be required to destroy any off-site computer files created during automatic system back up which are subsequently stored securely by the receiving Party

ARTICLE 10

REPRESENTATIONS AND WARRANTIES

10.1 Authority and Binding Agreement. Exelixis and BMS each represents and warrants to the other that (a) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (b) it has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder; and (c) the Agreement has been duly executed and delivered on behalf of each Party and constitutes a legal, valid and binding obligation of such Party that is enforceable against it in accordance with its terms subject to bankruptcy, insolvency, reorganization, arrangement, winding-up, moratorium, and similar laws of general application affecting the

enforcement of creditors' rights generally, and subject to general equitable principles, including the fact that the availability of equitable remedies, such as injunctive relief or specific performance, is in the discretion of the court.

10.2 No Conflicts. Exelixis and BMS each represents and warrants that, to the best of its knowledge, it has not entered, and shall not enter, into any agreement with any Third Party that is in conflict with the rights granted to any other Party under this Agreement, and has not taken any action that would in any way prevent it from granting the rights granted to any other Party under this Agreement, or that would otherwise materially conflict with or adversely affect the rights granted to any other Party under this Agreement.

10.3 Litigation. Exelixis and BMS each represents and warrants that, to the best of its knowledge, it is not aware of any pending or threatened litigation (and has not received any communication) that alleges that its activities related to this Agreement have violated, or that by conducting the activities as contemplated in this Agreement it would violate, any of the intellectual property rights of any other Person (after giving effect to the license grants in this Agreement).

10.4 No Adverse Proceedings. Except as otherwise notified to the other Party, there is not pending or, to the knowledge of such Party, threatened, against such Party, any claim, suit, action or governmental proceeding that would, if adversely determined, materially impair the ability of such Party to perform its obligations under this Agreement.

10.5 Consents. Exelixis and BMS each represents and warrants that, to the best of its knowledge, all necessary consents, approvals and authorizations of all regulatory and governmental authorities and other Persons (i) required to be obtained by such Party in connection with the execution and delivery of this Agreement have been obtained (or will have been obtained prior to such execution and delivery) and (ii) required to be obtained by such Party in connection with the performance of its obligations under this Agreement have been obtained or will be obtained prior to such performance.

10.6 No Debarment. Each Party hereby certifies to the other that it has not used, and will not use the services of any person disqualified, debarred, banned, subject to debarment or convicted of a crime for which a person could be debarred by the FDA under 21 U.S.C. 335a, as amended (or subject to a similar sanction of any other Regulatory Authority), in any capacity in connection with any of the services or work provided under any Combined Therapy Trial and that this certification may be relied upon in any applications to the FDA or any other Regulatory Authority. It is understood and agreed that this certification imposes a continuing obligation upon each Party to notify the other promptly of any change in the truth of this certification. Upon request by a Party, the other Party agrees to provide a list of persons used to perform the services or work provided under any activities conducted for or on behalf of such Party or any of its Affiliates pursuant to this Agreement who, within the five years preceding the Effective Date, or subsequent to the Effective Date, were or are convicted of one of the criminal offenses required by 21 U.S.C. 335a, as amended, to be listed in any application for approval of an abbreviated application for drug approval.

10.7 Compliance with Applicable Law. Exelixis and BMS each represents and warrants that it shall comply with all Applicable Law of the country or other jurisdiction, or any court or agency thereof, applicable to the performance of its activities hereunder or any obligation or transaction hereunder, including those pertaining to the production and handling of drug products, such as those set forth by the Regulatory Agencies, as applicable, and the applicable terms of this Agreement, in the performance of its obligations hereunder.

10.8 Affiliates. Exelixis and BMS each represents and warrants that, to the extent the intellectual property, Regulatory Documentation or Technology licensed by it hereunder are Controlled by its Affiliates or a Third Party, it has the right to use, and has the right to grant (sub)licenses to the other Party to use, such intellectual property, Regulatory Documentation or Technology in accordance with the terms of this Agreement.

10.9 Ethical Business Practices. Exelixis and BMS each represents and warrants that neither it nor its Affiliates will make any payment, either directly or indirectly, of money or other assets, including the compensation such Party derives from this Agreement (collectively a "Payment"), to government or political party officials, officials of International Public Organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing (collectively "Officials") where such Payment would constitute violation of any law, including the Foreign Corrupt Practices Act of 1977, 15 U.S.C. §§ 78dd-1, et seq. In addition, regardless of legality, neither it nor its Affiliates will make any Payment either directly or indirectly to Officials if such Payment is for the purpose of improperly influencing decisions or actions with respect to the subject matter of this Agreement. All activities will be conducted in compliance with the U.S. False Claims Act and the U.S. Anti-Kickback Statute.

10.10 Single Agent Compound Safety Issues. Each Party represents and warrants that, to the best of its knowledge, it is not aware of any material safety or toxicity issue with respect to its Single Agent Compound(s) that are not reflected in the investigator's brochure(s) for its Single Agent Compound(s) existing as of the Effective Date.

10.11 Accounting. Each Party represents and warrants that all transactions under the Agreement shall be properly and accurately recorded in all material respects on its books and records and that each document upon which entries in such books and records are based is complete and accurate in all material respects.

10.12 Compliance with Ono Agreements. BMS will use Commercially Reasonable Efforts to comply with its obligations under the Ono-BMS Agreements (and not to voluntarily terminate same) to the extent necessary for each Combined Therapy Trial to be completed in accordance with the terms of this Agreement and for Exelixis to receive the rights and benefits provided to it under this Agreement.

10.13 Compliance with Ipsen-Exelixis Agreements and Takeda-Exelixis Agreements. Exelixis will use Commercially Reasonable Efforts to comply with its obligations under the Ipsen-Exelixis Agreements and the Takeda-Exelixis Agreements (and not to voluntarily terminate same)

to the extent necessary for each Combined Therapy Trial to be completed in accordance with the terms of this Agreement and for BMS to receive the rights and benefits provided to it under this Agreement.

10.14 DISCLAIMER OF WARRANTY. THE EXPRESS REPRESENTATIONS AND WARRANTIES STATED IN THIS ARTICLE 10 ARE IN LIEU OF, AND THE PARTIES DO HEREBY DISCLAIM, ALL OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED OR STATUTORY, INCLUDING WITHOUT LIMITATION WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR USE, AND NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS.

ARTICLE 11

INDEMNIFICATION

11.1 BMS Indemnification. BMS hereby agrees to defend, hold harmless and indemnify (collectively, "***Indemnify***") Exelixis, its Affiliates, and their agents, directors, officers, and employees (the "***Exelixis Indemnitees***") from and against any and all liabilities, expenses and/or losses, including without limitation reasonable legal expenses and attorneys' fees (collectively "***Losses***") resulting from Third Party suits, claims, actions and demands (each, a "***Third Party Claim***") to the extent that they arise or result from (a) the negligence or intentional misconduct of BMS, any BMS Indemnitee or any (sub)licensee of BMS conducting activities on behalf of BMS under this Agreement; (b) any breach by BMS of any provision of this Agreement; (c) any injury to a subject in a Combined Therapy Trial caused solely by the development, use or manufacture of the BMS Compound(s); (d) any injury to a subject in a Combined Therapy Trial where it ultimately cannot be or is not determined if such injury is solely the direct result of the BMS Compound(s) on the one hand or the Exelixis Compound on the other hand, *provided that*, in the case of this clause (d), BMS shall only Indemnify the Exelixis Indemnitees for fifty percent (50%) of any such Loss; or (e) the use by BMS, its Affiliates, contractors or (sub)licensees of Combined Therapy Study Data, BMS Study Data, BMS Study Inventions, BMS Study Patent Rights, Combined Therapy Inventions and Combined Therapy Patent Rights outside the scope of this Agreement (other than with respect to Third Party Claims that are covered under Section 6.4)); but excluding, in each case ((a) through (e)), any such Losses to the extent Exelixis is obligated to Indemnify the BMS Indemnitees pursuant to Section 11.2.

11.2 Exelixis Indemnification. Exelixis hereby agree to Indemnify BMS, its Affiliates, and its and their agents, directors, officers, and employees (the "***BMS Indemnitees***") from and against any and all Losses resulting from Third Party Claims to the extent that they arise or result from (a) the negligence or intentional misconduct of Exelixis, or any Exelixis Indemnitee or any (sub)licensee of Exelixis conducting activities on behalf of Exelixis under this Agreement; (b) any breach by Exelixis of any provision of this Agreement; (c) any injury to a subject in a Combined Therapy Trial caused solely by the development, use or manufacture of the Exelixis Compound; (d) any injury to a subject in a Combined Therapy Trial where it ultimately cannot be or is not

determined if such injury is solely the direct result of the Exelixis Compound on the one hand or the BMS Compound(s) on the other hand; *provided that*, in the case of this clause (d), Exelixis shall only Indemnify the BMS Indemnitees for fifty percent (50%) of any such Loss; or (e) the use by Exelixisits Affiliates, contractors or (sub)licensees of Combined Therapy Study Data, Exelixis Study Data, Exelixis Study Inventions, Exelixis Study Patent Rights, Combined Therapy Inventions and Combined Therapy Patent Rights outside the scope of this Agreement (other than with respect to Third Party Claims that are covered under Section 6.4)), but excluding, in each case ((a) through (e)), any such Losses to the extent BMS is obligated to Indemnify the Exelixis Indemnitees pursuant to Section 11.1.

11.3 Indemnification Procedure. Each Party's agreement to Indemnify the other Party is conditioned on the performance of the following by the Party seeking indemnification: (a) providing written notice to the Indemnifying Party of any Loss of the types set forth in Section 11.1 and 11.2 within [*] after the Party seeking indemnification has knowledge of such Loss; provided that, any delay in complying with the requirements of this clause (a) will only limit the Indemnifying Party's obligation to the extent of the prejudice caused to the Indemnifying Party by such delay; (b) permitting the Indemnifying Party to assume full responsibility to investigate, prepare for and defend against any such Loss; (c) providing reasonable assistance to the Indemnifying Party, at the Indemnifying Party's expense, in the investigation of, preparation for and defense of any Loss; and (d) not compromising or settling such Loss without the Indemnifying Party's written consent, such consent not to be unreasonably withheld or delayed.

11.4 Separate Defense of Claims. In the event that the Parties cannot agree as to the application of Sections 11.1 and/or 11.2 to any particular Loss, the Parties may conduct separate defenses of such Loss. Each Party further reserves the right to claim indemnity from the other in accordance with Sections 11.1 and/or 11.2 upon resolution of the underlying claim, notwithstanding the provisions of Section 11.3(b).

11.5 Insurance. Each Party shall maintain commercially reasonable levels of insurance or other adequate and commercially reasonable forms of protection or self-insurance to satisfy its indemnification obligations under this Agreement. Each Party shall provide the other Party with written notice at least [*] prior to the cancellation, non-renewal or material change in such insurance or self-insurance which would materially adversely affect the rights of the other Party hereunder. The maintenance of any insurance shall not constitute any limit or restriction on damages available to a Party under this Agreement.

11.6 LIMITATION OF LIABILITY. NO PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES, INCLUDING BUT NOT LIMITED TO LOST PROFITS, ARISING FROM OR RELATING TO THIS AGREEMENT AND/OR SUCH PARTY'S PERFORMANCE HEREUNDER, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES AND REGARDLESS OF THE CAUSE OF ACTION (WHETHER IN CONTRACT, TORT, BREACH OF WARRANTY OR OTHERWISE). NOTHING IN THIS SECTION 11.6 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF A PARTY

UNDER SECTIONS 11.1 OR 11.2, OR DAMAGES AVAILABLE FOR BREACHES OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 9 OR FOR A PARTY'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT.

ARTICLE 12

TERM AND TERMINATION

12.1 Term. This Agreement shall be effective as of the Effective Date and, unless earlier terminated pursuant to Sections 12.2, 12.3 or 12.4 or any other termination right expressly stated in this Agreement, shall continue in effect until completion by all centers or institutions participating in the Combined Therapy Trials for such Combined Therapy combination, the delivery of all Study Data, including all completed case report forms, all final analyses and all final clinical study reports contemplated by the Combined Therapy Trials to both Parties, and the completion of any then agreed upon Statistical Analysis and Bioanalysis Plan (the "***Term***"); *provided* that if termination language in Section 2.7 applies, then the Term shall expire at such time.

12.2 Termination for Material Breach.

(a) Notice and Cure Period. If a Party (the "***Breaching Party***") is in material breach, the other Party (the "***Non-Breaching Party***") shall have the right to give the Breaching Party notice specifying the nature of such material breach. The Breaching Party shall have a period of [*] after receipt of such notice to cure such material breach (the "***Cure Period***") in a manner reasonably acceptable to the Non-Breaching Party. For the avoidance of doubt, this provision is not intended to restrict in any way a Party's right to notify the other Party of any other breach or to demand the cure of any other breach.

(b) Termination Right. The Non-Breaching Party shall have the right to terminate this Agreement, upon written notice, in the event that the Breaching Party has not cured such material breach within the Cure Period, *provided*, *however*, that if such breach is capable of cure but cannot be cured within the Cure Period, and the Breaching Party commences actions to cure such material breach within the Cure Period and thereafter diligently continue such actions, the Breaching Party shall have an additional [*] to cure such breach. If a Party contests such termination pursuant to the dispute resolution procedures under Section 13.3, such termination shall not be effective until a conclusion of the dispute resolution procedures in Section 13.3, as applicable, resulting in a determination that there has been a material breach that was not cured within the Cure Period (or, if earlier, abandonment of the dispute by such Party).

12.3 Termination for Bankruptcy. A Party may terminate this Agreement if, at any time, the other Party shall file, in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the other Party or of the other Party's assets, or if the other Party proposes a written agreement of composition or extension of its debts,

or if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed or stayed within [*] after the filing thereof, or if the other Party will propose or be a party to any dissolution or liquidation, or if the other Party shall make an assignment for the benefit of its creditors.

12.4 Termination due to Material Safety Issue; Clinical Hold.

(a) BMS or Exelixis shall each have the independent right to immediately suspend the treatment of subjects in the Combined Therapy Trial and terminate this Agreement upon written notice if it deems it necessary to protect the safety, health or welfare of subjects enrolled in any Combined Therapy Trial due to the existence of a Material Safety Issue. In the event of a termination due to a Material Safety Issue, prior to the terminating Party providing written notice, each Party's safety committee shall, to the extent practicable, meet and discuss in good faith the safety concerns raised by the terminating Party and consider in good faith the input, questions and advice of the non-terminating Party, but should any dispute arise in such discussion, the dispute resolution processes set forth in Sections 2.7 or 13.3 shall not apply to such dispute and the terminating Party shall have the right to issue such notice and such suspension shall take effect without the Parties first following the procedures set forth in Sections 2.7 or 13.3 and the Agreement shall subsequently terminate once the Combined Therapy Trial has been wound down pursuant to Section 12.5.

(b) If a Clinical Hold with respect to either the BMS Compound(s) or the Exelixis Compound should arise at any time after the Effective Date, the Parties will meet and discuss the basis for the Clinical Hold, how long the Clinical Hold is expected to last, and how they might address the issue that caused the clinical hold. If, after [*] of discussions following the Clinical Hold, a Party reasonably concludes that the issue is not solvable or that unacceptable and material additional costs/delays have been and/or will continue to be incurred in the conduct of the Combined Therapy Trial, then such Party may immediately terminate this Agreement.

12.5 Effect of Termination. Upon expiration or termination of this Agreement, (a) the licenses granted to each Party to conduct a Combined Therapy Trial in Sections 3.1 and 3.2 shall terminate, and (b) the Parties shall use reasonable efforts to wind down activities under this Agreement in a reasonable manner and avoid incurring any additional expenditures or non-cancellable obligations; *provided that*, in the case of termination pursuant to Section 12.4, the Conducting Party may continue to dose subjects enrolled in any then ongoing Combined Therapy Trial through completion of the applicable Protocol if dosing is required by the applicable Regulatory Authority(ies) and/or Applicable Law(s). Any such wind-down activities will include the return to a Party, or destruction, of all of such Party's Compound provided to the other Party and not consumed in the Combined Therapy Trials. If applicable, upon termination of this Agreement, the Parties shall remain responsible pursuant to the terms of this Agreement for any expenses incurred that are associated with terminating any ongoing clinical trial work and/or result from such ongoing activities under this Agreement solely to the extent such activities are deemed necessary by the Conducting Party (after discussion at a meeting of the JDC) based on reasonable medical judgment to protect the health of subjects participating in any Combined Therapy Trial.

12.6 Survival. The following Articles and Sections of this Agreement, all definitions relating thereto, and any other provisions of this Agreement that by their nature are intended to survive expiration or termination of this Agreement shall survive any expiration or termination of this Agreement for any reason: Section 2.1(b) (fifth sentence), Section 2.1(d) (last two sentences), Section 2.1(e) (last two sentences), Article 6 ("*Intellectual Property*"), Section 7.1 ("*Combined Therapy Trial Expenses*"), Section 7.2 ("*Invoicing; Payment*"), Section 7.4 ("*Audit*"), Section 8.1 ("*Records*"), Section 8.2 ("*Ownership of Study Data*"), Section 8.3 ("*Use of Study Data*"), Section 8.4 ("*Access to Study Data*"), Section 8.5 ("*Samples*"), Section 8.6, Section 8.7, Article 9 ("*Confidentiality*"); Article 10 ("*Representations and Warranties*"), Article 11 ("*Indemnification*"), Section 12.5 ("*Effect of Termination*"), Section 12.6 ("*Survival*"), Section 13.1 ("*Entire Agreement*"), Section 13.2 ("*Governing Law*"), Section 13.3 ("*Dispute Resolution*"), Section 13.4 ("*Injunctive Relief*"), Section 13.6 ("*Notices*"), Section 13.7 ("*No Waiver, Modifications*"), Section 13.8 ("*No Strict Construction*"), Section 13.9 ("*Independent Contractor*"), Section 13.10 ("*Assignment; Licenses*"), Section 13.11 ("*Headings*"), Section 13.13 ("*Severability*"), Section 13.15 ("*No Benefit to Third Parties*"), and Section 13.17 ("*Construction*").

ARTICLE 13

MISCELLANEOUS

13.1 Entire Agreement. The Parties acknowledge that this Agreement shall govern all activities of the Parties with respect to the Combined Therapy Trials from the Effective Date forward. This Agreement, including the Exhibits hereto and together with the Protocols, the Supplement Agreement (as defined below in Section 13.16), Quality Agreement, Supply Agreement and Pharmacovigilance Agreement, sets forth the complete, final and exclusive agreement between the Parties concerning the subject matter hereof and supersedes all prior agreements and understandings between the Parties with respect to such subject matter. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties with respect to such subject matter other than as are set forth in this Agreement. All Exhibits attached hereto are incorporated herein as part of this Agreement.

13.2 Governing Law. This Agreement shall be governed and construed in accordance with the internal laws of the State of New York, USA, excluding any choice of law rules that may direct the application of the laws of another jurisdiction.

13.3 Dispute Resolution.

(a) In the event of any dispute, controversy or claim arising out of, relating to or in connection with any provision of this Agreement (each a "***Dispute***"), other than a JDC Dispute or a Publication Dispute or a dispute as to whether a Material Safety Issue exists, the Parties shall refer such Dispute promptly to the Alliance Managers for resolution. If the Alliance Managers are unable to resolve such Dispute within [*] after a matter has been presented to them, then upon the request of either Party by written notice, the Parties shall refer such Dispute to the Executive Officers. This Agreement shall remain in effect during the pendency of any such dispute. In the event that

no resolution is made by them in good faith negotiations within [*] after such referral to them, such unresolved Dispute shall be referred to the [*] of Exelixis or his or her designee, and the [*] of BMS or his or her designee for attempted resolution by good faith negotiations within [*] after such referral is made. In the event such officers are unable to resolve such Dispute within such [*] period then, if such Dispute constitutes an Arbitration Matter, such Dispute shall be resolved through arbitration in accordance with the remainder of this Section 13.3; *provided, however*, that with respect to any such Dispute that relates to a matter described in Section 13.4, either Party shall have the right to seek an injunction or other equitable relief without waiting for the expiration of such [*] negotiation period, and with respect to any JDC Dispute or Publication Dispute, the specific dispute resolution processes contained in Sections 2.7 or 9.6(b), as applicable, will apply.

(b) If a Dispute that constitutes an Arbitration Matter remains unresolved after escalation to the senior executives as described above, either Party may refer the matter to arbitration as described herein. Any arbitration under this Agreement shall be conducted under the auspices of the American Arbitration Association by a panel of three (3) arbitrators pursuant to that organization's Commercial Arbitration Rules then in effect; *provided, however*, that the Parties hereby agree that the time schedule for the appointment of arbitrators and the time schedule for submission of the statement of defense shall follow the American Arbitration Association Arbitration Rules. The fees and expenses of the arbitrators shall be borne in equal shares by the Parties. Each Party shall bear the fees and expenses of its legal representation in the arbitration. The arbitral tribunal shall not reallocate either the fees and expenses of the arbitrators or of the Parties' legal representation. The arbitration shall be held in New York, New York, USA, which shall be the seat of the arbitration. The language of the arbitration shall be English.

13.4 Injunctive Relief. Notwithstanding anything herein to the contrary, a Party may seek an injunction or other injunctive relief from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss or damage on a provisional basis. For the avoidance of doubt, if a Party (a) discloses Confidential Information of the other Party other than as permitted under Article 9, (b) uses (in the case of Exelixis) the BMS Compound(s) or BMS Technology or (in the case of BMS) the Exelixis Compound or Exelixis Technology in any manner other than as expressly permitted under this Agreement or (c) otherwise is in material breach of this Agreement and such material breach could cause immediate harm to the value of the Exelixis Compound (by BMS) or the BMS Compound(s) (by Exelixis), the other Party shall have the right to seek an injunction or other equitable relief precluding such Party from continuing its activities related to the Combined Therapy Trials without waiting for the conclusion of the dispute resolution procedures under Section 13.3.

13.5 Force Majeure. The Parties shall be excused from the performance of their obligations under this Agreement (other than the payment of monies owed to the other Party) to the extent that such performance is prevented by force majeure and the non-performing Party promptly provides notice of the prevention to each 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 mean acts of

God, strikes or other concerted acts of workers, civil disturbances, fires, earthquakes, acts of terrorism, floods, explosions, riots, war, rebellion, sabotage or failure or default of public utilities or common carriers or similar conditions beyond the control of the Parties.

13.6 Notices. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement and shall be deemed to have been sufficiently given for all purposes if such notice is timely and is: (a) mailed by first class certified or registered mail, postage prepaid, return receipt requested, (b) sent by express delivery service, or (c) personally delivered. Unless otherwise specified in writing, the mailing addresses of the Parties shall be as described below.

For Exelixis: Exelixis, Inc.
Attn: EVP and General Counsel
210 East Grand Ave.
South San Francisco, CA 94080

With invoices to: [*]

Or: Exelixis, Inc.
Attn: AP Group
210 East Grand Ave.
South San Francisco, CA 94080

For BMS: Bristol-Myers Squibb Company
Route 206 and Province Line Road
Princeton, NJ 08543-4000
Attention: VP, Business Development

With a copy to: Bristol-Myers Squibb Company
Route 206 and Province Line Road
Princeton, NJ 08543-4000
Attention: VP & Assistant General Counsel, Licensing and Business Development

With invoices to: Bristol-Myers Squibb Company
Route 206 and Province Line Road
Princeton, NJ 08543-4000
Attention: VP, R&D Finance

Any such communication shall be deemed to have been received when delivered. It is understood and agreed that this Section 13.6 is not intended to govern the day-to-day business communications

necessary between the Parties in performing their duties, in due course, under the terms of this Agreement.

13.7 No Waiver; Modifications. It is agreed that no waiver by a Party hereto of any breach or default of any of the covenants or agreements herein set forth shall be deemed a waiver as to any subsequent and/or similar breach or default. No amendment, modification, release or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

13.8 No Strict Construction. This Agreement has been prepared jointly and shall not be strictly construed against either Party. No presumption as to construction of this Agreement shall apply against either Party with respect to any ambiguity in the wording of any provision(s) of this Agreement irrespective of which Party may be deemed to have authored the ambiguous provision(s).

13.9 Independent Contractor. The Parties are independent contractors of each other, and the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither Party shall be the agent of the other or have any authority to act for, or on behalf of, the other Party in any matter.

13.10 Assignment; Licensees.

(a) Assignment. No Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of each other Party, *except* that a Party may make such an assignment without each other Party's consent (a) to an Affiliate, (b) to a Third Party that merges with, consolidates with or acquires substantially all of the assets or voting control of the assigning Party or (c) to a Third Party that acquires all the rights to the Exelixis Compound, in the case of Exelixis, or the BMS Compound, in the case of BMS. Any assignment or attempted assignment by any Party in violation of the terms of this Section 13.10 shall be null and void and of no legal effect.

(b) Licensees. If a Party grants a third party a license (other than a license solely to make a Product for a Party and other than any license rights granted to Ono for the Ono Territory and Ipsen for the Ipsen Territory and Takeda for the Takeda Territory) to develop and commercialize its Single Agent Compound(s) on a worldwide basis or in any geographic region and/or for all purposes or a limited field, (a "**Licensee**"), such Party will obtain the Licensee's agreement to abide by the terms of this Agreement in the same manner as the licensor Party.

13.11 Headings. The captions to the several Sections and Articles hereof are not a part of this Agreement, but are included merely for convenience of reference only and shall not affect its meaning or interpretation.

13.12 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one (1) and the

same instrument. This Agreement may be executed by facsimile or electronic (e.g., .pdf) signatures and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

13.13 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law, and if the rights or obligations of a Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties.

13.14 Further Assurance. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in order to perfect any license, assignment or other transfer or any properties or rights under, or pursuant, to this Agreement.

13.15 No Benefit to Third Parties. The representations, warranties and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other parties.

13.16 Supplement Agreement. BMS, Exelixis and Ipsen shall execute the Supplement to the Clinical Trial Collaboration Agreement (the ***"Supplement Agreement"***) concurrently with the execution of this Agreement by BMS and Exelixis, and if the Supplement Agreement is not so executed concurrently with this Agreement, this Agreement shall be null and void and of no force or effect.

13.17 Construction.

(a) General. Except as otherwise explicitly specified to the contrary, (a) references to a Section, Article or Exhibit means a Section or Article of, or Exhibit to, this Agreement and all subsections thereof, unless another agreement is specified; (b) references to a particular statute or regulation include all rules and regulations promulgated thereunder and any successor statute, rules or regulations then in effect, in each case including the then-current amendments thereto; (c) words in the singular or plural form include the plural and singular form, respectively; (d) the terms "including," "include(s)," "such as," and "for example" used in this Agreement mean including the generality of any description preceding such term and will be deemed to be followed by "without limitation"; and (e) the words "hereof," "herein," "hereunder," "hereby" and derivative or similar words refer to this Agreement. No presumption as to construction of this Agreement shall apply against either Party with respect to any ambiguity in the wording of any provision(s) of

this Agreement irrespective of which Party may be deemed to have authored the ambiguous provision(s).

(b) No Response. Where a provision of this Agreement provides for a Party to respond within a designated period following written notice from the other Party (e.g., Sections 5.1(a)(vi) and 5.1(b)(v), and if such Party fails to respond, then the failure to respond shall not be deemed to create or imply: (i) that the non-responding Party agrees or disagrees with the proposed action to be taken by the other Party, (ii) any amendment, change or waiver of the terms of this Agreement, or (iii) any consent that an action proposed to be taken may be taken if it conflicts with the terms of this Agreement and/or waiver of any rights it may have to seek remedies at law or in equity for breach of this Agreement as a result of the action taken.

Signature page follows

IN WITNESS WHEREOF, the Parties hereto, intending to be legally bound hereby, have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

Exelixis, Inc.	**Bristol-Myers Squibb Company**
By: /s/ Gisela M. Schwab	By: /s/ Fouad Namouni
Name: Gisela M. Schwab, M.D.	Name: Fouad Namouni, M.D.
Title: President, Product Development and Medial Affairs, CMO	Title: Head of Oncology Development

[*] = 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.

Exhibit Index

Attached:

Exhibit A: Combined Therapy Studies Expected to be Conducted (as of Effective Date)

Exhibit B: Clinical Protocol Synopsis for Initial Trial for Renal Cell Carcinoma

Exhibit C: Clinical Protocol Synopsis for Initial Trial for Hepatocellular Carcinoma

Exhibit D: Press Release

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EXHIBIT A

Combined Therapy Studies Expected to be Conducted (as of Effective Date)

[*]

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EXHIBIT B

CLINICAL PROTOCOL SYNOPSIS FOR INITIAL TRIAL FOR RENAL CELL CARCINOMA

{Deleted content comprises approximately 5 pages}

[*]

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EXHIBIT C

CLINICAL PROTOCOL SYNOPSIS OF INITIAL TRIAL FOR HEPATOCELLUALR CARCINOMA

{Redacted content comprises approximately 2 pages}

[*]

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PRESS RELEASE

EXELIXIS AND BRISTOL-MYERS SQUIBB ENTER CLINICAL COLLABORATION FOR LATE-STAGE COMBINATION TRIAL IN FIRST-LINE RENAL CELL CARCINOMA

Companies intend to initiate pivotal trial evaluating CABOMETYX™ (cabozantinib) with Opdivo® (nivolumab) alone or in combination with Yervoy® (ipilimumab) in first-line renal cell carcinoma
Planning additional studies in bladder cancer and hepatocellular carcinoma

SOUTH SAN FRANCISCO, Calif. and NEW YORK -- DATE, 2017 -- Exelixis, Inc. (Nasdaq:EXEL) and Bristol-Myers Squibb Company (NYSE:BMY) today announced the companies have entered into a clinical development collaboration to evaluate CABOMETYX™ (cabozantinib), Exelixis' small molecule inhibitor of receptor tyrosine kinases, with Opdivo® (nivolumab), Bristol-Myers Squibb's PD-1 immune checkpoint inhibitor, either alone or in combination with Yervoy® (ipilimumab). The clinical development program, which will be co-funded by the companies, is expected to include a phase 3 pivotal trial in first-line renal cell carcinoma, with additional trials planned in bladder cancer, hepatocellular carcinoma (HCC), and potentially other tumor types.

"The safety and efficacy data from the phase 1 clinical trial evaluating CABOMETYX in combination with Opdivo are consistent with the preclinical scientific rationale for combining these two therapeutic modalities," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. "This clinical development collaboration will provide the resources and collaborative framework to fully evaluate the potential for this combination, with and without Yervoy, in both late-stage pivotal and exploratory trials in a variety of forms of cancer. We look forward to working with Bristol-Myers Squibb to further understand the role these combination therapies may play in helping patients on a global basis."

"Combining our Immuno-Oncology portfolio with promising agents which target different and complementary pathways is a key component of our strategy to improve treatment outcomes for patients," said Fouad Namouni, M.D., Head of Development, Oncology, Bristol-Myers Squibb. "We look forward to working with Exelixis, bringing together our knowledge and experience in oncology, to evaluate the potential clinical value of combining these therapies to treat multiple tumors."

The clinical development collaboration builds upon previously published preclinical and clinical data that provide a scientific rationale for combining CABOMETYX with immunotherapies, including phase 1 data of CABOMETYX in combination with Opdivo in patients with previously treated genitourinary tumors that were presented at the European Society for Medical Oncology (ESMO) 2016 Congress.

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Updated results from this part of the study as well as results from a second part evaluating the combination of CABOMETYX, Opdivo and Yervoy were presented at the American Society of Clinical Oncology 2017 Genitourinary Cancers Symposium during the poster discussion session (Abstract #293) on February 17 at the 2017 Genitourinary Cancers Symposium, which is being held in Orlando, Florida, February 16 – 18, 2017.

CABOMETYX and Opdivo have both received approval in the United States and European Union for specific uses in previously treated renal cell carcinoma, and both compounds are the subject of ongoing, global phase 3 pivotal trials in hepatocellular carcinoma. Opdivo is approved in the United States for previously treated bladder cancer.

About Exelixis' Collaboration with Ipsen

On February 29, 2016, Exelixis and Ipsen jointly announced an exclusive licensing agreement for the commercialization and further development of cabozantinib indications outside of the United States, Canada and Japan. On December 21, 2016, this agreement was amended to include commercialization rights for Ipsen in Canada. Ipsen, Exelixis' global partner for cabozantinib in all geographies outside the United States and Japan, has opted in to participate in the phase 3 pivotal trial in first-line renal cell carcinoma and will have access to the results to support potential future regulatory submissions. They may also participate in future studies at their choosing.

About Exelixis' Collaboration with Takeda

On January 30, 2017, Exelixis and Takeda jointly announced an exclusive licensing agreement for the commercialization and further development of cabozantinib indications in Japan. Takeda may also participate in these and future studies and have access to the results to support potential future regulatory submissions in their territories, if they opt into their funding obligations under the respective collaboration agreements.

Exelixis holds the exclusive rights to develop and commercialize cabozantinib in the United States.

About CABOMETYX™ (cabozantinib)

CABOMETYX is the tablet formulation of cabozantinib. Its targets include MET, AXL and VEGFR-1, -2 and -3. In preclinical models, cabozantinib has been shown to inhibit the activity of these receptors, which are involved in normal cellular function and pathologic processes such as tumor angiogenesis, invasiveness, metastasis and drug resistance.

CABOMETYX is available in 20 mg, 40 mg or 60 mg doses. The recommended dose is 60 mg orally, once daily.

On April 25, 2016, the FDA approved CABOMETYX tablets for the treatment of patients with advanced renal cell carcinoma who have received prior anti-angiogenic therapy. On September 9, 2016, the European Commission approved CABOMETYX tablets for the treatment of advanced renal cell carcinoma in adults who have received prior vascular endothelial growth factor (VEGF)-targeted therapy in the European Union, Norway and Iceland.

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About the *Opdivo* Clinical Development Program

Bristol-Myers Squibb's global development program founded on scientific expertise in the field of Immuno-Oncology includes a broad range of clinical trials studying *Opdivo*, across all phases, including Phase 3, in a variety of tumor types. To date, the *Opdivo* clinical development program has enrolled more than 25,000 patients.

About the Bristol-Myers Squibb and Ono Pharmaceutical Collaboration

In 2011, through a collaboration agreement with Ono Pharmaceutical Co., Bristol-Myers Squibb expanded its territorial rights to develop and commercialize *Opdivo* globally except in Japan, South Korea and Taiwan, where Ono had retained all rights to the compound at the time. On July 2014, Ono and Bristol-Myers Squibb further expanded the companies' strategic collaboration agreement to jointly develop and commercialize multiple immunotherapies – as single agents and combination regimens – for patients with cancer in Japan, South Korea and Taiwan.

CABOMETYX U.S. Important Safety Information

Hemorrhage: Severe hemorrhage occurred with CABOMETYX. The incidence of Grade ≥3 hemorrhagic events was 2.1% in CABOMETYX-treated patients and 1.6% in everolimus-treated patients. Fatal hemorrhages also occurred in the cabozantinib clinical program. Do not administer CABOMETYX to patients that have or are at risk for severe hemorrhage.

Gastrointestinal (GI) Perforations and Fistulas: Fistulas were reported in 1.2% (including 0.6% anal fistula) of CABOMETYX-treated patients and 0% of everolimus-treated patients. GI perforations were reported in 0.9% of CABOMETYX-treated patients and 0.6% of everolimus-treated patients. Fatal perforations occurred in the cabozantinib clinical program. Monitor patients for symptoms of fistulas and perforations. Discontinue CABOMETYX in patients who experience a fistula that cannot be appropriately managed or a GI perforation.

Thrombotic Events: CABOMETYX treatment results in an increased incidence of thrombotic events. Venous thromboembolism was reported in 7.3% of CABOMETYX-treated patients and 2.5% of everolimus-treated patients. Pulmonary embolism occurred in 3.9% of CABOMETYX-treated patients and 0.3% of everolimus-treated patients. Events of arterial thromboembolism were reported in 0.9% of CABOMETYX-treated patients and 0.3% of everolimus-treated patients. Fatal thrombotic events occurred in the cabozantinib clinical program. Discontinue CABOMETYX in patients who develop an acute myocardial infarction or any other arterial thromboembolic complication.

Hypertension and Hypertensive Crisis: CABOMETYX treatment results in an increased incidence of treatment-emergent hypertension. Hypertension was reported in 37% (15% Grade ≥3) of CABOMETYX-treated patients and 7.1% (3.1% Grade ≥3) of everolimus-treated patients. Monitor blood pressure prior to initiation and regularly during CABOMETYX treatment. Withhold CABOMETYX for hypertension that is not adequately controlled with medical management; when controlled, resume CABOMETYX at a reduced dose. Discontinue CABOMETYX for severe hypertension that cannot be controlled with anti-hypertensive therapy. Discontinue CABOMETYX if there is evidence of hypertensive crisis or severe hypertension despite optimal medical management.

Diarrhea: Diarrhea occurred in 74% of patients treated with CABOMETYX and in 28% of patients treated with everolimus. Grade 3 diarrhea occurred in 11% of CABOMETYX-treated patients and in 2% of everolimus-treated patients. Withhold CABOMETYX in patients who develop intolerable Grade 2 diarrhea

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or Grade 3-4 diarrhea that cannot be managed with standard antidiarrheal treatments until improvement to Grade 1; resume CABOMETYX at a reduced dose. Dose modification due to diarrhea occurred in 26% of patients.

Palmar-Plantar Erythrodysesthesia Syndrome (PPES): Palmar-plantar erythrodysesthesia syndrome (PPES) occurred in 42% of patients treated with CABOMETYX and in 6% of patients treated with everolimus. Grade 3 PPES occurred in 8.2% of CABOMETYX-treated patients and in <1% of everolimus-treated patients. Withhold CABOMETYX in patients who develop intolerable Grade 2 PPES or Grade 3 PPES until improvement to Grade 1; resume CABOMETYX at a reduced dose. Dose modification due to PPES occurred in 16% of patients.

Reversible Posterior Leukoencephalopathy Syndrome (RPLS): RPLS, a syndrome of subcortical vasogenic edema diagnosed by characteristic finding on MRI, occurred in the cabozantinib clinical program. Perform an evaluation for RPLS in any patient presenting with seizures, headache, visual disturbances, confusion, or altered mental function. Discontinue CABOMETYX in patients who develop RPLS.

Embryo-fetal Toxicity: CABOMETYX can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with CABOMETYX and for 4 months after the last dose.

Adverse Reactions: The most commonly reported (≥25%) adverse reactions are: diarrhea, fatigue, nausea, decreased appetite, PPES, hypertension, vomiting, weight decreased, and constipation.

Drug Interactions: Strong CYP3A4 inhibitors and inducers: Reduce the dosage of CABOMETYX if concomitant use with strong CYP3A4 inhibitors cannot be avoided. Increase the dosage of CABOMETYX if concomitant use with strong CYP3A4 inducers cannot be avoided.

Lactation: Advise a lactating woman not to breastfeed during treatment with CABOMETYX and for 4 months after the final dose.

Reproductive Potential: Contraception—Advise females of reproductive potential to use effective contraception during treatment with CABOMETYX and for 4 months after the final dose. **Infertility —**CABOMETYX may impair fertility in females and males of reproductive potential.

Hepatic Impairment: Reduce the CABOMETYX dose in patients with mild (Child-Pugh score [C-P] A) or moderate (C-P B) hepatic impairment. CABOMETYX is not recommended for use in patients with severe hepatic impairment.

Please see full Prescribing Information at https://cabometyx.com/downloads/cabometyxuspi.pdf.

OPDIVO AND YERVOY INDICATIONS & IMPORTANT SAFETY INFORMATION

INDICATIONS

OPDIVO® (nivolumab) as a single agent is indicated for the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma. This indication is approved under accelerated approval based on progression-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

OPDIVO® (nivolumab) as a single agent is indicated for the treatment of patients with BRAF V600 wild-type unresectable or metastatic melanoma.

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OPDIVO® (nivolumab), in combination with YERVOY® (ipilimumab), is indicated for the treatment of patients with unresectable or metastatic melanoma. This indication is approved under accelerated approval based on progression-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

OPDIVO® (nivolumab) is indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving OPDIVO.

OPDIVO® (nivolumab) is indicated for the treatment of patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy.

OPDIVO® (nivolumab) is indicated for the treatment of patients with classical Hodgkin lymphoma (cHL) that has relapsed or progressed after autologous hematopoietic stem cell transplantation (HSCT) and post-transplantation brentuximab vedotin. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

OPDIVO® (nivolumab) is indicated for the treatment of patients with recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) with disease progression on or after platinum-based therapy.

OPDIVO® (nivolumab) is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

IMPORTANT SAFETY INFORMATION

WARNING: IMMUNE-MEDIATED ADVERSE REACTIONS

YERVOY can result in severe and fatal immune-mediated adverse reactions. These immune-mediated reactions may involve any organ system; however, the most common severe immune-mediated adverse reactions are enterocolitis, hepatitis, dermatitis (including toxic epidermal necrolysis), neuropathy, and endocrinopathy. The majority of these immune-mediated reactions initially manifested during treatment; however, a minority occurred weeks to months after discontinuation of YERVOY.

Assess patients for signs and symptoms of enterocolitis, dermatitis, neuropathy, and endocrinopathy and evaluate clinical chemistries including liver function tests (LFTs), adrenocorticotropic hormone (ACTH) level, and thyroid function tests at baseline and before each dose.

Permanently discontinue YERVOY and initiate systemic high-dose corticosteroid therapy for severe immune-mediated reactions.

Immune-Mediated Pneumonitis

OPDIVO can cause immune-mediated pneumonitis. Fatal cases have been reported. Monitor patients for signs with radiographic imaging and for symptoms of pneumonitis. Administer corticosteroids for Grade 2 or more severe pneumonitis. Permanently discontinue for Grade 3 or 4 and withhold until resolution for

Grade 2. In patients receiving OPDIVO monotherapy, fatal cases of immune-mediated pneumonitis have occurred. Immune-mediated pneumonitis occurred in 3.1% (61/1994) of patients. In patients receiving OPDIVO with YERVOY, immune-mediated pneumonitis occurred in 6% (25/407) of patients.

In Checkmate 205 and 039, pneumonitis, including interstitial lung disease, occurred in 4.9% (13/263) of patients receiving OPDIVO. Immune-mediated pneumonitis occurred in 3.4% (9/263) of patients receiving OPDIVO: Grade 3 (n=1) and Grade 2 (n=8).

Immune-Mediated Colitis

OPDIVO can cause immune-mediated colitis. Monitor patients for signs and symptoms of colitis. Administer corticosteroids for Grade 2 (of more than 5 days duration), 3, or 4 colitis. Withhold OPDIVO monotherapy for Grade 2 or 3 and permanently discontinue for Grade 4 or recurrent colitis upon re-initiation of OPDIVO. When administered with YERVOY, withhold OPDIVO and YERVOY for Grade 2 and permanently discontinue for Grade 3 or 4 or recurrent colitis. In patients receiving OPDIVO monotherapy, immune-mediated colitis occurred in 2.9% (58/1994) of patients. In patients receiving OPDIVO with YERVOY, immune-mediated colitis occurred in 26% (107/407) of patients including three fatal cases.

In a separate Phase 3 study of YERVOY 3 mg/kg, severe, life-threatening, or fatal (diarrhea of ≥7 stools above baseline, fever, ileus, peritoneal signs; Grade 3-5) immune-mediated enterocolitis occurred in 34 (7%) patients. Across all YERVOY-treated patients in that study (n=511), 5 (1%) developed intestinal perforation, 4 (0.8%) died as a result of complications, and 26 (5%) were hospitalized for severe enterocolitis.

Immune-Mediated Hepatitis

OPDIVO can cause immune-mediated hepatitis. Monitor patients for abnormal liver tests prior to and periodically during treatment. Administer corticosteroids for Grade 2 or greater transaminase elevations. Withhold for Grade 2 and permanently discontinue for Grade 3 or 4 immune-mediated hepatitis. In patients receiving OPDIVO monotherapy, immune-mediated hepatitis occurred in 1.8% (35/1994) of patients. In patients receiving OPDIVO with YERVOY, immune-mediated hepatitis occurred in 13% (51/407) of patients.

In a separate Phase 3 study of YERVOY 3 mg/kg, severe, life-threatening, or fatal hepatotoxicity (AST or ALT elevations >5x the ULN or total bilirubin elevations >3x the ULN; Grade 3-5) occurred in 8 (2%) patients, with fatal hepatic failure in 0.2% and hospitalization in 0.4%.

Immune-Mediated Neuropathies

In a separate Phase 3 study of YERVOY 3 mg/kg, 1 case of fatal Guillain-Barré syndrome and 1 case of severe (Grade 3) peripheral motor neuropathy were reported.

Immune-Mediated Endocrinopathies

OPDIVO can cause immune-mediated hypophysitis, immune-mediated adrenal insufficiency, autoimmune thyroid disorders, and Type 1 diabetes mellitus. Monitor patients for signs and symptoms of hypophysitis, signs and symptoms of adrenal insufficiency, thyroid function prior to and periodically during treatment, and hyperglycemia. Administer hormone replacement as clinically indicated and corticosteroids for Grade 2 or greater hypophysitis. Withhold for Grade 2 or 3 and permanently discontinue for Grade 4 hypophysitis. Administer corticosteroids for Grade 3 or 4 adrenal insufficiency. Withhold for Grade 2 and permanently discontinue for Grade 3 or 4 adrenal insufficiency. Administer hormone-replacement therapy for hypothyroidism. Initiate medical management for control of

hyperthyroidism. Withhold OPDIVO for Grade 3 and permanently discontinue for Grade 4 hyperglycemia.

In patients receiving OPDIVO monotherapy, hypophysitis occurred in 0.6% (12/1994) of patients. In patients receiving OPDIVO with YERVOY, hypophysitis occurred in 9% (36/407) of patients. In patients receiving OPDIVO monotherapy, adrenal insufficiency occurred in 1% (20/1994) of patients. In patients receiving OPDIVO with YERVOY, adrenal insufficiency occurred in 5% (21/407) of patients. In patients receiving OPDIVO monotherapy, hypothyroidism or thyroiditis resulting in hypothyroidism occurred in 9% (171/1994) of patients. Hyperthyroidism occurred in 2.7% (54/1994) of patients receiving OPDIVO monotherapy. In patients receiving OPDIVO with YERVOY, hypothyroidism or thyroiditis resulting in hypothyroidism occurred in 22% (89/407) of patients. Hyperthyroidism occurred in 8% (34/407) of patients receiving OPDIVO with YERVOY. In patients receiving OPDIVO monotherapy, diabetes occurred in 0.9% (17/1994) of patients. In patients receiving OPDIVO with YERVOY, diabetes occurred in 1.5% (6/407) of patients.

In a separate Phase 3 study of YERVOY 3 mg/kg, severe to life-threatening immune-mediated endocrinopathies (requiring hospitalization, urgent medical intervention, or interfering with activities of daily living; Grade 3-4) occurred in 9 (1.8%) patients. All 9 patients had hypopituitarism, and some had additional concomitant endocrinopathies such as adrenal insufficiency, hypogonadism, and hypothyroidism. 6 of the 9 patients were hospitalized for severe endocrinopathies.

Immune-Mediated Nephritis and Renal Dysfunction

OPDIVO can cause immune-mediated nephritis. Monitor patients for elevated serum creatinine prior to and periodically during treatment. Administer corticosteroids for Grades 2-4 increased serum creatinine. Withhold OPDIVO for Grade 2 or 3 and permanently discontinue for Grade 4 increased serum creatinine. In patients receiving OPDIVO monotherapy, immune-mediated nephritis and renal dysfunction occurred in 1.2% (23/1994) of patients. In patients receiving OPDIVO with YERVOY, immune-mediated nephritis and renal dysfunction occurred in 2.2% (9/407) of patients.

Immune-Mediated Skin Adverse Reactions and Dermatitis

OPDIVO can cause immune-mediated rash, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), some cases with fatal outcome. Administer corticosteroids for Grade 3 or 4 rash. Withhold for Grade 3 and permanently discontinue for Grade 4 rash. For symptoms or signs of SJS or TEN, withhold OPDIVO and refer the patient for specialized care for assessment and treatment; if confirmed, permanently discontinue. In patients receiving OPDIVO monotherapy, immune-mediated rash occurred in 9% (171/1994) of patients. In patients receiving OPDIVO with YERVOY, immune-mediated rash occurred in 22.6% (92/407) of patients.

In a separate Phase 3 study of YERVOY 3 mg/kg, severe, life-threatening, or fatal immune-mediated dermatitis (eg, Stevens-Johnson syndrome, toxic epidermal necrolysis, or rash complicated by full thickness dermal ulceration, or necrotic, bullous, or hemorrhagic manifestations; Grade 3-5) occurred in 13 (2.5%) patients. 1 (0.2%) patient died as a result of toxic epidermal necrolysis. 1 additional patient required hospitalization for severe dermatitis.

Immune-Mediated Encephalitis

OPDIVO can cause immune-mediated encephalitis. Evaluation of patients with neurologic symptoms may include, but not be limited to, consultation with a neurologist, brain MRI, and lumbar puncture. Withhold OPDIVO in patients with new-onset moderate to severe neurologic signs or symptoms and evaluate to rule out other causes. If other etiologies are ruled out, administer corticosteroids and

permanently discontinue OPDIVO for immune-mediated encephalitis. In patients receiving OPDIVO monotherapy, encephalitis occurred in 0.2% (3/1994) of patients. Fatal limbic encephalitis occurred in one patient after 7.2 months of exposure despite discontinuation of OPDIVO and administration of corticosteroids. Encephalitis occurred in one patient receiving OPDIVO with YERVOY (0.2%) after 1.7 months of exposure.

Other Immune-Mediated Adverse Reactions

Based on the severity of adverse reaction, permanently discontinue or withhold treatment, administer high-dose corticosteroids, and, if appropriate, initiate hormone-replacement therapy. Across clinical trials of OPDIVO the following clinically significant immune-mediated adverse reactions occurred in <1.0% of patients receiving OPDIVO: uveitis, iritis, pancreatitis, facial and abducens nerve paresis, demyelination, polymyalgia rheumatica, autoimmune neuropathy, Guillain-Barré syndrome, hypopituitarism, systemic inflammatory response syndrome, gastritis, duodenitis, sarcoidosis, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), myositis, myocarditis, rhabdomyolysis, motor dysfunction, vasculitis, and myasthenic syndrome.

Infusion Reactions

OPDIVO can cause severe infusion reactions, which have been reported in <1.0% of patients in clinical trials. Discontinue OPDIVO in patients with Grade 3 or 4 infusion reactions. Interrupt or slow the rate of infusion in patients with Grade 1 or 2. In patients receiving OPDIVO monotherapy, infusion-related reactions occurred in 6.4% (127/1994) of patients. In patients receiving OPDIVO with YERVOY, infusion-related reactions occurred in 2.5% (10/407) of patients.

Complications of Allogeneic HSCT after OPDIVO

Complications, including fatal events, occurred in patients who received allogeneic HSCT after OPDIVO. Outcomes were evaluated in 17 patients from Checkmate 205 and 039, who underwent allogeneic HSCT after discontinuing OPDIVO (15 with reduced-intensity conditioning, 2 with myeloablative conditioning). Thirty-five percent (6/17) of patients died from complications of allogeneic HSCT after OPDIVO. Five deaths occurred in the setting of severe or refractory GVHD. Grade 3 or higher acute GVHD was reported in 29% (5/17) of patients. Hyperacute GVHD was reported in 20% (n=2) of patients. A steroid-requiring febrile syndrome, without an identified infectious cause, was reported in 35% (n=6) of patients. Two cases of encephalitis were reported: Grade 3 (n=1) lymphocytic encephalitis without an identified infectious cause, and Grade 3 (n=1) suspected viral encephalitis. Hepatic veno-occlusive disease (VOD) occurred in one patient, who received reduced-intensity conditioned allogeneic HSCT and died of GVHD and multi-organ failure. Other cases of hepatic VOD after reduced-intensity conditioned allogeneic HSCT have also been reported in patients with lymphoma who received a PD-1 receptor blocking antibody before transplantation. Cases of fatal hyperacute GVHD have also been reported. These complications may occur despite intervening therapy between PD-1 blockade and allogeneic HSCT.

Follow patients closely for early evidence of transplant-related complications such as hyperacute GVHD, severe (Grade 3 to 4) acute GVHD, steroid-requiring febrile syndrome, hepatic VOD, and other immune-mediated adverse reactions, and intervene promptly.

Embryo-Fetal Toxicity

Based on their mechanisms of action, OPDIVO and YERVOY can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with an OPDIVO- or YERVOY- containing regimen and for at least 5 months after the last dose of OPDIVO.

Lactation

It is not known whether OPDIVO or YERVOY is present in human milk. Because many drugs, including antibodies, are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from an OPDIVO-containing regimen, advise women to discontinue breastfeeding during treatment. Advise women to discontinue nursing during treatment with YERVOY and for 3 months following the final dose.

Serious Adverse Reactions

In Checkmate 037, serious adverse reactions occurred in 41% of patients receiving OPDIVO (n=268). Grade 3 and 4 adverse reactions occurred in 42% of patients receiving OPDIVO . The most frequent Grade 3 and 4 adverse drug reactions reported in 2% to <5% of patients receiving OPDIVO were abdominal pain, hyponatremia, increased aspartate aminotransferase, and increased lipase. In Checkmate 066, serious adverse reactions occurred in 36% of patients receiving OPDIVO (n=206). Grade 3 and 4 adverse reactions occurred in 41% of patients receiving OPDIVO. The most frequent Grade 3 and 4 adverse reactions reported in ≥2% of patients receiving OPDIVO were gamma-glutamyltransferase increase (3.9%) and diarrhea (3.4%). In Checkmate 067, serious adverse reactions (73% and 37%), adverse reactions leading to permanent discontinuation (43% and 14%) or to dosing delays (55% and 28%), and Grade 3 or 4 adverse reactions (72% and 44%) all occurred more frequently in the OPDIVO plus YERVOY arm (n=313) relative to the OPDIVO arm (n=313). The most frequent (≥10%) serious adverse reactions in the OPDIVO plus YERVOY arm and the OPDIVO arm, respectively, were diarrhea (13% and 2.6%), colitis (10% and 1.6%), and pyrexia (10% and 0.6%). In Checkmate 017 and 057, serious adverse reactions occurred in 46% of patients receiving OPDIVO (n=418). The most frequent serious adverse reactions reported in at least 2% of patients receiving OPDIVO were pneumonia, pulmonary embolism, dyspnea, pyrexia, pleural effusion, pneumonitis, and respiratory failure. In Checkmate 025, serious adverse reactions occurred in 47% of patients receiving OPDIVO (n=406). The most frequent serious adverse reactions reported in ≥2% of patients were acute kidney injury, pleural effusion, pneumonia, diarrhea, and hypercalcemia. In Checkmate 205 and 039, among all patients (safety population [n=263]), adverse reactions leading to discontinuation (4.2%) or to dosing delays (23%) occurred. The most frequent serious adverse reactions reported in ≥1% of patients were infusion-related reaction, pneumonia, pleural effusion, pyrexia, rash and pneumonitis. Ten patients died from causes other than disease progression, including 6 who died from complications of allogeneic HSCT. Serious adverse reactions occurred in 21% of patients in the safety population (n=263) and 27% of patients in the subset of patients evaluated for efficacy (efficacy population [n=95]). In Checkmate 141, serious adverse reactions occurred in 49% of patients receiving OPDIVO. The most frequent serious adverse reactions reported in at least 2% of patients receiving OPDIVO were pneumonia, dyspnea, respiratory failure, respiratory tract infections, and sepsis. In Checkmate 275, serious adverse reactions occurred in 54% of patients receiving OPDIVO (n=270). The most frequent serious adverse reactions reported in at least 2% of patients receiving OPDIVO were urinary tract infection, sepsis, diarrhea, small intestine obstruction, and general physical health deterioration.

Common Adverse Reactions

In Checkmate 037, the most common adverse reaction (≥20%) reported with OPDIVO (n=268) was rash (21%). In Checkmate 066, the most common adverse reactions (≥20%) reported with OPDIVO (n=206) vs dacarbazine (n=205) were fatigue (49% vs 39%), musculoskeletal pain (32% vs 25%), rash (28% vs 12%), and pruritus (23% vs 12%). In Checkmate 067, the most common (≥20%) adverse reactions in the OPDIVO plus YERVOY arm (n=313) were fatigue (59%), rash (53%), diarrhea (52%), nausea (40%),

pyrexia (37%), vomiting (28%), and dyspnea (20%). The most common (≥20%) adverse reactions in the OPDIVO (n=313) arm were fatigue (53%), rash (40%), diarrhea (31%), and nausea (28%). In Checkmate 017 and 057, the most common adverse reactions (≥20%) in patients receiving OPDIVO (n=418) were fatigue, musculoskeletal pain, cough, dyspnea, and decreased appetite. In Checkmate 025, the most common adverse reactions (≥20%) reported in patients receiving OPDIVO (n=406) vs everolimus (n=397) were asthenic conditions (56% vs 57%), cough (34% vs 38%), nausea (28% vs 29%), rash (28% vs 36%), dyspnea (27% vs 31%), diarrhea (25% vs 32%), constipation (23% vs 18%), decreased appetite (23% vs 30%), back pain (21% vs 16%), and arthralgia (20% vs 14%). In Checkmate 205 and 039, among all patients (safety population [n=263]) and the subset of patients in the efficacy population (n=95), respectively, the most common adverse reactions (≥20%) were fatigue (32% and 43%), upper respiratory tract infection (28% and 48%), pyrexia (24% and 35%), diarrhea (23% and 30%), and cough (22% and 35%). In the subset of patients in the efficacy population (n=95), the most common adverse reactions also included rash (31%), musculoskeletal pain (27%), pruritus (25%), nausea (23%), arthralgia (21%), and peripheral neuropathy (21%). In Checkmate 141, the most common adverse reactions (≥10%) in patients receiving OPDIVO were cough and dyspnea at a higher incidence than investigator's choice. In Checkmate 275, the most common adverse reactions (≥ 20%) reported in patients receiving OPDIVO (n=270) were fatigue (46%), musculoskeletal pain (30%), nausea (22%), and decreased appetite (22%).

In a separate Phase 3 study of YERVOY 3 mg/kg, the most common adverse reactions (≥5%) in patients who received YERVOY at 3 mg/kg were fatigue (41%), diarrhea (32%), pruritus (31%), rash (29%), and colitis (8%).

Checkmate Trials and Patient Populations

Checkmate 067 - advanced melanoma alone or in combination with YERVOY; **Checkmate 037 and 066** - advanced melanoma; **Checkmate 017** - squamous non-small cell lung cancer (NSCLC); **Checkmate 057** - non-squamous NSCLC; **Checkmate 025** - renal cell carcinoma; **Checkmate 205/039** - classical Hodgkin lymphoma; **Checkmate 141** – squamous cell carcinoma of the head and neck; **Checkmate 275** - urothelial carcinoma.

Please see U.S. Full Prescribing Information for OPDIVO and YERVOY, including **Boxed WARNING regarding immune-mediated adverse reactions** for YERVOY.

About Exelixis

Exelixis, Inc. (Nasdaq:EXEL) is a biopharmaceutical company committed to the discovery, development and commercialization of new medicines with the potential to improve care and outcomes for people with cancer. Since its founding in 1994, three products discovered at Exelixis have progressed through clinical development to receive regulatory approval. Currently, Exelixis is focused on advancing cabozantinib, an inhibitor of multiple tyrosine kinases including MET, AXL and VEGF receptors, which has shown clinical anti-tumor activity in more than 20 forms of cancer and is the subject of a broad clinical development program. Two separate formulations of cabozantinib have received regulatory approval to treat certain forms of kidney and thyroid cancer and are marketed for those purposes as CABOMETYX™ tablets (U.S. and EU) and COMETRIQ® capsules (U.S. and EU), respectively. Another Exelixis-discovered compound, COTELLIC® (cobimetinib), a selective inhibitor of MEK, has been approved in major territories including the United States and European Union, and is being evaluated for further potential indications by Roche and Genentech (a member of the Roche Group) under a collaboration with

[*] = 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.

Exelixis. For more information on Exelixis, please visit www.exelixis.com or follow @ExelixisInc on Twitter.

About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information about Bristol-Myers Squibb, visit us at BMS.com or follow us on LinkedIn, Twitter, YouTube and Facebook.

Exelixis Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to: the expectation that the clinical development program will include a phase 3 pivotal trial in first-line renal cell carcinoma, with additional trials planned in bladder cancer, HCC and potentially other tumor types; the clinical potential for the combination of CABOMETYX and Opdivo, with and without Yervoy, in both late-stage pivotal and exploratory trials in a variety of forms of cancer; Exelixis' plan to work with Bristol-Myers Squibb to further understand the role these combination therapies may play in helping patients on a global basis; the anticipated timing for updated results from the phase 1 trial of CABOMETYX in combination with Opdivo in patients with previously treated genitourinary tumors; Ipsen's rights to access the results from the phase 3 pivotal trial in first-line renal cell cancer to support potential regulatory submissions; the potential for Ipsen and Takeda to participate in future studies under the clinical collaboration; Exelixis' commitment to the discovery, development and commercialization of new medicines with the potential to improve care and outcomes for people with cancer; Exelixis' focus on advancing cabozantinib; and the continued development of cobimetinib. Words such as "expected," "planned," "potential," "look forward," "may," "will," "committed," "focused," or other similar expressions identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements are based upon Exelixis' current plans, assumptions, beliefs, expectations, estimates and projections. Forward-looking statements involve risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in the forward-looking statements as a result of these risks and uncertainties, which include, without limitation: Exelixis' ability and the ability of its collaborators to conduct clinical trials of CABOMETYX in combination with Opdivo and Yervoy sufficient to achieve a positive completion; risks related to the potential failure of the combination of these compounds to demonstrate safety and efficacy in clinical testing; Exelixis' dependence on its collaboration partners, including, the level of their investment in the resources necessary to successfully develop CABOMETYX in combination with Opdivo and Yervoy; the complexities and challenges associated with regulatory review and approval processes; the availability of data at the referenced time; the degree of market acceptance of CABOMETYX and the availability of coverage and reimbursement for CABOMETYX; the risk that unanticipated developments could adversely affect the commercialization of CABOMETYX; Exelixis' dependence on third-party vendors; Exelixis' ability to protect the company's intellectual property rights; market competition; changes in economic and business conditions, and other factors discussed under the caption "Risk Factors" in Exelixis' quarterly report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 3, 2016, and in Exelixis' future filings with the SEC. The forward-looking statements made in this press release speak only as of the date of this press release. Exelixis expressly disclaims any duty, obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Exelixis' expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

Bristol-Myers Squibb Company Forward-Looking Statements

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding the research, development and commercialization of pharmaceutical products. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statement can be guaranteed. Among other risks, there can be no guarantee that the compound discussed in this release, either alone or in combination with Opdivo or Yervey, will be successfully developed or approved for any of the indications described in this release. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Bristol-Myers Squibb's business, particularly those identified in the cautionary factors discussion in Bristol-Myers Squibb's Annual Report on Form 10-K for the year ended December 31, 2015 in our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K. Bristol-Myers Squibb undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

[*] = 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.

Exelixis Contacts:

Investors:
Susan Hubbard
EVP, Public Affairs & Investor Relations
Exelixis, Inc.
(650) 837-8194, shubbard@exelixis.com
Media:
Hal Mackins
For Exelixis, Inc.
(415) 994-0040, hal@torchcomllc.com

Bristol-Myers Squibb Contacts:

Media:
Ken Dominski, 609-252-5251, ken.dominski@bms.com
Lisa McCormick Lavery, 609-252-7602, lisa.mccormicklavery@bms.com

Investors:
Tim Power, 609-252-7509, timothy.power@bms.com
Bill Szablewski, 609-252-5894, william.szablewski@bms.com

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Exhibit 10.3

SUPPLEMENT TO THE
CLINICAL TRIAL COLLABORATION AGREEMENT

This **SUPPLEMENT TO THE CLINICAL TRIAL COLLABORATION AGREEMENT** (the "***Supplement***") is made and entered into effective as of February 24, 2017 (the "***Effective Date***") by and among Exelixis, Inc., a Delaware corporation, located at 210 East Grand Avenue, South San Francisco, CA 94080 ("***Exelixis***"), Bristol-Myers Squibb Company, a Delaware corporation, headquartered at 345 Park Avenue, New York, New York 10154 ("***BMS***") and Ipsen Pharma SAS, a French Corporation having an address at 65 Quai Georges Gorse, 92100 Boulogne-Billancourt, France ("***Ipsen***"). The terms in this Supplement with initial letters capitalized, whether used in the singular or the plural, shall have the meaning set forth herein, or if not defined herein, as set forth in the Agreement (as defined below).

RECITALS

WHEREAS, concurrently with entering into this Supplement, Exelixis and BMS are entering into a certain Clinical Trial Collaboration Agreement dated [February ●], 2017 (the "***Agreement***") to enable them to collaborate with each other to sponsor one or more clinical trials of a combination therapy using Exelixis's tyrosine kinase inhibitor known as ***"Cabozantinib"***, certain rights to which are licensed by Exelixis to, and shared by Exelixis with Ipsen and Takeda Pharmaceutical Company Ltd. (***"Takeda"***), and BMS' human monoclonal antibody that binds PD-1 known as ***"Nivolumab"***, certain rights to which are licensed by BMS from, and shared by BMS with, Ono Pharmaceutical Co. Ltd. ("***Ono***"), with or without BMS's CTLA-4 monoclonal antibody known as "***Ipilimumab***".

WHEREAS, Exelixis and Ipsen entered into a Collaboration and License Agreement dated February 29, 2016 (such agreement, as amended from time to time, the **"Ipsen-Exelixis Agreement**"), wherein Exelixis and Ipsen formed a collaboration for the continued development of and commercialization of Cabozantinib and wherein Exelixis granted to Ipsen certain exclusive rights to develop and commercialize Cabozantinib worldwide, with the exception of the United States and Japan (the "***Ipsen Territory***");

WHEREAS, Exelixis, under the Agreement, shall grant to BMS certain patent rights, access to Regulatory Documentation, and Rights of Cross-Reference for the sole purpose of conducting the clinical trials and filing for regulatory approvals as contemplated therein;

WHEREAS, BMS further requires from Ipsen certain additional patent rights, access to Regulatory Documentation, and Rights of Cross-Reference under Ipsen's control in the Ipsen Territory for the sole purpose of conducting the clinical trials and filing for regulatory approvals as contemplated in the Agreement;

WHEREAS, in consideration of Ipsen granting to BMS certain patent rights, access to Regulatory Documentation, and Rights of Cross-Reference under Ipsen's control in the Ipsen Territory, Ipsen requires from BMS and Exelixis certain additional patent rights, access to Regulatory Documentation and Rights of Cross-Reference under BMS's control, which shall be obtained from BMS for the sole purpose of submitting any portion of the Combined Therapy Study Data to support certain of Ipsen's regulatory filings and approval in the Ipsen Territory for a Combination Therapy under the Ipsen-Exelixis Agreement; and

WHEREAS, under the Agreement, Ipsen as Exelixis' collaboration partner and exclusive licensee in the Ipsen Territory will contribute to the fulfillment of the clinical trials contemplated in the Agreement, and will be provided data from BMS and Exelixis as well as Exelixis' interest in certain patent rights, Regulatory Documentation and Rights of Cross-Reference under Exelixis' control arising from such clinical trials and the Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual promises and covenants contained herein, Exelixis, BMS and Ipsen agree as follows:

1. COLLABORATION SCOPE; BACKGROUND; CERTAIN DEFINITIONS

1.1 Scope of Collaboration between Exelixis and BMS. Exelixis and BMS intend, pursuant to the Agreement, to collaborate to conduct (i) the clinical trials identified in Exhibit A of the Agreement (referred to as the "***Initial Trials***") and (ii) such other clinical trials evaluating a Combined Therapy of the BMS Compound(s) with the Exelixis Compound as Exelixis and BMS may agree to conduct pursuant to the terms of the Agreement (any such trial in (i) or (ii), a "***Combined Therapy Trial***").

1.2 Protocol review and conduct of Combined Therapy Trials

(a) The final Protocol for each Combined Therapy Trial shall be subject to review and approval of both the Exelixis-BMS JDC under the Agreement and the Exelixis-Ipsen Joint Steering Committee (as described in the Ipsen-Exelixis Agreement) before such Combined Therapy Trial can be Initiated.

(b) Either Exelixis or BMS shall be primarily responsible for the conduct of each Combined Therapy Trial (either Exelixis or BMS, with respect to such Combined Therapy Trial, the "***Conducting Party***", and the other of Exelixis or BMS, with respect to the same Combined Therapy Clinical trial, the "***Non-Conducting Party***"). Each Combined Therapy Trial shall be conducted under a combination IND unless a Regulatory Authority requires otherwise, for which the Conducting Party will be the sponsor of record (the "***Combined Therapy IND***").

(c) Ipsen acknowledges and agrees to Article 5 of the Agreement, which sets forth rights and responsibilities of the Conducting Party and the Non-Conducting Party in fulfillment of the Combined Therapy Trials.

1.3 Certain Definitions.

(a) The following terms when used in connection with Ipsen in this Supplement shall have the meaning set forth in the Agreement except that any reference in such terms to "a Party" or "such Party" or "the applicable Party" shall be replaced with a reference to "Ipsen" and any reference to "the other Party" shall be replaced with a reference to "BMS" or "Exelixis" as the context requires: ***"Affiliates", "Commercially Reasonable Efforts", "Control"*** and ***"Controlled".***

(b) ***"Ipsen Invention"*** shall mean any invention or Technology, whether or not patentable, that is made, conceived, generated or first actually reduced to practice by or on behalf of Ipsen (or an Affiliate of Ipsen), whether solely or jointly with BMS, Exelixis (and/or any Affiliate of BMS or Exelixis) and/or any Third Party in the course of activities under this Supplement, including but not limited to activities in connection with the JCS-WG, or directly relating to any Study Data, any Invention, any Confidential Information of BMS or any Confidential Information of Exelixis.

(c) When granted by Ipsen in this Supplement "***Right of Cross-Reference***" shall mean, with regard to BMS as the Conducting Party, allowing the applicable Regulatory Authority in a country to have access to relevant information (by cross-reference, incorporation by reference or otherwise) contained in Regulatory Documentation (and any data contained therein) filed with such Regulatory Authority with respect to the Exelixis Compound (and, in the case of BMS as the Non-Conducting Party, the Right to Cross-Reference the Combined Therapy IND), only to the extent necessary for the conduct of a Combined Therapy Trial in such country or as otherwise expressly permitted or required under the Agreement and/or this Supplement to enable BMS to exercise its rights or perform its obligations under the Agreement and/or this Supplement, and, except as to information contained in the Combined Therapy IND relating to the Combined Therapy, without the disclosure of such information to BMS.

2. APPROVALS BY IPSEN AND EXELIXIS

2.1 Combined Therapy Trial Approvals. Ipsen and Exelixis have agreed to the division of responsibilities for the Initial Trials, including but not limited to BMS' right to be the Conducting Party and holder of the Combined Therapy IND for the RCC and HCC studies, as identified in Exhibit A to the Agreement. Ipsen and Exelixis have agreed to amend the Global Development Plan (as that term is defined in the Ipsen-Exelixis Agreement) to include the Combined Therapy Trial for RCC as described in Exhibit B of the Agreement and the Protocol for such trial. Consistent with its agreement to said Exhibit A, Ipsen has agreed to consider, in good faith, Protocol(s) for such additional Combined Therapy Trials as may be approved by the Exelixis-BMS JDC, including the final Protocol for HCC as preliminarily outlined in Exhibit C of the Agreement, and if acceptable and approved by the Exelixis-Ipsen Joint Steering Committee under the Ipsen-Exelixis Agreement, that Combined Therapy Trials will be added to the Ipsen-Exelixis Global Development Plan under the Ipsen-Exelixis Agreement in due course.

2.2 Approved Protocols. With respect to Combined Therapy Trials for which the Protocols are: (a) reviewed and approved by the Exelixis-BMS JDC under the Agreement, and (b) approved by the Exelixis-Ipsen Joint Steering Committee and added to the Global Development

Plan under the Ipsen-Exelixis Agreement; the rights and obligations of Exelixis, BMS, and Ipsen under such Protocols and this Supplement and the Agreement will prevail over any conflicting terms in the Ipsen-Exelixis Agreement (and for any amendments to the Agreement, provided that Ipsen will have reviewed any such amendments in full).

3. GRANTS, REPRESENTATIONS, AND WARRANTIES BY IPSEN

3.1 License Grant. Ipsen hereby grants, and shall cause its Affiliates to grant, to BMS a non-exclusive, worldwide, non-transferable, free of charge and royalty-free license (and for the avoidance of doubt, free and clear of any payment by BMS to Ipsen and Exelixis) under Ipsen's interest in the Exelixis Independent Patent Rights, Exelixis Technology, and Exelixis Regulatory Documentation and under the Licensee Technology (as that term is defined in the Ipsen-Exelixis Agreement) in the Ipsen Territory to use the Exelixis Compound, solely to the extent necessary to discharge BMS's obligations under the Agreement with respect to the conduct of the Combined Therapy Trials.

3.2 Sublicenses. BMS shall further have the right to grant sublicenses, under the licenses granted to it under Section 3.1 above, to Affiliates and to Third Parties, solely to the extent required for a Third Party to perform its duties with respect to the conduct of the Combined Therapy Trials, solely as necessary to assist BMS in carrying out its responsibilities with respect to the Combined Therapy Trials, and otherwise in accordance with the Agreement.

3.3 Right of Cross Reference. Ipsen hereby grants, and shall cause its Affiliates to Grant, to BMS a Right of Cross-Reference to the relevant Regulatory Documentation Controlled by Ipsen and its Affiliates for the Exelixis Compound and the Combined Therapy (i) for the conduct of any Combined Therapy Trial, and (ii) with respect to regulatory filings and approvals, solely to the extent required to submit regulatory filings and seek approvals for the BMS Compound(s) as part of a Combined Therapy or if required by the relevant Regulatory Authority (which right shall survive any expiration or termination of this Supplement and the Agreement). In such case, Ipsen shall reasonably cooperate with Exelixis and BMS and make written authorizations and other filings with the applicable Regulatory Authority reasonably required to effect such Right of Cross-Reference.

3.4 No Implied Licenses. Except as specifically set forth in this Supplement, no right or license or other intellectual property interest, shall be granted to BMS by Ipsen by implication or otherwise in any intellectual property of Ipsen, including any Patent Rights controlled by Ipsen or its Affiliates not specifically licensed herein.

3.5 Representations and Warranties. Ipsen represents and warrants that: (a) it has the corporate power and authority and the legal right to enter into this Supplement and perform its obligations hereunder; (b) it has the corporate power and authority and the legal right to assist in the performance of the obligations under the Agreement that are agreed to by Exelixis but require further licenses, rights, and/or assistance from Ipsen; (c) it has reviewed the Agreement in full, and to the extent not otherwise provided for under this Supplement, it shall grant all licenses and rights

that are necessary and desirable, and provide such assistance as is reasonably necessary, for Exelixis and BMS to exercise their rights and to fulfil their obligations under the Agreement and/or this Supplement.

4. GRANTS, REPRESENTATIONS, AND WARRANTIES BY EXELIXIS AND BMS

4.1 License Grant.

(a) Subject to the terms and conditions of the Agreement, Exelixis hereby grants to Ipsen a non-exclusive, non-transferable, free of charge and royalty-free sublicense (and for the avoidance of doubt, free and clear of any payment by Ipsen to BMS) under the BMS Independent Patent Rights, BMS Technology and BMS Regulatory Documentation, solely to the extent that Exelixis has been granted license rights to the BMS Independent Patent Rights, BMS Technology, BMS Regulatory Documentation and Right of Cross Reference to BMS Regulatory Documentation under the Agreement. Such sublicense rights are limited to use of any portion of the Combined Therapy Study Data and Right of Cross-Reference reasonably needed to support regulatory filing and approval of a Combined Therapy, or if required by the relevant Regulatory Authority, in the Ipsen Territory in accordance with and under the Ipsen-Exelixis Agreement (which right shall survive any expiration or termination of this Supplement and the Agreement). In such case, BMS and Exelixis shall reasonably cooperate with Ipsen to make written authorizations and other filings with the applicable Regulatory Authority reasonably required to effect such Right of Cross-Reference.

(b) Subject to the terms and conditions of the Agreement, Exelixis hereby grants, and shall cause its Affiliates to grant, to Ipsen an exclusive, non-transferable, royalty-free sublicense under (i) Exelixis' interest in the Combination Therapy Patent Rights and Combined Therapy Inventions, (ii) Exelixis Technology, (iii) Exelixis Independent Patent Rights, (iv) Exelixis Study Inventions, (v) Exelixis Study Patent Rights and (vi) Exelixis Regulatory Documentation, in the Ipsen Territory for purposes of using any portion of the Combined Therapy Study Data to support Ipsen's regulatory filing and approval of a Combined Therapy in the Ipsen Territory, or if required by the relevant Regulatory Authority, and performing Ipsen's obligations under the Ipsen-Exelixis Agreement, including conducting development, regulatory and commercialization activities in accordance with the Ipsen-Exelixis Agreement.

4.2 Sublicenses. Ipsen shall further have the right to grant sublicenses, under the licenses granted to it under Section 4.1 above, to Affiliates and to Third Parties, solely to the extent required for an Affiliate or Third Party to perform its duties, solely as necessary to assist Ipsen in carrying out its responsibilities with respect to using any portion of the Combined Therapy Study Data to support Ipsen's regulatory filing and approval for a Combined Therapy in the Ipsen Territory, or if required by the relevant Regulatory Authority.

4.3 No Implied Licenses. Except as specifically set forth in this Supplement, no right or license or other intellectual property interest, shall be granted by Exelixis to Ipsen by implication or otherwise in any intellectual property of BMS, including any Patent Rights controlled by BMS or its Affiliates not specifically licensed herein.

4.4. Additional Combined Therapy Trials. In the event Exelixis and BMS decide to conduct further Combined Therapy Trials beyond the Initial Trials as set forth in Section 5.4 of the Agreement, Exelixis shall ensure that Ipsen is granted access to any data arising from such additional Combined Therapy Trials, subject to Ipsen agreeing to amend the Global Development Plan of the Ipsen-Exelixis Agreement to include such additional Combined Therapy Trials and the Protocol for such Trials.

4.5 Representations and Warranties.

(a) Exelixis represents and warrants that: (a) it has the corporate power and authority and the legal right to enter into this Supplement and perform its obligations hereunder; (b) it has the corporate power and authority and the legal right to assist in the performance the obligations under the Agreement that are agreed to with BMS but require further licenses, rights, and/or assistance from BMS; (c) to the extent not otherwise provided for under this Supplement, it shall grant all licenses and rights that are necessary and desirable, and provide such assistance as is reasonably necessary, for Ipsen to exercise its rights and to fulfil its obligations under this Supplement.

(b) BMS represents and warrants that: (a) it has the corporate power and authority and the legal right to enter into this Supplement and perform its obligations hereunder; (b) it has the corporate power and authority and the legal right to assist in the performance the obligations under the Agreement that are agreed to with Exelixis but require further licenses, rights, and/or assistance from Exelixis; (c) to the extent not otherwise provided for under this Supplement, it shall grant all licenses and rights that are necessary and desirable, and provide such assistance as is reasonably necessary, for Ipsen to exercise its rights and to fulfil its obligations under this Supplement.

5. IPSEN PARTICIPATION

5.1 The Joint Clinical Study Working Group. Under Section 2.4 of the Agreement, BMS and Exelixis will establish a joint clinical study working group (the "***JCS-WG***"), which will meet at least [*] and be co-chaired by one Exelixis representative and one BMS representative. As further described therein, the JCS-WG shall be responsible for the coordination and execution of all joint operational matters (i.e., clinical drug supply, response to regulatory agency questions, data exchange, pharmacovigilance, etc.). The Conducting Party shall provide such update on progress of the Combined Therapy Trials in writing to the Non-Conducting Party members of the JCS-WG on a [*] basis, which update shall contain information about overall progress, recruitment status, interim analysis (if results available), final analysis and other information relevant to the conduct of the Combined Therapy Trials.

5.2 Confidentiality and Invention Assignment.

(a) Ipsen acknowledges and agrees that the agendas, proceedings, documents, discussions, and minutes of the JCS-WG are Confidential Information of BMS, Exelixis, or both BMS and Exelixis under the Agreement, as defined therein and the terms and conditions of Sections

9.1, 9.2 and 9.3 shall be binding upon Ipsen with respect to such Confidential Information and any other Confidential Information of BMS and/or Exelixis received by Ipsen under this Supplement to the same extent that such terms and conditions are binding upon a receiving Party of Confidential Information. Ipsen's representatives will not use Confidential Information it receives arising from its participation in the JCS-WG for any purpose outside of its participation in the JCS-WG, and otherwise in accordance with Article 9 of the Agreement. All representatives of Ipsen who participate in the JCS-WG shall execute a form of confidentiality and invention assignment agreement mutually acceptable to BMS and Exelixis, which will have been reviewed and approved by Ipsen, before participating in the JCS-WG. All representatives of Ipsen who participate in any meeting with a Regulatory Authority must be bound by a written agreement having confidentiality and use obligations that apply to Confidential Information of BMS and/or Exelixis and that are at least as restrictive as those binding upon Exelixis in the Agreement and that cover the meetings with the applicable Regulatory Authority.

(b) Ipsen further agrees that all Ipsen Inventions will be deemed Inventions (as defined under the Agreement) made, conceived, generated or first actually reduced to practice by or on behalf of Exelixis, and ownership of such Inventions will be governed by the Agreement. For clarity, all Ipsen Inventions shall be assigned by Ipsen to BMS or Exelixis in accordance with Article 6 of the Agreement, and Ipsen shall assign and hereby assigns (and shall cause its Affiliates and contractors to assign) all right, title and interest in any Exelixis Study Inventions or Combined Therapy Study Inventions to Exelixis, and all right, title and interest in any BMS Study Inventions to BMS. For the avoidance of doubt, Ipsen shall have a license to such assigned Ipsen Inventions under Section 4.1 of this Supplement. Any assignments necessary to accomplish the foregoing are hereby made, and Ipsen shall execute such further documents and provide other assistance as may be reasonably requested by the assignee party to perfect that party's rights in such Ipsen Inventions, all at the assignee party's expense. The assignee party shall have the sole right but not the obligation to prepare, file, prosecute (including any proceedings relating to reissues, reexaminations, protests, interferences, oppositions, post-grant reviews or similar proceedings and requests for patent extensions) and maintain any Patent Rights at its own expense.

5.3 Ipsen JCS-WG Participation. Subject to Section 5.2 above, Ipsen's representatives, each having expertise in development activities and regulatory affairs, will participate in the JCS-WG and will contribute to its proceedings in order to enable the JCS-WG to fulfill the specific responsibilities defined in Section 2.4(b) of the Agreement. Ipsen may from time to time invite other Ipsen qualified personnel on an *ad hoc* basis to attend the JCS-WG, subject to Exelixis' and BMS' approval of such qualified personnel to attend such meeting, which approval shall not be unreasonably withheld or delayed.

Exelixis shall ensure that all agendas of the JCS-WG are circulated to Ipsen's identified representative to the JCS-WG at least [*] prior to such meetings to the extent any such agendas are circulated between Exelixis and BMS; and shall ensure that minutes of each JCS-WG meetings are circulated to Ipsen's identified representative to the JCS-WG in a timely manner but no later than [*] following such meeting, or if later, promptly upon receipt by Exelixis.

5.4 Conduct. Each of Exelixis, BMS and Ipsen shall use Commercially Reasonable Efforts to perform and fulfill its respective activities under this Supplement, and shall do so in accordance with Applicable Law.

6. MISCELLANEOUS

6.1 Full Force and Effect. This Supplement is deemed incorporated into, and governed by all other terms of, the Agreement. The provisions of the Agreement remain in full force and effect.

6.2 Term; Survival. This Supplement shall be effective as of the Effective Date and expire or terminate upon expiration or termination of the Agreement. The following Sections of this Supplement, all definitions relating thereto and any other provisions of this Supplement that by their nature are intended to survive expiration or termination of this Supplement shall survive any expiration or termination of this Supplement for any reason: Sections 1.3, 2.2, 3.3, 4.1, 4.2, 4.3, 4.5, 5.2, 6.2, 6.3, 6.5 through 6.12, 6.14 and 6.16.

6.3 Governing Law. This Supplement shall be governed and construed in accordance with the internal laws of the State of New York, USA, excluding any choice of law rules that may direct the application of the laws.

6.4 Force Majeure. The parties shall be excused from the performance of their obligations under this Agreement (other than the payment of monies owed to another party) to the extent that such performance is prevented by force majeure and the non-performing party promptly provides notice of the prevention to each 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 Supplement, force majeure shall mean acts of God, strikes or other concerted acts of workers, civil disturbances, fires, earthquakes, acts of terrorism, floods, explosions, riots, war, rebellion, sabotage or failure or default of public utilities or common carriers or similar conditions beyond the control of the parties.

6.5 No Waiver; Modifications. It is agreed that no waiver by a party hereto of any breach or default of any of the covenants or agreements herein set forth shall be deemed a waiver as to any subsequent and/or similar breach or default. No amendment, modification, release or discharge shall be binding upon the parties unless in writing and duly executed by authorized representatives of all parties.

6.6 No Strict Construction. This Supplement has been prepared jointly and shall not be strictly construed against any party. No presumption as to construction of this Supplement shall apply againstany party with respect to any ambiguity in the wording of any provision(s) of this Supplement irrespective of which party may be deemed to have authored the ambiguous provision(s).

6.7 Independent Contractor. The parties are independent contractors of each other, and the relationship between the parties shall not constitute a partnership, joint venture or agency. No party shall be the agent of another party or have any authority to act for, or on behalf of, another party in any matter.

6.8 Assignment. No party may assign or transfer this Supplement or any rights or obligations hereunder without the prior written consent of each other party, *except* that a party may make such an assignment without each other party's consent (a) to an Affiliate, (b) to a Third Party that merges with, consolidates with or acquires substantially all of the assets or voting control of the assigning party or (c) to a Third Party that acquires all the rights to the Exelixis Compound, in the case of Exelixis or the case of Ipsen, or the BMS Compound, in the case of BMS. Any assignment or attempted assignment by any party in violation of the terms of this Section 6.7 shall be null and void and of no legal effect.

6.9 Headings. The captions to the several Sections and Articles hereof are not a part of this Supplement, but are included merely for convenience of reference only and shall not affect its meaning or interpretation.

6.10 Counterparts. This Supplement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one (1) and the same instrument. This Supplement may be executed by facsimile or electronic (e.g., .pdf) signatures and such signatures shall be deemed to bind each party hereto as if they were original signatures.

6.11 Severability. If any provision of this Supplement is held to be illegal, invalid or unenforceable under any present or future law, and if the rights or obligations of a party under this Supplement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Supplement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Supplement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Supplement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the parties.

6.12 No Benefit to Third Parties. The representations, warranties and agreements set forth in this Supplement are for the sole benefit of the parties and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other parties.

6.13 The Agreement. BMS and Exelixis shall execute the Agreement concurrently with the execution of this Supplement by BMS, Exelixis and Ipsen, and if the Agreement is not so executed concurrently with this Supplement, this Supplement shall be null and void and of no force or effect.

6.14 Construction. Except as otherwise explicitly specified to the contrary, (a) references to a Section, Article or Exhibit means a Section or Article of, or Exhibit to, this Supplement and all subsections thereof, unless another agreement is specified; (b) references to a particular statute or regulation include all rules and regulations promulgated thereunder and any successor statute, rules or regulations then in effect, in each case including the then-current amendments thereto; (c) words in the singular or plural form include the plural and singular form, respectively; (d) the terms "including," "include(s)," "such as," and "for example" used in this Supplement mean including the generality of any description preceding such term and will be deemed to be followed by "without limitation"; and (e) the words "hereof," "herein," "hereunder," "hereby" and derivative or similar words refer to this Supplement. No presumption as to construction of this Supplement shall apply against any party with respect to any ambiguity in the wording of any provision(s) of this Supplement irrespective of which party may be deemed to have authored the ambiguous provision(s).

6.15 Further Assurance. Each of Exelixis, BMS and Ipsen duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the another party may reasonably request in order to perfect any license, assignment or other transfer or any properties or rights under, or pursuant, to this Supplement.

6.16 Entire Agreement. Exelixis, Ipsen and BMS agree that this Supplement sets forth the complete, final and exclusive agreement between Exelixis, Ipsen and BMS collectively concerning the subject matter hereof and supersedes all prior agreements and understandings by and between Exelixis, Ipsen and BMS collectively with respect to such subject matter. For the avoidance of doubt, this Supplement does not supersede the Agreement or the Ipsen-Exelixis Agreement. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between Exelixis, Ipsen and BMS collectively with respect to such subject matter other than as are set forth in this Supplement.

[*]

[*] = 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.

IN WITNESS WHEREOF, Exelixis, BMS and Ipsen, intending to be legally bound hereby, have caused this Supplement to the Clinical Trial Agreement to be executed by their duly authorized representatives as of the Effective Date.

Exelixis, Inc.

By: /s/ Gisela M. Schwab
Name: Gisela M. Schwab, M.D.
Title: President, Product Development and Medical Affairs, CMO

Ipsen Pharma SAS

By: /s/ Francois Garnier
Name: Francois Garnier
Title: EVP General Counsel

Bristol-Myers Squibb Company

By: /s/ Fouad Namouni

Name: Fouad Namouni, M.D.
Title: Head of Oncology Department

[Signature Page to the Supplement to the Clinical Trial Agreement]

Exhibit 12.1

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 except for the three months ended March 31, 2017. The following table sets forth our ratio of earnings to fixed charges for the three months ended March 31, 2017 and our deficiency of earnings to cover fixed charges for the other periods presented.

	Three Months Ended March 31, 2017	Year Ended December 31,			
		2016	2015	2014	2013
Fixed charges:					
Interest expense	$ 4,420	$ 33,060	$ 40,680	$ 41,362	$ 38,779
Interest portion of rental expense	160	721	755	886	935
Total fixed charges	$ 4,580	$ 33,781	$ 41,435	$ 42,248	$ 39,714
Earnings available for fixed charges:					
Net income (loss) before income taxes	$ 16,834	$ (70,222)	$ (161,689)	$ (261,479)	$ (238,288)
Fixed charges per above	4,580	33,781	41,435	42,248	39,714
Total earnings available for fixed charges	$ 21,414	$ (36,441)	$ (120,254)	$ (219,231)	$ (198,574)
Ratio of earnings to fixed charges	4.68	N/A	N/A	N/A	N/A
Deficiency of earnings available to cover fixed charges	N/A	$ (70,222)	$ (161,689)	$ (261,479)	$ (238,288)

Exhibit 31.1

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: May 1, 2017

Exhibit 31.2

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: May 1, 2017

Exhibit 32.1

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 March 31, 2017, 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 1st day of May 2017.

/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)